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Dr. Chipley’s academic credentials include:

The B.A. Rice University, Houston, Texas where he majored in history and Russian language, the M.Div. from Southeastern Baptist Theological Seminary, Wake Forest, North Carolina, the M.A. in clinical psychology from the University of Louisville, the M.D. from the University of Louisville, and the Ph.D. in Humanities from the University of Louisville, earned with the dissertation, “William Faulkner and Alcoholism: Distilling Facts and Fiction.” Dr. Chipley was accepted into the psychiatry residency in at the University of Louisville in 2000, but health issues led him to resign that position just prior to completion of the PGY-1 year.

Since December, 2006, Dr. Chipley has served as the Counseling Coordinator for the students and residents of the Health Science Center Campus programs of the University of Louisville.

Dr. Chipley has been involved with the annual conference, the Clinical Application so the Principles in the Treatment of Addiction and Substance Abuse (CAPTASA) since 2009 and has presented there several times. A working group of professionals derived from that conference, in conjunction with the Healing Place, Louisville, the Recovery Kentucky centers of the Kentucky Housing Corporation and the Center for Drug and Alcohol Research at the University of Kentucky spawned research that was published in 2018 with Dr. Chipley as co-author, on “Characteristics and Experiences of Buprenorphine-Naloxone Use Among Polysubstance Users.” Prior to publication, Dr. Chipley presented the research in April, 2017 at the National Prescription Drug Abuse & Heroin Summit in Atlanta, Georgia.

Dr. Chipley recently accepted a second a three-year term as board member for the Beacon House, a Louisville transitional living program for men seeking abstinence-based recovery.
**Background:** Buprenorphine is an opioid that, like other opioid drugs, can produce effects such as pain reduction, a pleasurable “high,” sleepiness, physical dependence and addiction. It has become a street-trafficked drug. Buprenorphine products are the dominantly used class of the three FDA approved Medication Assisted Treatments for Opioid Use Disorder. The other MAT opioid, methadone, can cause death in high doses -- even when used alone -- and it can only be distributed through licensed clinics. Buprenorphine products, however, can be prescribed by physicians and nurse practitioners in office-based practices. The third MAT is naltrexone, which has the opposite effects of opioids and even blocks those effects when other opioids are consumed at the same time. Some claims for buprenorphine products have proven not to be true. People bluntly report ability to get a “high” within clinically approved doses despite early claims otherwise. Buprenorphine is commonly diverted and abused, despite early claims that the drug would not lend itself to such patterns. Most of the research studies by developers and marketers carefully selected subjects who only had opioid use disorder, mostly those only with prescription opioid-use disorder and, rarely, those only with heroin-use disorders. In contrast, this study looks at the real-world conditions and experiences collected on 1,674 people who report themselves as having a history of disordered use of many different drugs (including alcohol) and who have recently engaged in a recovery program to become abstinent from all substances that cause a “high,” or which mask unpleasant emotions.

**Key Findings** for those reporting prior use of buprenorphine products in the prior 6 months:
- 4.2% had only obtained buprenorphine by legal prescription
- 60% had only obtained buprenorphine by illegal means
- 35.9% had obtained buprenorphine by both legal and illegal means
- 10% had overdosed with buprenorphine while taking other drugs or alcohol
- No matter how obtained, 56.1% to 81.2% report getting a good “high” on buprenorphine
- **Efficacy:** 25.2% = helped 31.5% = no effect 43.3% = made problems worse

**Implications of Research:** 1. People who report a strong history of polysubstance use may not be good candidates for buprenorphine product MAT. 2. Public policy might well be shaped to address the established problem of buprenorphine abuse and diversion.


“Among those with a history of buprenorphine use, one-third of the lifetime Bup-Nx (buprenorphine with naloxone) group and 40% of the recent Bup-Nx group had received Bup-Nx by prescription and over 90% of both groups had obtained buprenorphine without a prescription at least once. Among those who had received prescribed Bup-Nx, over 80% said they had sold, traded, or given away their prescribed buprenorphine at least once. Thus, diversion of Bup-Nx was prevalent; a finding that may not surprise clinicians who have been working on the front lines with opioid-using patients using opioids, but it is striking to see the figures from this large survey. Some of the survey findings suggested potential harm reduction effects of buprenorphine use, including expected beneficial effects (e.g., reduced craving and withdrawal symptoms) and helping “get through rough days.” However, other findings were of concern. Most of the Bup-Nx users had used other drugs in combination with Bup-Nx and used Bup-Nx to get high. Overdoses involving Bup-Nx with other drugs were reported by 5% of the lifetime Bup-Nx group and 10% of the recent Bup-Nx group.”
Experience of buprenorphine among polysubstance users

Findings from real-world conditions...

1,674 Individuals

Buprenorphine is an opioid that, like other drugs can produce effects such as pain reduction, a pleasurable "high", sleepiness, physical dependence and addiction. It has become a street trafficked drug.

Method of obtaining

<table>
<thead>
<tr>
<th>Legal</th>
<th>4%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal and illegal</td>
<td>36%</td>
</tr>
<tr>
<td>Illegal Only</td>
<td>60%</td>
</tr>
</tbody>
</table>

Most of those using buprenorphine obtained it only through illegal means.

Overdose

10% overdosed with buprenorphine while taking other drugs.

Getting "High"

56-81%

No matter how obtained, most reported getting a good "high" on buprenorphine.

Effect of buprenorphine

43%

25.2% reported it helped
31.5% reported no effect
43.3% reported it made problems worse

Diversion

80%

80% said they had sold, traded or given away their prescription at least once

Implications:

1) People who report a strong history of polysubstance use may not be good candidates for buprenorphine product MAT.
2) Public policy should address buprenorphine abuse and diversion.


# Different Warnings about Buprenorphine Products

<table>
<thead>
<tr>
<th>NAME (chemical/s), formulation, CSA Schedule</th>
<th>INDICATION</th>
<th>RECOMMENDED DAILY DOSING OF OPIOID</th>
<th>BOXED WARNINGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suboxone® (buprenorphine/naloxone), sublingual film, C-III</td>
<td>Opioid Dependence</td>
<td>8mg - 16mg</td>
<td>-</td>
</tr>
<tr>
<td>Zubsov® (buprenorphine/naloxone), sublingual tablet, C-III</td>
<td>Opioid Dependence</td>
<td>5.7 - 11.4 mg</td>
<td>-</td>
</tr>
<tr>
<td>Bunavail® (buprenorphine), C-III</td>
<td>Opioid Dependence</td>
<td>8.4 mg</td>
<td>-</td>
</tr>
<tr>
<td>Butrans® (buprenorphine), transdermal, C-III</td>
<td>Pain</td>
<td>5-20 mcg/hour</td>
<td>X</td>
</tr>
<tr>
<td>Belbuca® (buprenorphine) buccal film, C-III</td>
<td>Pain</td>
<td>75-900 mcg</td>
<td>X</td>
</tr>
</tbody>
</table>

- **X** = Black box warning in the prescribing information
- **-** = No boxed warning in the prescribing information
Buprenorphine and FAERS Data


**Detailed FDA Adverse Events Reporting 1998-2018**

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

**Data verification steps:**

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.
Number of U.S. Emergency Department Visits Involving Buprenorphine Increases Nearly Ten-Fold from 2005 to 2010

"Availability of buprenorphine is less restricted than other treatments for opioid dependence, such as methadone, which can only be administered in specialized clinics. Although this availability can increase access to treatment, it can also increase the potential for diversion and misuse by those who are not opioid dependent. Such use can lead to buprenorphine dependence or abuse" (SAMHSA, p. 1).

The estimated number of emergency department visits in which buprenorphine was involved as either a direct cause or a contributing factor increased from 3,161 in 2005 to 30,135 in 2010, according to a recently released report from the Substance Abuse and Mental Health Services Administration (SAMHSA). More than half (52%) of these buprenorphine-related emergency department (ED) visits were for the nonmedical use of pharmaceuticals (see CESAR FAX, Volume 21, Issue 47). According to the authors, "the buprenorphine in these visits may have been misused or abused, either for psychoactive effects or in an attempt to self-treat for opioid dependence (without a prescription), or the buprenorphine may have been used appropriately but mixed with other drugs that were being abused or misused" (p. 3-4). The authors also suggest that "for patients who may be attempting to self-treat opioid dependence using buprenorphine without a prescription, expanding access to treatment and putting these patients in the care of a certified physician may help reduce the nonmedical use of buprenorphine and subsequent ED visits" (p. 6).

Estimated Number of U.S. Emergency Department Visits Involving Buprenorphine, 2005-2010

*The estimate was statistically significantly different from the estimate for 2010 at the .05 level.

NOTES: Emergency department visits involving buprenorphine are those in which buprenorphine was involved as either a direct cause or a contributing factor to the visit. Nonmedical use includes taking more than the prescribed dose of a prescription medication or more than the recommended dose of an over-the-counter (OTC) medication or supplement, taking a prescription medication prescribed for another individual, being deliberately poisoned with a pharmaceutical by another person, or misusing or abusing a prescription medication, an OTC medication, or a dietary supplement. In this report, buprenorphine refers to both buprenorphine alone and the buprenorphine-naloxone formulation.

2014 NFLIS Finds Nearly Three Times More Buprenorphine Than Methadone Reports

The National Forensic Laboratory Information System (NFLIS) collects drug test results from law enforcement-encountered drug items submitted to and analyzed by state and local forensic laboratories across the country. NFLIS data can provide valuable information about trends in the drugs seized by U.S. law enforcement. In 2014, the number of NFLIS reports for buprenorphine reached a high of 15,209, almost three times the number of methadone reports (5,559). Buprenorphine reports increased from 90 in 2003 (one year after buprenorphine was approved to treat opioid dependence) to 15,209 in 2014. In contrast, methadone reached a peak of 10,016 reports in 2009, and has since decreased each year. In 2014, the Northeast had the highest rate of buprenorphine reports (9.79 per 100,000 persons aged 15 or older), while the West had the lowest rate (2.09 per 100,000 persons). More information about buprenorphine can be found in the CESAR FAX Buprenorphine Series, available online at http://go.umd.edu/cesarfaxbuprenorphine.

Estimated Number of Total NFLIS Reports for Methadone and Buprenorphine, 2001-2014

NOTES: Estimates are calculated using the National Estimates Based on All Reports (NEAR) methodology, which has strong statistical advantages for producing national and regional estimates. Estimates are based on drug cases and items submitted to participating state and local laboratories during the calendar year and analyzed within three months of the end of the calendar year. Up to three drugs can be reported for each drug item (or exhibit) analyzed by a laboratory. State and local policies related to the enforcement and prosecution of specific drugs may affect drug item submissions to laboratories for analysis. Laboratory policies and procedures for handling drug evidence may also vary. For example, some analyze all items submitted, while others analyze only selected items. Many laboratories do not analyze drug evidence if the criminal case was dismissed from court or if no person could be linked to the item. Thus, NFLIS data might underestimate the availability of drugs in the illicit market that state or local labs do not systematically identify.

SOURCES: Adapted by CESAR from data provided by the U.S. Drug Enforcement Administration (DEA), Office of Diversion Control, Drug and Chemical Evaluation Section, Data Analysis Unit and from NFLIS Annual Reports (available online at https://www.nflis.deadiversion.usdoj.gov/Reports.aspx).
Indivior Inc. Indicted for Fraudulently Marketing Prescription Opioid

Company Allegedly Lied to Doctors and Public Health Care Benefit Programs About the Safety and Diversion Risks of Suboxone Film

A federal grand jury sitting in Abingdon, Virginia, has indicted Indivior Inc. (formerly known as Reckitt Benckiser Pharmaceuticals Inc.) and Indivior PLC (Indivior) for engaging in an illicit nationwide scheme to increase prescriptions of Suboxone Film, an opioid drug used in the treatment of opioid addiction, the Department of Justice announced.

According to the indictment, Indivior obtained billions of dollars in revenue from Suboxone Film prescriptions by deceiving health care providers and health care benefit programs into believing that Suboxone Film was safer, less divertible, and less abusable than other opioid-addiction treatment drugs. Indivior also is alleged to have sought to boost profits by using a "Here to Help" program to connect opioid-addicted patients to doctors the company knew were prescribing opioids at high rates and in a clinically unwarranted manner.

"The deadly opioid epidemic continues to devastate communities and families across our nation," said Principal Deputy Associate Attorney General Jesse Panuccio of the Department of Justice. "The Department of Justice intends to hold accountable those who are in position to know the harm opioid abuse inflicts, but instead choose to profit illegally from the pain of others. Manufacturers, distributors, pharmacies, and doctors should all be on notice that they must follow the law and act responsibly."

"Opioid addiction is a national epidemic. The indictment alleges that, rather than marketing its opioid-addiction drug responsibly, Indivior promoted it with a disregard for the truth about its safety and despite known risks of diversion and abuse," said Assistant Attorney General Jody Hunt. "The Department of Justice is committed to holding opioid manufacturers accountable for such unlawful conduct."

According to the indictment, Indivior developed Suboxone Film around 2007 as a patent-protected alternative to the tablet form of Suboxone, which was then about to face generic drug competition. The primary ingredient in both Suboxone Film and tablets is buprenorphine, a highly potent opioid. Indivior promoted Suboxone Film as safer and less-divertible than its tablet form, even though the company lacked any scientific evidence to support those claims. In particular, Indivior aggressively marketed Suboxone Film, without an established basis, as having a "lower risk of child exposure" and a "less divertible/abusable formulation." Indivior made these and other false and misleading claims in marketing materials and through representations to physicians, pharmacists, and health care benefit programs throughout the country. The indictment also alleges that, to further its scheme, Indivior announced a "discontinuance" of its tablet form of Suboxone based on supposed "concerns regarding pediatric exposure to" tablets, when in fact Indivior executives knew the primary reason for the discontinuance was to delay the Food and Drug Administration's approval of generic tablet forms of the drug.
The indictment further alleges that Indivior used its “Here to Help” internet and telephone program as part of its scheme to induce physicians to write prescriptions for Suboxone Film. Touted as a resource for opioid-addicted patients, Indivior used the program in part to connect patients to doctors it knew were prescribing Suboxone and other opioids to more patients than allowed by federal law, at high doses, and in suspect circumstances. The indictment alleges that Indivior executives and employees knew from statistical and numerous firsthand reports that some doctors in the Here to Help referral system were issuing prescriptions in a careless and clinically unwarranted manner.

Indivior’s scheme, as asserted in the indictment, was highly successful, converting thousands of opioid-addicted patients over to Suboxone Film and causing state Medicaid programs to expand and maintain coverage of Suboxone Film at substantial cost to the government. Until earlier this year, when Suboxone Film became subject to generic competition, Indivior retained a high portion of the opioid-addiction treatment market.

The indictment charges Indivior with conspiracy to commit wire fraud, mail fraud, and health care fraud. In addition, the indictment charges the company with one count of health care fraud, four counts of mail fraud, and twenty-two counts of wire fraud. An indictment merely alleges that crimes have been committed. All defendants are presumed innocent until proven guilty beyond a reasonable doubt.

“As this case makes clear, our office will aggressively prosecute health care fraud cases and particularly those that target people struggling with opioid addiction,” First Assistant United States Attorney Daniel P. Bubar of the Western District of Virginia said today. “We are grateful for the tireless investigative work of our partners at FDA, Virginia Medicaid Fraud Control Unit, HHS, and the U.S. Postal Service for taking on these types of important investigations.”

“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,” said Attorney General Mark R. Herring. “It’s incredibly frustrating that while we have been working to remove the stigma around medication-assisted treatment and make it more widely available, Indivior was allegedly conspiring to exploit patients, taxpayers, and the expansion of MAT. My team and I are proud to have helped lead this investigation, and look forward to helping bring it to a just and fair conclusion.”

“Opioid addiction is a public health emergency and medication-assisted opioid treatment options are an important tool for combatting this crisis. This investigation revealed that Indivior tried to mislead FDA and game the system by attempting to bar competition for Suboxone from the market,” said Melinda K. Plaisier, FDA Associate Commissioner for Regulatory Affairs. “We will continue to pursue and bring to justice those who participate in these schemes to the detriment of public health.

The United States Attorney’s Office for the Western District of Virginia and the Department of Justice’s Consumer Protection Branch are prosecuting the case. The case was investigated by the Food and Drug Administration’s Office of Criminal Investigations, the Virginia Attorney General’s Medicaid Fraud Control Unit, Department of Health and Human Services’ Office of the Inspector General, and United States Postal Service Office of Inspector General. Additional information about the Consumer Protection Branch and its enforcement efforts may be found at http://www.justice.gov/civil/consumer-protection-branch. For more information about the U.S. Attorney’s Office for the Western District of Virginia, visit its website at https://www.justice.gov/usao-wdva.

This prosecution is part of a coordinated effort by the Department’s Prescription Interdiction & Litigation (PIL) Task Force to deploy all available criminal, civil, and regulatory tools to hold opioid manufacturers accountable for unlawful practices and to ensure that prescription opioid products are marketed truthfully.
The relationship between diversion-related attitudes and sharing and selling buprenorphine

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Abstract

Objective: Buprenorphine medication-assisted treatment (B-MAT) is an efficacious and popular outpatient treatment for opioid use disorder. However, the likelihood of buprenorphine diversion is a public health concern. We examined the relationship between attitudes toward diversion as predictors of both sharing and selling buprenorphine.

Method: Participants (n = 476) were patients undergoing short-term inpatient opioid detoxification. Multinomial logistic regression was used to estimate the adjusted association of sharing and selling buprenorphine with demographics, substance use behaviors, and attitudes toward sharing and selling buprenorphine.

Results: Among the two hundred persons who had ever been prescribed buprenorphine (73.4% male, 89% heroin users), 50.5% reported they had shared buprenorphine and 28.0% reported they had sold buprenorphine. Controlling for other covariates, the odds of sharing buprenorphine were 3.17 (95% CI 1.21; 8.32) times higher for persons who agreed that it was "right to share buprenorphine with dope sick friends" than for those who did not agree with this attitude. Attitudes toward selling (OR 2.92; 95% CI 1.35; 6.21) and sharing (OR 4.12; 95% CI 1.64; 10.32) buprenorphine were the only significant correlates of selling, with the odds of selling exponentially greater among persons with favorable attitudes toward sharing or selling buprenorphine.

Conclusions: Although considered diversion, sharing B-MAT is normative among B-MAT patients. Assessing B-MAT patients' attitudes about diversion may help identify patients requiring enhanced oversight, education, or intervention aimed at modifying attitudes to reduce their likelihood to share or sell buprenorphine.

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1. Introduction

Buprenorphine-based medication-assisted treatment (B-MAT) is a recommended long-term recovery strategy for persons with opioid use disorder (Volkow, Frieden, Hyde & Cha, 2014). However, legitimate concerns about the risk for diversion, or the "unauthorized rerouting or misappropriation of prescription medication to someone other than for whom it was intended" (Lofwall & Walsh, 2014), undermine the application of B-MAT. Particularly considering the recent two-year, $1 billion federal allocation to expand MAT for opioid use disorders (Office of the Press Secretary, The White House, 2016), identifying factors associated with diversion and related risk outcomes is warranted.

1.1. Buprenorphine diversion

Outpatient B-MAT is increasingly available and is effective in preventing relapse, emergency department admissions and overdose, and improving the likelihood for long-term recovery (for review see Mattick, Mattick, Breen, Kimber and Davoli, 2014; Parran et al., 2010). While the ease of self-administration and sublingual formulation of buprenorphine enhance the feasibility of B-MAT approaches, they also increase the likelihood for diversion—prevalence rates for buprenorphine diversion are exponentially higher than those for methadone diversion (Winstock and Lea, 2010; Winstock, Lea & Sheridan, 2008; Johnson & Richert, 2015a). From just 2006 to 2009, B-MAT patients reporting buprenorphine diversion nearly doubled and emergency department visits attributed to buprenorphine abuse more than tripled (Mattick, Mattick, Breen, Kimber and Davoli, 2014). The proliferation of buprenorphine and new modes of non-medical administration (e.g., injection) have contributed to an increase in buprenorphine-related consequences, including overdose (Lee, Klein-Schwartz, Welsh and Doyon, 2013; Bretteville-Jensen, Lilhehagen, Gjersing and Andreas,
Manager of opioid treatment facilities in PA and WV indicted for distributing suboxone, health care fraud

PITTSBURGH, Pa. — A federal grand jury indicted the manager of an opioid addiction treatment practice with sites in Pennsylvania and West Virginia, the Justice Department announced Tuesday.

Christopher Handa, 47, of Pittsburgh, Pennsylvania, is named in a four-count indictment for unlawfully dispensing controlled substances and health care fraud.

Handa, a manager at Redirections Treatment Advocates, LLC, is accused of conspiring to create and submit unlawful prescriptions for buprenorphine, also known as subutex or suboxone. Redirections Treatment Advocates, LLC is believed to have had locations in Washington and Bridgeville in Pennsylvania, plus sites in Morgantown, Moundsville, and Weirton.

Buprenorphine can treat pain and addiction to narcotic pain relievers, but carries a high risk of addiction.

Federal investigators searched six locations in five different cities Jan. 10, the Department of Justice confirmed Tuesday.

A listing of the locations included sites in Morgantown, Moundsville, and Weirton.

Handa is additionally accused of submitting fraudulent claims to Medicaid for payments to cover the costs of unlawfully prescribed buprenorphine.


"We are unified with our sister districts to combat those who believe they can hide behind professional services and violate the law," said Powell. "We will continue our joint effort to prosecute the opioid crisis at its very source."

Handa could face up to 40 years in prison if convicted of all charges; including a maximum sentence of 10 years in prison and a fine of up to $250,000 for each of the two counts charging him with unlawfully dispensing buprenorphine, a Schedule III controlled substance; a maximum sentence of 10 years and a fine of up to $1 million for the
charge of conspiracy to unlawfully dispense a Schedule III controlled substance; and a maximum 10-year sentence and a fine of up to $250,000 for one count of health care fraud.

The indictment is the third in Western Pennsylvania since Sessions announced the formation of the Opioid Fraud and Abuse Detection Unit, which conducted the investigation.

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