PILL PRESS LAWS: A FORGOTTEN ASPECT OF COUNTERFEIT DRUGMAKING – UPDATE

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Numerous recently-enacted laws and regulations across the United States limit opioid prescriptions and place quotas on opioid production. While these supply-based laws and regulations may somewhat reduce the potential for individuals to develop a dependence on prescription opioids, they do not reduce the demand for opioids from those who are already dependent. When opioid prescriptions become more difficult to obtain, those who are opioid dependent may turn to illegal means to obtain the drugs. Drug traffickers, motivated by large profit potentials, fill this void by making counterfeit medications, often containing fentanyl or fentanyl analogs, to meet the high demand for prescription drugs within the illegal drug market.

The first U.S. reports of counterfeit pills containing fentanyl emerged in a handful of jurisdictions in 2015. By October 2019, all U.S. jurisdictions reported them. One reason for the proliferation is the ease with which drug traffickers can enter this market. With only a few thousand dollars, a person can purchase a pill press, pill molds, and dies that mimic trademarked pharmaceuticals and enough illicitly imported fentanyl to generate $5 to $20 million in sellable counterfeit pills. Given the simple manufacturing process and low startup costs, counterfeiting is an attractive area for drug traffickers, albeit one that creates substantial health risks to consumers. Despite this, however, there are relatively few federal or state laws governing access to pill press machines, and those that exist do not provide for substantial oversight or assessment.

In this fact sheet, the Legislative Analysis and Public Policy Association (LAPPA) reviews: (1) what pill presses are and how people obtain them; (2) why fentanyl is an often-used drug in counterfeit pills and the health concerns this poses; and (3) the limited, currently-in-force, applicable state and federal laws. LAPPA first published this factsheet in March 2021. In this updated version, items (1) and (2) remain the same while there are some changes to item (3), the section on state and federal laws.

PILL PRESS MACHINES

Originally conceived as a tool for pharmaceutical development and manufacturing, a pill press—also called a tableting machine—is a mechanical device that compresses powder into tablets by running the powder through a machine fitted with a die mold that determines the shape of and markings on the tablets. Pill presses vary in size and capacity, with desktop machines able to make approximately 1,800 pills per hour to industrial machines that can produce over a million pills in an hour. A similar type of tool is an encapsulating machine or capsule filling machine. Instead of pressing powder into a tablet like a pill press does, an encapsulating machine packs the powder into a gelatin capsule. Encapsulating machines range from small manual devices costing around $30 to large industrial scale machines. For purposes of simplicity, LAPPA uses the term “pill press” in the factsheet to refer to both pill presses and encapsulating machines, as the same laws, regulations, and health concerns apply to both. A variety of domestic and international pharmaceutical industrial equipment companies manufacture pill presses, and the Drug Enforcement Administration (DEA) recognizes 102 companies as legitimate suppliers of pill presses.

Pill presses are readily available to small and large drug trafficking organizations, as well as independent individuals, through online sources. New and used pill presses can be purchased on sites like eBay and the international auction site, Alibaba. Pursuant to its policies, Amazon bans pill presses from its platform, but there are anecdotal reports that sellers can post and sell banned items on the site. Amazon stocks and sells a variety of manual encapsulating devices. In addition to a pill press, counterfeit drug makers also need counterfeit die molds to convincingly shape and mark counterfeit pills to make them look legitimate. While counterfeit die molds are difficult to obtain on the open Web, they are available for purchase on the “dark Web,” an area of the internet that is not accessible to traditional search engines and used for illegal activity. To demonstrate how relatively inexpensive

and accessible pill presses and counterfeit die molds are, the DEA conducted an online search of auction websites in April 2016 and discovered a pill press capable of producing 5,000 pills per hour priced at $995 and die molds for oxycodone and Xanax pills priced at $115 and $130, respectively.

FENTANYL: THE DANGEROUS SUBSTANCE OF CHOICE

Because of fentanyl's wide availability, low cost, and high potency, counterfeit pill manufacturers often choose it for use in their operations. Fentanyl can be purchased on the dark Web, usually from Chinese suppliers, for a few thousand dollars. With as little as one kilogram (2.2 pounds) of fentanyl powder, drug traffickers can produce hundreds of thousands of pills and generate large amounts of revenue. For example, if a drug trafficker purchases one kilogram of fentanyl and uses one milligram of fentanyl per pill, he or she could generate one million pills. According to the DEA, in U.S. markets, counterfeit pills containing fentanyl sell at prices between $10 and $20 per pill. Using these numbers, a drug trafficker could generate between $10 to $20 million in sales from one kilogram of fentanyl.

Using counterfeit die molds, tableting binders and fillers, and food-grade dyes with a pill press, drug traffickers can make counterfeit pills look like a variety of prescription pills. In sophisticated operations, a counterfeit pill can be visibly identical to its legitimate prescription form and only distinguishable through chemical testing. Counterfeit pills containing fentanyl often look like prescription opioids, including OxyContin, Vicodin, or Percocet. Interestingly, authorities have also found fentanyl in counterfeit benzodiazepines, like Xanax or Valium. The presence of fentanyl in non-opioid counterfeit pills suggests that drug traffickers will utilize fentanyl to expand their customer base and further increase their profit margins.

Traffickers typically refer to the counterfeit pills by the brand or generic name they mimic, meaning that a consumer is often unaware that he or she purchased counterfeit pills, often containing fentanyl. This lack of knowledge makes counterfeit pills particularly dangerous. Even if a consumer knows that the pill is counterfeit, there is no way to know if, or how much, fentanyl is in the pill. The dosage of fentanyl per pill can vary widely between drug vendors and batches. In 2019, the DEA conducted a sampling of counterfeit tablets nationwide and found that 27 percent contained a lethal dose of fentanyl. As of 2022, the number increased to 60 percent. A lethal dosage of fentanyl to an opioid-naïve individual is two milligrams, equivalent in size to a few grains of salt, and much smaller than a lethal dose of heroin (30 milligrams). Consumers who lack knowledge that purchased pills contain fentanyl—or, at the very least, that the pills contain a particular amount of fentanyl—risk inaccurately dosing themselves and failing to take adequate harm reduction precautions, such as carrying naloxone or ingesting the pills near a friend or acquaintance.

While fentanyl is the most commonly used substance in counterfeit pills, the DEA reports that counterfeit pills are compounded with other substances, such as methamphetamine. Drug trafficking organizations use powdered methamphetamine to create counterfeit prescription stimulants, such as Adderall. As with counterfeit pills containing fentanyl, counterfeits containing methamphetamine pose a high risk of overdose or death to unknowing consumers.

FEDERAL AND STATE LAWS GOVERNING PILL PRESSES

Pill presses on their own are not dangerous if used for legitimate purposes including for medical, scientific, and commercial reasons. Issues arise, however, when these machines land in the hands of organizations or individuals seeking to create counterfeit controlled substances. Federal laws that limit access to pill presses exist, but the laws largely rely on self-reporting when machines are bought or sold. Under the Controlled Substances Act (CSA or the Act), all participants in a transaction involving a pill press are required to "keep a record of the transaction for two years after the date of the transaction," including "the date of the regulated transaction, the identity of each party to the regulated transaction, …a description of the [pill press], and a description of the method of transfer," and

provide this record to the U.S. Attorney General via the DEA Diversion Control Division.[1] The registration requirement does little to deter clandestine pill press operations from starting up, however, because illegitimate sellers and buyers can simply ignore these requirements. Thus, as a practical matter, the registration mandate only serves as an additional penalty for counterfeit drug operations once discovered by law enforcement. However, and perhaps foreshadowing increased enforcement in the future, in February 2024, the DEA issued a letter to "e-commerce companies" reminding them that if such companies sell pill presses, they are deemed to be "regulated entities under the Controlled Substances Act (CSA) [and] generally required to comply with CSA recordkeeping, identification, and reporting requirements on the distribution, importation, and exportation of pill press machines."[2]

The CSA partially addresses the registration loophole by making pill presses that are possessed or transferred in violation of the Act subject to forfeiture.[3] U.S. Customs and Border Protection (CBP) has the authority to seize pill presses that are imported into the U.S. without registration. Illicit operators have adapted to this risk, however. The sheer numbers of packages that go through U.S. customs make enforcement difficult, and the problem is exacerbated by foreign sellers who advertise the ability to get shipments past inspectors. For example, pill press sellers may break the machines down into multiple packages, describing them on manifests as "toys," "grain mill mixing machine[s]," or "laboratory glassware." Alternately, 3D printing technologies allow some individuals to bypass shipping altogether by purchasing and downloading printing instructions for pill press parts and fabricating the machinery in homes or warehouses. Although 3D printed machines and molds are far less durable than traditional pill presses, they are nevertheless functional for a period of time and are considerably more difficult to intercept.

Because pill presses have a variety of legitimate uses, the mere possession of a pill press is not against the law. Under the CSA, it is against the law to be in possession of a pill press, if the owner "know[s], intend[s], or ha[s] reasonable cause to believe, that [the pill press] will be used to manufacture a controlled substance or listed chemical."[4] In contrast, there are no legitimate uses to counterfeit die molds. Therefore, regardless of intent, it is illegal under the CSA to make, distribute, or possess any die mold or other similar object designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark on any drug as to render it a counterfeit drug.[5] Under current law, an individual who illegally possesses a pill press or die mold is subject to up to four years of imprisonment, a fine, or both. However, if an individual commits such a violation more than once or in combination with violating a law related to narcotic drugs, marijuana, or depressant or stimulant substances, the individual will be sentenced to up to eight years of imprisonment, a fine, or both. This is separate from any federal penalties that would ensue for the unlawful act of knowingly or intentionally creating; distributing or dispensing; or possessing with the intent to distribute or dispense, a counterfeit substance.[6]

In recent years, several federal legislators offered bipartisan legislation to place harsher penalties on the illegal possession of pill presses. As of the date of this publication, none of these bills passed. In 2017, H.R. 3283 proposed to restrict the mailing of pill presses and other counterfeiting materials and make it a crime to knowingly mail equipment that could be used to manufacture counterfeit controlled substances to an unauthorized person.[7] Violators would have been subject to a fine, up to a year in prison, or both. In 2018, the Substance Tableting and Encapsulating Enforcement and Registration Act, or STEER Act, proposed to require anyone wishing to possess a pill press to affirmatively register it by applying to the Attorney General.[8] Moreover, the possession of a pill press

[1] 21 U.S.C. § 830(a) (2024) (referring to pill presses as "tableting machines" and "encapsulating machines"); *see also* 21 C.F.R. § 1310.05(b)(2) and (c) (2024).
[2] *DEA Issues Letter to E-Commerce Companies on the Sale of Pill Presses Used to Make Fentanyl Pills*, U.S. Drug Enforcement Administration (February 26, 2024), https://www.dea.gov/press-releases/2024/02/26/dea-issues-letter-e-commerce-companies-sale-pill-presses-used-make.
[3] 21 U.S.C. § 881(a)(9) (2024).
[4] 21 U.S.C. § 843(a)(6) (2024).
[5] *Id.* at § 843(a)(5).
[6] 21 U.S.C. § 841(a)(2) (2024).
[7] To restrict the mailability of tableting machines, encapsulating machines, and controlled substance counterfeiting materials, and for other purposes., H.R. 3283, 115th Cong. (1st Sess. 2017).
[8] S. 3281, 155th Cong. (2nd Sess. 2018); H.R. 6554, 155th Cong. (2nd Sess. 2018).

without an appropriate, regularly updated registration would result in criminal penalties. In 2019, several senators introduced the Criminalizing Abused Substance Templates (CAST) Act of 2019.[9] This bill would have made it a crime to knowingly possess a die mold with the intent to manufacture a counterfeit Schedule I or II substance. A violator would have been subject to a prison term of up to 20 years and a fine. On March 10, 2023, two members of the House of Representatives reintroduced the bill as the CAST Act of 2023.[10] As of March 2024, it remains pending in the House.

Most states rely on federal laws related to pill presses to keep bad actors in check. As of March 2024, eight states—Florida,[11] Hawaii,[12] Mississippi,[13] North Carolina,[14] Tennessee,[15] Texas,[16] Utah,[17] and Washington[18]—have enacted their own laws with respect to pill presses. Although this is a small number of states, it represents double the number of state laws in effect in March 2021. Moreover, proposed state legislation involving pill presses, previously scarce, is increasing in recent years. In 2023 and in the 2024 session to date, legislators in Arizona,[19] Connecticut,[20] Georgia,[21] Massachusetts,[22] New York,[23] Ohio,[24] Oregon,[25] Virginia,[26] and Wisconsin[27] introduced bills to more tightly regulate the possession, use, or transfer of pill presses.

CONCLUSION

The availability of counterfeit pills containing fentanyl, methamphetamine, or other controlled substances is likely to continue due to the relative ease and low costs associated with obtaining the necessary materials and equipment needed to establish a counterfeit pill operation. Counterfeit drugs produced through illicitly obtained pill presses and die molds present the possibility of injury or death to consumers who do not know what substances, or how much of a substance, a pill contains. To effectively reduce the risks associated with counterfeit drugs it is necessary to attack the problem from the source through the development of laws and systems that can stop counterfeit machinery from ending up in the wrong hands.

RESOURCES

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[9] S. 2573, 116th Cong. (1st Sess. 2019); H.R. 4510, 116th Cong. (1st Sess. 2019).
[10] H.R. 1549, 118th Cong. (2nd Sess. 2024).
[11] FLA. STAT. ANN. § 893.147(7) (West 2024).
[12] HAW. REV. STAT. ANN. § 329-63 (West 2024).
[13] MISS. CODE ANN. § 41-29-315 (West 2024).
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ABOUT THE LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

The Legislative Analysis and Public Policy Association (LAPPA) is a 501(c)(3) nonprofit organization whose mission is to conduct legal and legislative research and analysis and draft legislation on effective law and policy in the areas of public safety and health, substance use disorders, and the criminal justice system.

LAPPA produces up-to-the-minute comparative analyses, publications, educational brochures, and other tools ranging from podcasts to model laws and policies that can be used by national, state, and local criminal justice and substance use disorder practitioners who want the latest comprehensive information on law and policy. Examples of topics on which LAPPA has assisted stakeholders include naloxone laws, treatment in emergency settings, alternatives to incarceration for those with substance use disorders, medication for addiction treatment in correctional settings, and syringe services programs.

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