



# **ILLEGAL PILL PRESSES: AN OVERLOOKED THREAT TO AMERICAN PATIENTS**

**A JOINT PROJECT BY:**

**NATIONAL ASSOCIATION OF BOARDS OF  
PHARMACY, NATIONAL ASSOCIATION OF  
DRUG DIVERSION INVESTIGATORS, AND  
THE PARTNERSHIP FOR SAFE MEDICINES**

**MARCH 2019**



## EXECUTIVE SUMMARY

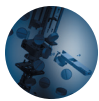
For less than \$500, an individual with ill intent can purchase a pill press and a counterfeit pill mold that allows them to turn cheap, readily available, unregulated ingredients into a six-figure profit. Criminals rely upon these pill presses to create dangerous counterfeit medications with toxic substances such as cheaply imported fentanyl (analogues). Their deadly home-made products have reached 46 states in the United States. Of grave concern is the significant lack of manufacturing control utilized in the making of these counterfeit products.

The inexperience of these “garage manufacturers” has killed unsuspecting Americans in 30 states.

Counterfeit medications that can kill someone with a single pill are a reality that is increasing at an alarming rate. This is a critical health issue that all three of our organizations are urgently striving to stay on top of.

How do these criminals get their hands on pill presses? How are they evading customs inspections? Is possession of these presses illegal and if so, why are more people not charged with it?

Recently, the National Association of Boards of Pharmacy, National Association of Drug Diversion Investigators and The Partnership for Safe Medicines joined together to research the extent of the pill press challenge for law enforcement and other first responders. Key findings include:



- 1. Pill presses are broadly available for sale on the Internet and virtually untracked.** These devices are successfully smuggled through customs because the enormous volume of packages makes compliance challenging. Data from Customs and Border Protection (CBP) shows pill press seizures at International Mail Facilities are increasing every year, growing 19 fold from 2011 to 2017.<sup>1</sup>
- 2. The broad availability and sale of pill presses allow novice criminals to make millions of doses** of nearly perfect-looking counterfeits that can have deadly consequences.
- 3. Possession of a pill press, while not well regulated, is at most a violation of a Drug Enforcement Administration (DEA) registration requirement carrying no jail time.** It only becomes a crime once you add a counterfeit pill mold. However, the prosecution of individuals for possession of a pill press with a counterfeit pill mold is also a rare occurrence and does not carry a sentence high enough to be a deterrent.
- 4. Disrupting the availability of pill presses will be a challenging process.** Our research suggests that increasing criminal penalties for the possession or non-registration of a pill press alone is not likely to provide a sufficient deterrent because it relies on a change in charging behavior by prosecutors. Note: Some law enforcement interviewed suggested adding a sentencing enhancement that increases penalties for committing a drug-related crime with a pill press and suggested exploring serialization or registration as a technique to increase the frequency of indictments for illegal possession and manufacturing operations.

### METHODOLOGY

To develop this study, staff from all three of our organizations conducted many hours of interviews, studied dozens of prosecutions, and reviewed interviews with many families of victims killed by illegally pressed pills.

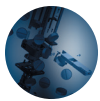
The National Association of Boards of Pharmacy (NABP), the National Association of Drug Diversion Investigators (NADDI), and The Partnership for Safe Medicines (PSM) each bring complementary expertise in patient safety, law enforcement, and regulatory issues related to the secure pharmaceutical supply chain. The goal of this whitepaper is to help understand why America has seen a sudden increase in domestic counterfeit production, what its impact may be on patient safety and law enforcement, and what is required to address the problem.



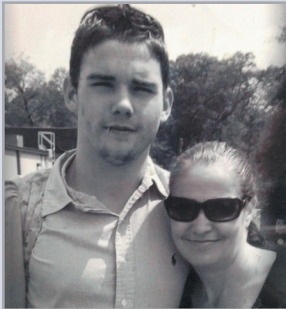
## INTRODUCTION

We are currently living through a public health emergency of unprecedented proportions: the opioid crisis. A factor that has made this crisis worse is how cheap and accessible tabletting machines (often called pill presses) and counterfeit pill molds are a readily available tool to drug traffickers and organized criminal organizations. According to a 2016 Drug Enforcement Administration (DEA) brief, a small investment of \$1,000 for a pill press and a pill mold, and a few thousand more for materials, including illicitly imported fentanyl and binding agents, could yield between \$5 to \$20 million in sellable counterfeit opioid pills.<sup>2</sup> Desktop pill presses can produce hundreds of pills per hour while easily fitting inside the trunk of a car. The demand and supply for these counterfeit pills have increased rapidly due to a multitude of varying factors. As regulators and policymakers focus on the problem of opioid overprescribing by implementing important regulations such as prescription limits and production quota reductions, the street price of genuine diverted opioids increases. This creates the unintended consequence of providing upwards pricing pressure for counterfeit opioids. In addition, illegal websites, many of them posing as Canadian pharmacies and/or operating on the increasingly accessible dark web, have proliferated and peddle an ever-increasing supply of counterfeit opioids to unsuspected patients.<sup>3</sup> Now pill presses provide an even faster and easier way to supply the increased demand.

Today, pill presses, pill molds, and the ingredients to make counterfeit pills are illegally smuggled into the United States through trafficking networks, commercial cargo, and small packages with ease. The overall number of products being shipped in small packages creates a volume so large that many things, including pill presses and molds, are easily concealed. Since fentanyl (analogues) is very potent, importing just a kilogram of illicit fentanyl can help create a multi-million dollar operation. The pill presses themselves hide amongst the even larger amount of non-medical products, machine parts, industrial parts, and legitimate merchandise. Pill presses are such a poorly-recognized item that sellers can merely break them into three parts to completely obscure their nature.



## COUNTERFEIT PILL MADE WITH FENTANYL KILLED YOUNG FATHER-TO-BE



Before he died of acute fentanyl poisoning on February 15, 2015, Joe Patterson had a lot to look forward to. The 23-year-old Georgia resident worked for Sherwin-Williams while he pursued a degree in exercise science and he was

preparing for the birth of his first child. Instead, Joe died after taking oxycodone given to him by a friend after he pulled a muscle at the gym. As the investigation unfolded, Joe’s mother, Lisa Hicks, learned the pill he had taken was a counterfeit that contained fentanyl. It was manufactured using a portable pill press that fit in the trunk of a car. “If that pill press had not been available,” she said, “my son would be alive today.” ●

Once illegal pill presses arrive in the United States, the “bootleg” product created can wreak havoc across an entire city in a single weekend. United States law enforcement has seized pill presses capable of producing thousands of counterfeit pills per hour. A single, poorly-made counterfeit containing one extra milligram of fentanyl is deadly. As PSM’s research shows, fake pill makers both in the United States and outside the United States frequently add toxic levels of fentanyl to counterfeit pills. More than half of the states in the United States have seen deaths due to these counterfeits containing lethal doses of synthetic opioids, especially fentanyl (analogues).

While people struggling with substance use disorder are at the highest risk of being exposed to these dangerous counterfeits, the increased presence of deadly fentanyl-laced counterfeits in this country has seeped into every community. As these pills circulate, they find their

way into the bottles and medicine cabinets of people who were unaware of the existence and potency of these “knockoff” products. These “knockoff” pills are finding their way into the hands of United States residents and killing them. The existence of a counterfeit pill in America endangers all Americans, not just the purchaser.

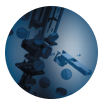
While the DEA has issued regulations requiring individuals to notify the agency of every importation or sale of pill presses, the rule appears to be blatantly ignored by criminals. No license or permit is required, the pill press does not need to be registered, and record-keeping requirements are inadequate. As a result, law enforcement continues to seize pill presses and die molds used by criminals

and criminal organizations to make perfect replicas of prescription medicine. In 2017 alone, CBP seized 92 pill presses, a significant increase over all previous years back to 2011. To help combat this increasing issue, in early 2018 representatives from NABP, NADDI, and PSM began working together to provide actionable analysis and recommendations on the mounting fentanyl crisis. This paper is our first effort in this space: to understand, to educate, and to reduce the danger that pill presses pose to the American public.

### Customs Clearance Easily

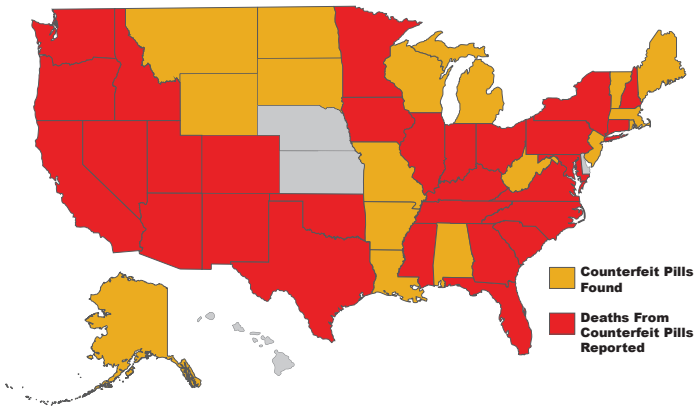
Concerning shipment, if our customers have a good capacity for customs clearance, we would send the whole machine at once; if not, we would detach it into 3parts, pack into 3 parcels and deliver separately, finally pass custom easily. We have sent machines to USA, UK, Canada, Australia, Russia, Germany, India, Netherlands, Brazil etc. Rich experience makes us more reliable.

On their “About Us” page, [www.tabletpresspillpress.com](http://www.tabletpresspillpress.com) explains how they sneak pill presses through customs by disassembling them (January 8, 2019).



While domestically manufactured counterfeits are especially pernicious and the foreign-made counterfeit medication is plentiful, there is a small chance it will be identified,

**46 STATES HAVE A DEADLY FENTANYL PILL PROBLEM**



intercepted and seized at the border. Agents from the United States Food and Drug Administration (FDA) and CBP seize hundreds of counterfeit medical products daily, but the volume means many counterfeits still get through.

Pill presses enable the growth of domestic production of counterfeit medicines. Domestic criminals making and selling counterfeit pills locally can evade FDA and CBP by making their product in their homes, basements, and garages and sell them illegally through street sales, or mail order using the open Internet and the dark web.

When we looked at prosecutions of pill presses and pill molds, a critical tool in the illegal manufacturing process, we did not find the volume of indictments for illegal ownership we expected. We wondered why there were increasing reports of pill press seizures at the border and during domestic law enforcement actions, yet so few people ever appear to be prosecuted for it. Were pill presses really illegal to own or just to use? Who’s responsible for enforcing the laws governing them? Are there impediments to prosecution? Where are criminals getting the presses? How do they learn how to operate them? Where do they obtain the other ingredients required to make pills?

Currently, both domestic and foreign counterfeiters are flooding America with fake pills, many of which are made with illegal fentanyl (analogues). While people view counterfeit fentanyl pills as the danger, one must not forget any counterfeit production base in the United States poses a growing and present threat even without using fentanyl in any fake pills. The broad ability to produce counterfeits with other ingredients (or no active ingredients at all) still endangers patients. This black-market counterfeit production progression will pose a danger to Americans for decades unless we improve our regulatory processes, provide resources to law enforcement to combat the production method, and remove this equipment from the hands of criminals using it to victimize Americans.

**IN SAN DIEGO, A BABY DIED AFTER ACCIDENTALLY INGESTING A COUNTERFEIT FENTANYL PILL**

On the morning of September 18, 2017, while his parents were sleeping, ten-month-old Leo Holtz put a pretty colored pill that had fallen out of his father’s pocket into his mouth. Around 8:25 am his parents woke and found their baby blue and unresponsive. They called 9-1-1, but Leo could not be revived and was declared dead at Rady Children’s Hospital. According to *The San Diego Union-Tribune*, investigators believe Leo’s father, Colin, bought the pills from Melissa Scanlan, who sourced her counterfeit oxycodone pills from a drug cartel in Mexico. However, even if the counterfeit fentanyl pills came from someone else, nothing will ever change the fact that ten-month-old Leo Holtz’s life was cut short because of a counterfeit oxycodone pill made with fentanyl. ●

Kristina Davis, “Details Emerge in Fentanyl Overdose Deaths of Baby, Woman Linked to Alleged ‘Drug Llama,’” *The San Diego Union-Tribune*, September 23, 2018, <http://bit.ly/2AB8W8h>.



## ILLEGAL PILL PRESSES: AN OVERLOOKED THREAT

We hope that our research will yield policy changes that save lives by helping law enforcement take these machines out of the hands of criminals, adequately prosecute and punish these criminals and stem the tide of these dangerous counterfeits.



# NABP

NATIONAL ASSOCIATION OF  
BOARDS OF PHARMACY



National Association of Drug Diversion Investigators®



### A NOTE ON TERMINOLOGY

Pill presses are also called tableting machines, encapsulating machines, or capsule filling machines in various contexts. For the sake of comprehension, we will always use the term “pill presses” unless we’re referring to a specific incident where a more specific name is more accurate. For more information about the machines in this area, see this article from PharmaTechnologist.com.<sup>4</sup>

There are dozens of molecular analogues for fentanyl, a popular ingredient used in counterfeit pills made both in the United States and abroad and smuggled into America.<sup>5</sup> Unless we are referring to a specific incident, when we talk about “fentanyl” we mean “any fentanyl analogue.”



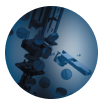
## WHAT IS A PILL PRESS?

A pill press is a mechanical device that compresses powder into tablets of uniform size by running the powder through a machine fitted with die molds that determine the shape of and markings on the tablets. These machines were originally conceived of as tools for pharmaceutical development and manufacturing and dietary supplement makers, but drug traffickers use them to make counterfeit pills laced with fentanyl, MDMA tablets, and other illicit drugs. Pill presses vary in capacity from “desktop machines” that can make approximately 1,800 pills an hour, to massive industrial machines that can produce 1.6 million pills per hour.<sup>6</sup>

Pill presses are manufactured by a variety of domestic and international companies who produce pharmaceutical industrial equipment. An impact statement attached to the submission of new regulations in 2016 indicated that there are 102 companies that the DEA recognizes as legitimate suppliers of these machines. Of those, 46 domestic suppliers are required to keep records of pill press sales for two years, and to report them to the Attorney General. Another 56 pill press importers and exporters must also follow those requirements but are also required to notify the agency of every transaction involving importing or exporting a machine involved in the creation of controlled substances.<sup>7</sup> These, presumably, are the companies that the DEA recognizes as legitimate.

The scale of the illicit manufacturing or resale market of pill presses lacks accurate documentation. However, there is strong evidence that pill presses are readily available through domestic and international sources online. Corporations who manufacture the machines freely advertise and sell them on commercial websites. An eBay search on August 24, 2018 revealed used and new pill presses being openly sold by domestic suppliers, and a similar





# ILLEGAL PILL PRESSES: AN OVERLOOKED THREAT

The screenshot shows the Alibaba.com search results for "pill press machine". The page includes the Alibaba logo, navigation menus, and search filters. The search results section displays 1861 results, with four product listings visible. The listings include:

- Ad Cheap Electric Honey Pill Making**: A large industrial pill press machine.
- Ad C&C600 Single Punch Tablet Press**: A smaller, single-punch tablet press machine.
- Ad pill press machine**: A machine with CE, FDA, and GMP certifications, labeled ZPT17.
- Ad single punch cheap pill tablet press machine**: A compact, single-punch tablet press machine.

Results from a search on “pill press machine” on Alibaba, an auction website, October 10, 2018.

search on the international auction site Alibaba yielded results from all over the world. In some cases, a homegrown drug trafficker would not have to buy a pill press: some criminal organizations package them, disassembled, with illicit fentanyl, often purchased on the dark web.<sup>8</sup>

The same pharmaceutical manufacturing suppliers who make and sell pill presses also sell additional, non-active ingredients that one needs to make tablets. Canada-based Tablet Press Club, for example, sells “tableting binders, excipients and lubricants” for small scale pill production.<sup>9</sup> These ingredients—including an all-in-one mix offered by LFA Tablet Presses and food-grade dyes to color pills—are also available on Amazon.<sup>10</sup>

The screenshot shows a product listing for "Customize Punch Dies, Tablet Die/Punch Mould" by Jinhu Minsheng Pharmaceutical Machinery Co., Ltd. The listing includes:

- Product Image**: A grid of various custom punch dies with different shapes and markings.
- Price**: US \$40-80 / Units | 1 Unit/Units (Min. Order)
- Supplier Information**: Jinhu Minsheng Pharmaceutical Machinery Co., Ltd. (Manufacturer), 4 YRS, CN.
- Trust Badges**: Gold Supplier, Trade Assurance, Onsite Check.
- Rating**: 4.9/5 Satisfied (5 Reviews)
- Transaction Level**: 72 Transactions, \$340,000+, Response Time <24h, Response Rate 94.3%.
- Shipping**: Less than Container Load (LCL) Service to US. Includes options for Trade Assurance, Payment (VISA, TT, e-Checking), and Shipping (Transparent and fair price, 24/7 online support, Online tracking).

Assorted die molds listed on Alibaba, August 24, 2018.



## ILLEGAL PILL PRESSES: AN OVERLOOKED THREAT

The final equipment needed is the counterfeit die molds or punch dies to shape convincing counterfeit pills. Counterfeiters have purchased them—and pill presses—from dark web marketplaces,<sup>11</sup> but until recently you could acquire counterfeit die molds in the shapes of Xanax or M-30 (oxycodone) pills on the open web from eBay and other platforms from distributed sellers. Now, it is rare to see an active listing for counterfeit die molds. Instead, a listing on Bonanza or Alibaba will advertise generic die molds and end with a note informing buyers that many other molds are in stock, and to contact them.

Tablet Press Machine

Home > Rectangle and oval molds

Round molds

Round molds with logo

**Rectangle and oval molds**

Irregular shape molds

Custom-made molds

Rotary press machine molds

TDP spareparts

Best Selling

Rectangle and oval molds

Rectangle and oval molds

S903 Tablet Press Die Tablet Press Molds TDP Dies Molds Stamp TDP Punch Die TDP0/1.5/5/6 \$119.00

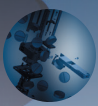
b 974 3 0 Tablet Press Die Tablet Press Molds TDP Dies Molds Stamp TDP Punch Die TDP0/1.5/5/6 \$139.00

Xanax/2 15X5mm Tablet Press Die Tablet Press Molds TDP Dies Molds Stamp TDP Punch Die TDP0/1.5/5/6 \$99.00

Punch die molds sold openly online. Because of their small size, smuggling them is a great deal easier than smuggling an entire pill press. Die molds advertised October 3, 2018.

The alarming rates of illegal controlled substances are reaching epidemic proportions. Buying illicit controlled substances is illegal, but they are still readily available on the Internet, both from dark web sellers and through simple Google searches. A January 2018 report by the Senate’s Permanent Subcommittee on Investigations noted that the subcommittee had been able to launch investigations on six fentanyl traffickers they had found simply by searching “fentanyl for sale” on Google. Sellers preferred payment in cryptocurrency and offered to ship the fentanyl in small packages through United States mail.<sup>12</sup>

By themselves, pill presses are not dangerous. There are a number of legitimate uses for them that do not involve creating counterfeit controlled substances. They are a tool utilized to manufacture dangerous products by criminals who can easily purchase fentanyl, counterfeit die molds, and industrial grade pharmaceutical ingredients. In the 21st century, the deterrents to entering this deadly market are minimal. If we can provide practices to disrupt and prevent what has become a cottage industry by restricting the sale of pill presses we will save many lives.



# HOW DO THESE PILL PRESSES FIND THEIR WAY INTO THE HANDS OF CRIMINAL COUNTERFEITERS?

This question is best answered with a story of a great law enforcement interdiction.

It all started with a package at an International Mail Facility.<sup>13</sup>

The declaration said the package contained a “hole puncher,” but upon examination, CBP concluded it was a pill press. CBP queried the DEA because it is illegal to import pill presses without prior permission from the agency.

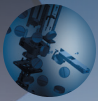
The DEA Coordinator alerted field agents working on a case in the Long Beach, California area about the shipment and its intended destination. Multiple teams around the country were already working on investigations related to Subject Gary Resnik and his ring of drug dealers. The DEA obtained a warrant to put a GPS tracker on the pill press, and in April it was released to ship to Resnik and followed by law enforcement.

It’s important to recognize when the interdiction process works. In this case, CBP caught the illegal pill press despite attempts to mislabel it to evade detection. Not only was it found, but it became a direct conduit and useful tool in uncovering a ring of counterfeiters and preventing the potential poisoning deaths of countless Americans. This is the type of story we heard over and over again as we talked to law enforcement; criminal conspiracies to make counterfeits require specific materials, and those materials are the threads you can follow to discover the crime and eradicate a criminal organization.

Based upon this data and other information gleaned during the investigation, the DEA agents working the case raided three locations used by the gang and seized six pill presses, presumably including the one shipped to them that was being monitored by law enforcement. While this case clearly outlines a success and is a great example of how the process is supposed to work, a few important lessons can be drawn from this example:

1. Discovery of an illegal pill press’s importation is often used by law enforcement to locate illegal production sites, to uncover a counterfeiting ring, or to provide probable cause for search warrants and further investigation.
2. This case study shows how well the interdiction and investigation teams can work, but also exemplifies how the criminal organization had already gotten their hands on five other pill presses that evaded interdiction.

Seizures of pill presses are up 19-fold since 2011.<sup>14</sup> In Tennessee alone, law enforcement seized 12 pill presses in 2017.<sup>15</sup>



# IS THERE AN INDUSTRY OF OVERSEAS PILL PRESS MANUFACTURERS SELLING INTO THE UNITED STATES?

Absolutely. It is often difficult to identify these presses during shipment because many measures are taken to cloak their identity, or methods are utilized to breakdown the presses into several pieces which are shipped separately. Although most pill presses do not look dangerous, their ability to cause great harm is very well documented.

This vendor provides very high end pill presses and customs broker services to get your pill press past customs and into the United States.

Many foreign sellers of pill presses are brazen about circumventing regulations in the United States and around the world. As one vendor boasted on their website:

*“Concerning shipment, if our customers have a good capacity for customs clearance, we would send the whole machine at once; if not, we would detach it into 3 parts, pack into 3 parcels and deliver separately, finally pass custom easily. We have sent machines to USA, UK, Canada, Australia, Russia, Germany, India, Netherlands, Brazil etc. Rich experience makes us more reliable.”<sup>16</sup>*



## WHAT DATA DO WE HAVE ON ILLEGAL PILL PRESS USAGE?

When law enforcement finds counterfeit medicines in pill or capsule form, it is almost impossible to know if their origin was domestic or foreign. Whereas, counterfeits seized at the border, of course, are international in nature. Law enforcement does not always find the nexus to the production machinery when they seize counterfeit pills on the street; thus, it is difficult to know the volume of domestic production.

During our research, it was common to hear from law enforcement departments that they have seized one or more pill presses in the last two years. In continuing our research, NABP, NADDI, and PSM are currently running a survey of law enforcement officers inquiring about their experiences encountering pill presses in the field. To help us learn about the prevalence of pill presses, please ask any law enforcement you work with to take our survey at [https://safedrug/pillpress\\_survey](https://safedrug/pillpress_survey).

## WHERE DO CRIMINALS LEARN HOW TO USE PILL PRESSES?

In a *20/20* episode aired Friday, September 28, 2018, the lawyer of one drug counterfeiter reported that his client learned how to make the pill mix that would become counterfeit Percocet pills from the same place he bought his pill press and supplies: online.<sup>17</sup>

Instructions and tutorials about how to use pill presses are readily available on the Internet. UK-based LFA Machines Oxford, Ltd. (which also has a headquarters in Texas) offers extensive YouTube video tutorials showing how to use the machines they sell, and publishes blog entries about the finer points of pill making: “*we cover everything from the design of your tablets, the grease you should be using, common problems faced by producers such as yourself to what are the latest trends in sports nutrition.*”<sup>18</sup> A Chinese supplier, Foshan KOS Industry Trade Co, Ltd., “*shoots videos to teach our customers how to disassemble, assemble, operate machines.*” Those, too, are available on YouTube.<sup>19</sup> Even less legitimate looking operations such as TDPMolds.com, which lists a phone number in Louisiana and sells presses, as well as, oxycodone and Xanax molds, also publish videos online.<sup>20</sup>



# WHAT LAWS AND REGULATIONS GOVERN OWNERSHIP AND USE OF A PILL PRESS AND COUNTERFEIT DIE MOLDS?

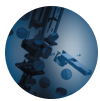
What someone is doing	Is it illegal under federal law?
Possession of a pill press without a counterfeit pill mold	Possession of the pill press is, in and of itself, not illegal. Buying or selling requires notification to the DEA, but we are not aware of either a serious penalty or a fine for failing to do so. <sup>21</sup>
Possession of a counterfeit pill mold with or without a pill press	21 U.S.C. § 333 levies up to 1 year in jail and/or a fine of \$1,000. When combined with attempts to defraud or mislead, 3 years and/or \$10,000
Use of counterfeit pill press/pill mold in commerce	15 U.S.C. § 1114 creates civil liability for anyone who reproduces or conducts commerce in the items that violate trademarks. 15 USC § 1116 discusses the rules around seizing items that violate registered trademarks.
Introducing counterfeit pharmaceuticals into interstate commerce or trafficking in controlled substances	These crimes vary at state and federal levels and are already illegal in well-understood ways, whether or not a pill press is utilized. For example, both the Federal Food, Drug, and Cosmetic Act and the Controlled Substances Act provide for jail time and significant criminal and civil penalties for manufacturing counterfeit controlled substances. <sup>22</sup>

## FEDERAL LAWS AND REGULATIONS

Several areas of federal law govern the use of pill presses and/or counterfeit die molds.

15 USC § 1116 (in the Commerce and Trade code), courts may grant an order to seize goods sold under a counterfeit mark, and that the entity requesting the seizure will have to “prove that the facts supporting findings of fact and conclusions of law necessary to support such order” at a hearing between 10 and 15 days after the order is granted. If a seizure is determined to be wrongful, the person who suffered damages may demand relief.<sup>23</sup>

21 USC §331 of the Food, Drug, and Cosmetic Act covers “making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other



thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.”<sup>24</sup> A first offense carries a penalty of not more than one year in jail and/or a fine of \$1,000 unless there is an attempt to defraud or mislead, in which case the penalties for first and subsequent violations of three years imprisonment and/or \$10,000. The actual manufacture or sale of the counterfeit drug comes with a maximum sentence of 10 years.<sup>25</sup>

Additionally, buying, selling, reselling, giving, importing, and exporting of pill presses is regulated by DEA. Any time a change of ownership occurs for one of these machines, the DEA requires you to file an electronic report. Importation requires this notification to be made in advance. Domestic transactions require that this notification is submitted within 15 days of the transaction. Domestic transactions also require additional verbal notification to the local DEA office or Special Agent in Charge. The electronic requirement for all transactions including domestic was added in 2017 and is outlined in this helpful presentation from the DEA’s Diversion Control Department.<sup>26</sup>

Not surprisingly, criminals engaged in the illegal manufacturing process are not reporting their pill press purchases to the DEA.

### STATE AND LOCAL LAWS AND REGULATIONS

Many states, but not all, have laws that govern the practice of manufacturing of prescription medication. These statutes often look a lot like the Federal Food, Drug, and Cosmetic Act. Illegally owning a pill press with a mold to produce counterfeit pills is a criminal violation of these state laws.

It is important to note the distinction here: the possession of the mold that makes the copy of the trademarked pill (that imprints the trademarked logo) is an illegal act under state law. A few states regulate the pill press itself.

We have, however, identified two state laws that regulate pill presses alone:

- One provision of Florida’s HB21, enacted into law in March 2018, “makes it a crime to possess, purchase, deliver, or sell a tableting machine, encapsulating machine, or controlled substance counterfeiting material for the purpose of illegally manufacturing controlled substances.” The law newly specifies that a person who possesses, purchases, delivers, sells, or possesses with intent to sell or deliver a pill press without a permit may be charged with either a second- or third-degree felony, depending on whether they knew or had reason to believe the machine would be used to manufacture controlled substances or counterfeit controlled substances.<sup>27</sup>
- Title 6, Chapter 481 of the Texas Health and Safety Code specifically lists “tableting machines” as chemical laboratory apparatus regulated in its Controlled Substances Act.<sup>28</sup>

It is significant that Florida’s HB21 is pertinent only to the illegal production of controlled substances and does not prohibit unlawful manufacturing of other counterfeit medicine. If for example, a suspect used a pill press to counterfeit a medicine used in cancer treatment



they could not be charged under this law. This is not an abstract fear. PSM has documented that counterfeit cancer medications have been found extensively in the United States for over a decade, ending with major investigations of criminal wholesalers that wrapped up in 2015. While these counterfeiters were infused, there are many chemotherapy treatments given in pill form.

We are not aware of regulations at the county, city, or township level that govern the ownership or sale of pill presses or of pharmaceutical manufacturing, but we do not have the resources to search all those statutes. If you know of a county, city, or township-level regulation of pill presses, please notify us at [editors@safemedicines.org](mailto:editors@safemedicines.org).

## HOW DO OTHER COUNTRIES REGULATE PILL PRESSES?

Since 2016, when concern about fentanyl-laced counterfeit pills began to gain momentum,<sup>29</sup> Canada has passed federal laws to restrict the sale of pill press equipment, and the provinces of Alberta, Ontario and British Columbia have followed.

At the federal level, a May 2017 amendment to Canada's Controlled Drugs and Substances Act impedes counterfeit pill traffickers by requiring the registration of every pill press imported into the country with Health Canada. Violators would be fined by Health Canada.<sup>30</sup>

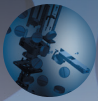
Alberta's Pharmacy and Drug (Pharmaceutical Equipment Control) Amendment Act of 2016 requires that anyone who owns, operates, or possesses pill press equipment must either be licensed under this Act, or be an institution pharmacy, a person specifically authorized to compound or manufacture drugs, or otherwise permitted by regulations. The penalties for the first and second offenses are not more than \$50,000 and \$125,000, respectively. Subsequent offenses carry a fine as large as \$375,000, six months in prison, or both.<sup>31</sup>

Ontario's Illegal Pill Press Act of 2017 limits the use of pill presses to pharmacists and people acting under the supervision of a pharmacist in a pharmacy for which a certificate of accreditation has been issued. The penalties range from a fine not to exceed \$200,000 and/or six months in prison for a first offense, to as much as \$500,000 and/or a two-year prison sentence for repeat offenders.<sup>32</sup>

British Columbia's Pill Press and Related Equipment Control Act of 2018 requires residents who want to sell equipment that can potentially be used to make illicit drugs to register and agree to a criminal record check. The law establishes notification requirements for when people acquire and dispose of the equipment and gives the province the authority to appoint inspectors. Penalties range from fines of not more than \$200,000 for a first conviction to not more than \$500,000, six months, or both for repeat offenders.<sup>33</sup>

In 2017, Manitoba declined to pass a similar bill.<sup>34</sup>





## HOW DO LAWS CRIMINALIZING PILL PRESSES COME INTO PLAY IN LAW ENFORCEMENT?

This was the most surprising aspect of our research. While it is a violation of regulation to buy a pill press without notifying the DEA, it is not illegal to own one. However, it is illegal to possess a pill press with a die mold that resembles a prescription pill or trademarked pharmaceutical drug.

Yet, criminals are unlikely ever to be charged with either of those crimes.

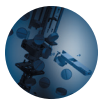
We have heard repeatedly from law enforcement that few people are charged under any of the pill press statutes. If you have a pill press, you are probably committing additional, more serious crimes, such as manufacturing counterfeit pills made with illegal controlled substances. What is essential to both law enforcement and public safety is that the crime ends. Discovering a pill press gives law enforcement a path to stop criminal behavior, but this path is less direct than we envisioned. Unless found in conjunction with a controlled substance or a die mold that violates a trademark, law enforcement is sometimes limited in their ability to seize pill presses.

### HOW PILL PRESSES ARE USEFUL IN CRIMINAL INVESTIGATIONS?

A pill press and the method by which it is acquired can be useful in proving criminal intent by an individual to manufacture, produce, and distribute illegal controlled substances and/or counterfeit substances.

In cases where there is a charge of manufacturing or distribution of counterfeit drugs and there is a pill press used to manufacture such counterfeit drugs, we have often seen the prosecutor not charge for possession of the pill press. However, the presence of the pill press bolsters the indictment of criminal(s) for manufacturing and/or distribution of a counterfeit substance. Instead of being its own indictable small crime, a pill press supports the proof of a much larger crime that creates a substantial risk of harm to human life.

Orlando, Florida resident Eric Falkowski, for example, was among seven individuals indicted for possession and distribution of fentanyl that caused serious bodily injury or death. Pills Falkowski manufactured and sold caused many overdoses and at least two deaths over the course of 2016. The indictment uses the facts of Falkowski's ownership and use of multiple pill presses to sketch a description of the criminal conspiracy which is the subject of the investigation. The prosecutor has chosen the possession and distribution charges because—when they cause death or serious harm—they carry a mandatory minimum sentences of 20 years in prison and a maximum fine of \$1 million.<sup>35</sup>



### **A PILL PRESS CAN TRIGGER A LARGER INVESTIGATION.**

As seen in the Resnik example earlier in this paper, the discovery of a pill press may indicate that someone is engaging in the crime of counterfeit medicine manufacturing. Following the pill press to its destination can lead investigators to members of a criminal conspiracy that they might not have known about. It can also provide reasonable cause needed to obtain a search warrant.

### **WHY DOESN'T EVERY SUSPECT CAUGHT WITH A PILL PRESS GET CHARGED WITH ILLEGAL POSSESSION OF A PILL PRESS?**

#### **Prosecutors do not like to “overcharge.”**

To our non-lawyer research team, this was not intuitive. Repeatedly prosecutors told us that they may not charge suspects with every possible crime because they already have sufficient charges for an indictment.

As Sam Louis, who has prosecuted many counterfeiters in his previous career in the United States Attorney's office in Southern District of Texas, said, “What sounds worse? Manufacturing counterfeit medicines not approved by the FDA or possession of an illegal pill press and pill molds? When the public or a judge reads an indictment, you want a gasp moment and a charge of ‘illegal possession of a pill press to make controlled substances’ doesn't provide that.”

#### **There aren't enough resources to pursue this charge over other crimes.**

Dan Zsido, a veteran law enforcement officer from Florida and the National Training and Education Director for NADDI, explained that there is no point bringing a charge that will be dropped. “Loading up a case with charges consumes valuable, limited, court resources with charges that are just going to be dropped or merged into the more major indictment anyway. This is how narcotics prosecutions have worked for years: if you get charged with trafficking, nobody will take the time to charge you with drug paraphernalia.”

During a background interview with an officer in a major metropolitan city, we asked, “What do you think would happen if you seized a pill press with pill molds and asked the district attorney to prosecute?” He replied that the district attorney in his city says they have resources to take 52 felony cases to trial a year. Why would you take this case when there are murders and drug distribution cases that pose a more clear and present danger to public safety than this? The officer seemed confident that a pill press and pill mold charge would not be prosecuted but simply pleaded out to a minimal charge. He said law enforcement would still happily confiscate the pill press, though, just to get it off the street.

One might argue that simply removing the illegal pill press and molds from the street is an ideal outcome with minimal resources expended. We heard from other local law enforcement agents that this would be taken more seriously in other jurisdictions, though.



## WHAT DOES IT MEAN THAT SO MANY CRIMINALS HAVE ACCESS TO PILL PRESSES AND MOLDS?

Advocates who study medicine safety detest the broadly dispersed, cottage industry of drug counterfeiters. As with the fear of small meth labs percolating throughout the country, they are concerned that hundreds of criminals are capable of producing millions of doses of perfect-looking but deadly fake medicines. It is a public health and public safety concern.

Even if you could make fentanyl in the United States disappear tomorrow, this manufacturing capacity would still exist. Criminals could turn to other substances to use as the active ingredient in their counterfeit medicines. Unfortunately, drug traffickers adapt to the “drug of the day,” so merely removing a specific controlled substance does not minimize the threat of drug activity; it’s a social behavior issue.

PSM’s Executive Director Shabbir Imber Safdar refers to fentanyl-based fake pills that began to show up in 2015 as part of the “third wave” of counterfeits to hit America. “The first wave was blister packs of fake medications sold to patients from fake Canadian pharmacies in the late 1990s. The second wave was wholesale adulterated cancer medications sold to American oncologists in the late 2000s. However, this third wave is most significant because the pills are being manufactured both domestically and imported from foreign counterfeiters. This wave of patient harm won’t be over until we have cleared out the domestic manufacturing capacity of garage pill presses.”



## 3D PRINTING

One of the questions that arose in our meetings over the course of 2018 was the potential impact of 3D printing on this rogue industry.

After talking to two experts in this field, we learned that 3D printing of medicines is possible, but requires extremely expensive machinery. Hobbyist 3D printers cannot be used to make medicine, and the machinery that does is beyond the hobbyist price range.

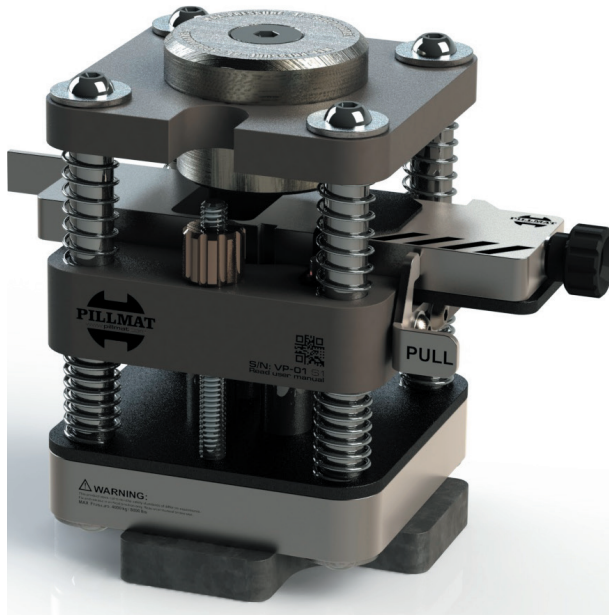
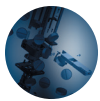
None the less, the 3D printing of pill presses and tablet molds is a real and current threat. While today's hobbyist 3D printers could only make a fragile, plastic pill press that would break pretty quickly, Computer Numerical Control (CNC) machining techniques are a much more significant threat.

Mose O'Griffin of Advanced Prototype Engineering explained it this way: "It boils down to how durable a mold is made. A 3D printed mold made out of extruded plastic wears out fast, after as little as 50 copies. It would be better to make a steel mold and polish it. It would take some skill, but you could measure the pill and make the CAD (Computer Aided Design) that way, or you could 3D scan the pill and then import the shape and make the mold. It costs \$20,000-30,000 to buy a 3D scanner, but you could rent time on one for much less. It's definitely not difficult. You could mill a mold with a CNC machine in a couple of days, spend some time polishing it, and go right into production."

For pill molds, both our experts told us that any of the popular pills currently counterfeited with fentanyl (analogues) were easy shapes to make knock-off molds for imprinting and suggested several different methods to go about making them including liquid molding, freehand CAD design and 3D-scanning an existing pill to create a digital file.

As a part of our research, we found CAD files for free online for a manual pill press (pictured below). The online CAD file repository said this file had been downloaded over 5,000 times.

Both of our experts said that we could feed those files directly to a 3D printer and build a pill press without difficulty, but the resulting pill press would probably break after a little production. With a bit more work, they said, we could use a CNC milling machine to make more durable parts out of sculpted aluminum. Though we did not find designs for pill molds, veteran FBI agent Tom Kubic and head of the Pharmaceutical Security Institute told us about a raid in Qatar over a decade ago where CAD files for trademarked pill shapes had been found, suggesting that these digital files have been around for a while now.



These are images of a pill press that you can 3D print from a free, online CAD file. Our fabrication experts said you could build it for less than \$400.

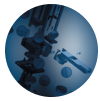
One of the impediments to 3D/CNC manufacturing of pill presses and molds is the cost of the machines required to produce high-end, durable parts. In response, a cottage industry has sprung up to rent time on machines or even produce parts on a contract basis. Shapeways, for example, is a service which allows you to upload an electronic file describing a 3D shape and for a small fee, receive the actual part back in the mail.<sup>36</sup>

Fabrication expert Tony Akens described the economics of this: “A CNC machine capable of milling a press out of aluminum would cost between \$3–4,000. You could even break apart the CAD file, outsource the production of each component, and assemble it. The CAD example you found online would cost under \$400 to have made this way.”

Both fabrication experts said that services that make 3D parts might not know what they were making. Even if they had an ethical concern about making a pill press for a customer, they might not recognize that the parts they were printing could be assembled into a pill press.

Like all digital goods, it is probably impossible to restrict access to these. For now, we hope that legal consequences will dissuade criminals from using digital files to produce real-world hardware that is illegal to possess.

Our research suggests that the ease of purchasing pill molds online probably makes it unnecessary to create your own. Our experts agreed that as long as you can buy pill presses and molds online and have a reasonable chance of getting them shipped to you, it would be cheaper and easier to do that than to fabricate them yourself.



## **IS IT A CRIME IF YOU 3D PRINT YOUR OWN PILL PRESS AND MOLDS INSTEAD OF ORDERING IT FROM A FOREIGN MANUFACTURER? CAN WE EVEN STOP PEOPLE FROM DOING IT?**

If you print your own press, in theory you should report it to the DEA, but there's not much of a penalty if you don't.

It is illegal to print or possess your own counterfeit pill mold to mimic legitimate medicine, whether or not you attach it to a pill press.

The harder question is, "Can we stop it?" In our research, we did not find evidence that 3D printing or CNC milling of pill presses or counterfeit punch dies are happening now in the criminal world; die molds and pill presses are so accessible through online ordering and smuggling that manufacturing one's own pill press is unnecessary.

# IS IT POSSIBLE TO TRACE PILLS BACK TO SPECIFIC PILL PRESSES AND DIE MOLDS TO PROSECUTE CRIMINALS?

In testimony to the United States Senate on October 2, 2018, FDA's Office of Criminal Investigations (FDA-OCI) Special Agent Daniel Burke outlined a key accomplishment in 2017, when they connected specific pills that killed Americans to seized pill molds in a clandestine lab:

“FDA-OCI also recently assisted DEA in their investigation of a massive overdose outbreak in the Nashville, Tennessee area. To link counterfeit Percocet pills containing fentanyl obtained from China to the point of manufacture, FDA's Forensic Chemistry Center (FDA-FCC) conducted an analysis of the tablet dies and punch tips seized from the suspects and compared them with counterfeit Percocet tablets obtained from the victims.

The FDA-FCC used 3D image analysis to determine that the tablet debossing profiles and overall surface morphology of the counterfeit Percocet tablets were consistent with the seized tablet punch tips. This toolmark evidence was used in the successful prosecution of eight defendants linked to the manufacture and distribution of the counterfeit Percocet pills containing fentanyl that caused at least seven hospitalizations and one death.”<sup>37</sup>

While we suspect this is not possible in every case, the ability to connect seized pill molds with counterfeit tablets that killed Americans is a valuable tool that we hope law enforcement uses whenever possible. To connect pills to seized pill molds would make for stronger prosecutions and in some cases, allow prosecutors to charge counterfeit manufacturers with homicide of the recipients they kill, in addition to counterfeit manufacturing and distribution.



## POLICY TOOLS

The problem of illegal pill press purchase, possession, and use will not be easy to solve in a world with porous borders. Though we are not making new policy recommendations in this document, we present a number of ways people have or suggested addressing the problem of widespread pill press availability in the hands of criminals.

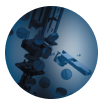
### **INCREASING PENALTIES FOR POSSESSING A PILL PRESS AND MOLDS OR COMMITTING A CRIME WITH A PILL PRESS AND MOLDS**

Some legislators have heard about the problem of pill presses and propose to enact or increase the penalty for possessing a pill press or pill mold with the intent to manufacture counterfeits; enhancements ranging from one to three years and increasing the fine. This is the approach taken by bipartisan, bicameral legislation at the federal level proposed by Sen. Bill Cassidy (R-LA) and Sen. Maggie Hassan (D-NH), and Rep. David Kustoff (R-TN-08) and Rep. Annie Kuster (D-NH-02) in the Substance Tableting and Encapsulating Enforcement and Registration (STEER) Act (S. 3281 / H.R. 6554).<sup>38</sup> This bill would penalize individuals who fail to register pill presses intended to manufacture controlled substances with the Attorney General, instead of waiting for individuals who get caught with them to get prosecuted. Additionally, the STEER Act may benefit from refinement to appropriately target illicit actors while minimizing burden on legitimate supply chain entities by including an exemption for FDA-registered and regulated manufacturers.

From what we have learned, criminals are not currently operating as if there is much of a threat of prosecution for owning a pill press with a counterfeit pill mold even though it is illegal today. We think it is impossible to deter criminals from obtaining and using an illegal-to-possess piece of equipment if they don't fear the legal penalties associated with it. We keep finding cases where criminals caught with an illegal pill press and molds do not face a charge for the pill press and molds for all the reasons we outlined previously. Realistically, unless prosecutors charge defendants for possession of pill presses and dies, increasing the penalty for having these items may not be an effective deterrent.

Some of our interview subjects recommended the possession of a pill press be considered an aggravating factor in United States sentencing guidelines, akin to possession of an illegal firearm to commit a crime. Today, if you commit a felony crime with a firearm, your sentence can be increased by one to three years, even without a separate firearm charge. The elegance of this solution lends itself to the pill press problem. It does not require a behavior change from either law enforcement investigators or prosecutors, and it creates a solid response to an issue with a substantial risk of harm to human life. They will still build cases against counterfeiters; they will still seize the pill press and use it to build a case against the suspects.





## **ILLEGAL PILL PRESSES: AN OVERLOOKED THREAT**

Both the state and federal justice systems utilize sentencing enhancements, so this approach could be effective for both state and federal policymakers who want to take action on this topic.

We did not interview enough people who work in state law enforcement to know whether or not increasing penalties at the state level would make a difference or not. We will be avidly watching the Florida law to see what kinds of effects it has on criminal use of pill presses and molds in the State of Florida.

### **INCREASING EDUCATION FOR LOCAL LAW ENFORCEMENT ABOUT PILL PRESSES**

Over and over again, law enforcement officers told us they had educated themselves about pill presses by looking at photos on the Internet. At the recent NADDI annual training in Norfolk, VA in October 2018, Sven Bergmann ran a “drill press or pill press” quiz to the 300+ attendees that showed just how hard it can be to tell the difference without education about pill presses. Educational training for law enforcement, such as that done by NADDI, is an ideal vehicle for familiarizing law enforcement with pill presses and the legal avenues of response

You can find NADDI trainings all over the country at [www.naddi.org](http://www.naddi.org). Not all NADDI training include pill press education, so inquire first before attending.

### **ENDING NOTIFICATION TO THE SHIPPER OF SEIZED PILL PRESSES AND PILL MOLDS AT THE BORDER**

If CBP intercepts a pill press ordered on the web from overseas, it is required to notify the shipper that their property has been seized and they are allowed to contest the seizure. You can see a list of seized property online at [www.forfeiture.gov](http://www.forfeiture.gov). This occurs unless law enforcement performs a controlled delivery.

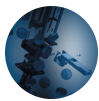
Notifying smugglers of their failure seems like an odd practice when dealing with something that should be considered criminal contraband. Required notification warns smugglers that a shipping route has become ineffective and helps them to adjust their smuggling methods.

Notifying smugglers about these seizures inadvertently helps them to improve their criminal enterprises, which runs counter to the goal of protecting Americans from counterfeit medications.

### **PROVIDING MORE INFORMATION ON PILL PRESS COMMERCE AND SEIZURES TO CONGRESS FOR OVERSIGHT**

A bipartisan group of legislators from the House Energy and Commerce Committee that has worked on legislation to stem the opioid crisis asked the DEA for more information about commerce and seizures of pill presses in 2017.<sup>39</sup>

Rather than an adversarial request, we view this inquiry as a well-intentioned effort to learn about the state of the problem and what resources or changes in the law are needed to be provided by Congress to most effectively address the burgeoning issue.



“As noted in the July 2016 DEA Intelligence Brief, traffickers purchase pill presses from China to create counterfeit pills to supply illicit United States drug markets. Under United States law, the DEA must be notified of the importation of a pill press,” wrote Reps. Walden, Pallone, and DeGette. “However, foreign pill press vendors often mislabel the equipment or send it disassembled to avoid law enforcement detection.”

The leaders continued: “To combat the fentanyl wave of the opioid crisis and consider potential legislative solutions, it is vital that the Committee receive more detailed information about pill press machine commerce and seizure data.”

As policy people, we are incredibly interested in all data about pill presses and molds in use in America.

### **CREATING REGISTRIES TO MAKE IT EASIER TO TRACE THE ORIGINS OF PILL PRESSES REGISTRY OR SERIALIZE PILL PRESS SYSTEMS**

Today there is no consistent registration or serialization of pill press machines. We repeatedly heard from interviewees that it is difficult to trace the illegal sale of these machines without a registration. Plenty of criminals order them under their own names. Should enforcement be stepped up, straw man purchases would become common. The aforementioned legislation co-sponsored by Sens. Cassidy and Hassan and Reps. Kustoff and Kuster creates a registry and penalties for failure to comply. Other law enforcement sources have suggested serializing them and taking the burden off of buyers.

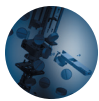
There is a large health supplements industry that creates their own pills that are not counterfeit pharmaceuticals that, presumably, may have some concerns about serialization or restrictions. Opposition to any proposal that changes traceability in this space is likely to encounter opposition or resistance from legal users and manufacturers of pill presses. Similarly, the proposed registry would impose significant burdens on already-highly regulated entities (e.g., biopharmaceutical manufacturers) that are not the source of diversion/manufacture of pill presses used to make counterfeit products. Accordingly, any registry/serialization system would need to be specifically targeted at those entities contributing to the problem.

Serialization and tracing are a much larger issue to be weighed than we have either expertise or time for in this paper.

### **DON'T ALLOW DRUG IMPORTATION**

Opposing drug importation is the one policy NABP, NADDI, and PSM already support, and for a good reason.

We are facing an unprecedented crisis of safety from outside and inside our borders. The safety of Americans is under unprecedented attack from counterfeiters inside and outside the United States. Importation would endanger Americans by creating an even larger volume of medical products that are already insufficiently screened. Given the new threat of pressing pills domestically, anything that increases the amount of medical products flowing over the border, including medical-grade chemicals that could be used to make counterfeits, is a bad idea.



*“The fact that we have been unable to stem the flood of criminals buying pill presses and illegally making counterfeits within our own country should cause us to panic about allowing importation of medicine from outside the secure supply chain of the United States.”*

*—Shabbir Safdar, Executive Director, PSM*

**Importation will flood the country with counterfeit medicines and even more fentanyl (analogues) products.**

Today the volume of medical products coming across the border is enormous. FDA Commissioner Scott Gottlieb, M.D. reported in March 2018 that less than 1% of all medical products coming into the country through International Mail Facilities are inspected.<sup>40</sup> Counterfeit medicines are already extremely difficult to detect. If we legalize drug importation, it will be the same as tripling the size of that haystack (or worse). Finding the fentanyl type substances used to make these counterfeit products domestically with unregulated pill presses will be even more difficult and will create an even higher risk of harm to human life.

**Importation will divert law enforcement resources from tackling the current opioid crisis**

Law enforcement resources are currently stretched thin stemming the tide of synthetic opioids that are flooding our country. Many of them are presently chasing counterfeit opioids that are flooding our streets, as well as, responding to the overwhelming increases in daily overdoses. If we flood the country with suspect medications through drug importation, our first responders' workload would significantly increase because of the increased suspect drug supply and the resulting fallout.

**Importation will put law enforcement in harm's way**

It is no secret that the easiest way to smuggle fentanyl (analogues) into the United States is to cloak its presence in other products or to put it in a small package and mail it. The drug's portability increases the risk of law enforcement and regulators unknowingly encountering the physical substance or its residue. In over a dozen states, first responders have been exposed to fentanyl (analogues) while serving warrants, cleaning emergency room bays, assisting overdose victims, conducting roadside searches, and many other scenarios. Direct contact with these toxic substances creates a substantial risk of harm to human life, and the potential of unknowingly transferring the substance to an innocent victim is an increasing reality.

**Importation will make it harder to find illegal pill presses**

The volume of packages at the border has overwhelmed our inspection systems, and through that volume, illegal pill presses and illicit fentanyl has flowed.

**We do not believe allowing drug importation is smart policy.**



# APPENDIX

## RELEVANT EXISTING LAWS AND PENDING LEGISLATION REGARDING PILL PRESSES

### *Federal Laws that specifically address pill presses*

21 USC 331: Prohibited acts<sup>41</sup>

21 USC 333: Penalties<sup>42</sup>

21 USC 334: Seizure<sup>43</sup>

21 USC 830: Regulation of listed chemicals and certain machines<sup>44</sup>

21 USC 843: Prohibited acts C<sup>45</sup>

21 USC 881: Forfeitures<sup>46</sup>

### **Legislation in progress that addresses pill presses**

H.R.3283—To restrict the mailability of tableting machines, encapsulating machines, and controlled substance counterfeiting materials, and for other purposes. (Introduced 7/18/2017)<sup>47</sup>

H.R.6554 / S.3281—Substance Tableting and Encapsulating Enforcement and Registration Act (Introduced 7/26/2018)<sup>48</sup>

S.3463—Blocking Deadly Fentanyl Imports Act (Introduced 09/18/2018)<sup>49</sup>

H.R.1781—Comprehensive Fentanyl Control Act (Introduced 03/29/2017)<sup>50</sup>

### **INTERVIEWS CONDUCTED:**

Below is a list of interviews we conducted as part of this paper. We often promised interviewees anonymity in order to allow them to speak freely about cases and case details they did not want to see exposed in the public sphere. Where we have done this, these interviews are marked <anonymous>.

- Tom Kubic, Pharmaceutical Security Institute, September 7, 2018
- Sam Louis, Partner, Clark Hill; PSM Board Member, former Deputy Criminal Chief of the Program Fraud Department of Justice in the Southern District of Texas, September 10, 2018



## ILLEGAL PILL PRESSES: AN OVERLOOKED THREAT

- <anonymous> Nashville Police Department Officer, September 10, 2018
- Tony Akins, 3D Printer Hobbyist, September 14, 2018
- Dr. Kenneth McCall, Pharmacist, Professor of Pharmacy at the University of New England, PSM Board Member, September 10, 2018
- Jeff Henise, fabrication expert, September 14, 2018
- George Karavetsos, Partner, DLA Piper, former head of the United States FDA's Office of Criminal Investigations, September 7, 2018
- <anonymous> Retired DEA Officer, September 17, 2019
- Mose O'Griffin, Advanced Prototype Engineering, 3D fabrication expert, September 21, 2018
- <anonymous> State Bureau of Investigation staff, September 21, 2018
- Lisa McElhaney, President of the North American Drug Diversion Investigators Association, November 30, 2018

## CASES OF INTEREST RELATED TO PILL PRESSES AND DIE MOLDS

1. Complaint, USA v. Wyatt Pasek et al, United States District Court for the Central District of California, 2018<sup>51</sup>
2. Indictment, USA v. Nathan Ott, et al United States District Court for the Middle District of Pennsylvania, 2017<sup>52</sup>
3. Complaint, USA v. Francisco Perez, et al, United States District Court for New Jersey, 2018 (heroin and tramadol)<sup>53</sup>
4. Complaint, USA v. Gino Carl Von Eckstein, United States District Court for the Northern District of California, 2018 (methamphetamine)<sup>54</sup>
5. Indictment, USA v. Ross Allen Riker, et al, United States District Court for the Southern District of Florida, 2018<sup>55</sup>
6. Indictment, USA v. Lewis Ray Chafin, Jr., United States District Court for the Western District of Arkansas, 2018<sup>56</sup>
7. Superseding Indictment, USA v. Johnny Clyde Benjamin, Jr., et al, United States District Court for the Southern District of Florida, 2017<sup>57</sup>
8. Second Superseding Indictment, USA v. Aaron Shamo, et al, United States District Court for the District of Utah, 2018<sup>58</sup>
9. Superseding Indictment, USA v. Alaa Mohammed Allawi, et al, United States District Court for the Western District of Texas, 2017 (fentanyl and methamphetamine)<sup>59</sup>
10. Complaint, USA v. Joshua J. Kelly, United States District Court for the Southern District of Florida, 2017<sup>60</sup>

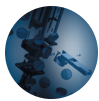


11. Indictment, USA v. Eric Hughes, et al, United States District Court for the District of South Carolina, 2017<sup>61</sup>
12. Superseding Indictment, USA v. Jonathan Barrett, et al, United States District Court for the Middle District of Tennessee, 2017<sup>62</sup>
13. Indictment, USA v. Jian Zhang, et al, United States District Court for the District of Northern Dakota, 2017<sup>63</sup>
14. Complaint and Indictment, USA v. Daniel O'Neil, et al, United States District Court for the Eastern District of New York, 2017<sup>64</sup>
15. Indictment, USA v. Gary Resnik, et al, United States District Court for the Central District of California, 2016<sup>65</sup>
16. Indictment, USA v. Nathaniel Jetter, United States District Court for the District of Utah, 2016<sup>66</sup>
17. Indictment, USA v. David Beckford, et al, United States District Court for the Northern District of California, 2016 (alprazolam)<sup>67</sup>
18. Indictment, USA v. Kia Zolfaghari, et al, United States District Court for the Northern District of California, 2016<sup>68</sup>
19. Indictment, USA v. Skyler Dean Prael, United States District Court for the Western District of Kentucky, 2016<sup>69</sup>
20. Complaint, USA v. Jason Oliviera, United States District Court for the District of Connecticut, 2013<sup>70</sup>



## FOOTNOTES

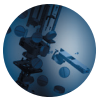
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