

LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

PILL PRESSES: SUMMARY OF STATE LAWS

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PILL PRESSES: SUMMARY OF STATE LAWS

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SUMMARY

In 2015, the first reports emerged of counterfeit pills containing fentanyl appearing in the United States.¹ Proliferation of these pills has accelerated rapidly, to the point that, as of October 2019, they had been found in each of the fifty states.² One reason for this is the ease with which individuals can enter the market for such drugs. With only \$1,000, one can purchase a pill press (also known as a tableting or encapsulating machine), faked pill molds and dies that mimic trademarked pharmaceuticals, and sufficient illicitly imported fentanyl to create between \$5 and \$20 million in counterfeit pills.³

While the controlled substances like fentanyl receive much attention, the presses and molds used to create counterfeit pills have been comparatively ignored. From inexpensive “desktop” presses that can produce hundreds of pills per hour to industrial-scale behemoths producing millions per hour, these machines are critical to producing picture-perfect counterfeits of recognizable drugs from oxycodone to aspirin. But looks can be deceiving, and a familiar-looking pill can disguise the presence of fentanyl or its analogues. Even more troubling is that, per a 2018 examination of seized tablets, 13 percent of fentanyl-containing pills contained lethal doses, an increase from 7 percent in 2017.⁴ But counterfeit drugs are not being made with fentanyl alone: multiple counterfeiters have produced fake Adderall pills containing methamphetamine,⁵ and counterfeit cancer treatment drugs have spread “extensively” in the United States for over a decade, some with ingredients no more uncommon than acetaminophen.^{6 7}

Federal laws exist to combat the use of pill presses to create counterfeit drugs, but they largely rely on self-reporting when such machines are bought or sold. Under the Controlled Substances Act (CSA), all participants in a transaction involving a tableting or encapsulating machine shall “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 tableting machine or encapsulating machine, and a description of the method of transfer,” and provide this record to the Attorney General of the United States.⁸ When black market drug manufacturers simply ignore these requirements, the registration mandate can only serve as an additional penalty for drug operations that are already

¹ “Deadly Counterfeit Pills Found In All 50 U.S. States; Deaths Now Reported In 42 Of Them,” *The Partnership for Safe Medicines*, October 26, 2019, <https://www.safemedicines.org/2020/10/deadly-counterfeit-pills-found-in-all-50-u-s-states.html>.

² *Id.*

³ “Counterfeit Pills Containing Fentanyls: A Global Threat,” *DEA Intelligence Brief*, July 2016, <http://bit.ly/2Gzqnd1>.

⁴ *Id.*

⁵ “Deadly Counterfeit Pills Found In All 50 U.S. States; Deaths Now Reported In 42 Of Them,” *The Partnership for Safe Medicines*, October 26, 2019, <https://www.safemedicines.org/2020/10/deadly-counterfeit-pills-found-in-all-50-u-s-states.html>.

⁶ “Illegal Pill Presses: An Overlooked Threat to American Patients,” *The Partnership for Safe Medicines*, March 2019, <https://www.safemedicines.org/wp-content/uploads/2019/03/IllegalPillPressReport-2019-SECURE.pdf>.

⁷ “Fake Cancer Medicine Found To Only Contain Acetaminophen,” *The Partnership for Safe Medicines*, February 25, 2019, <https://www.safemedicines.org/2019/02/fake-cancer-medicine-found-to-only-contain-acetaminophen.html>.

⁸ 21 U.S.C. § 830.

manufacturing fake drugs once discovered by law enforcement; it does little to deter these operations from starting up in the first place.

The CSA partially addresses this by making pill presses that are possessed or transferred in violation of the Act subject to forfeiture.⁹ U.S. Customs and Border Protection (CBP) can seize pill presses that are imported into the United States without proper registration. Both the buyers and sellers of pill presses 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 their ability to get their shipments past inspectors. Sellers break the machines down into multiple packages, describing them on manifests as “toys,” “children’s clothing,” “grain mill mixing machine,” or “laboratory glassware.”¹⁰ A new threat has emerged in the era of 3D printing: would-be drug manufacturers can avoid customs inspectors entirely by downloading the 3D plans for pill press parts and fabricating them themselves. Though such machines and molds are far less durable, they are nevertheless functional, and since they never actually “change hands” at all, they are considerably more difficult to intercept.¹¹

At the federal level, on its own, mere possession or distribution of a pill press is not against the law. It is only a violation when the owner of a pill press “know[s], intend[s], or ha[s] reasonable cause to believe, that it will be used to manufacture a controlled substance or listed chemical.”¹² The same cannot be said of the molds, punches, and dies that are used to replicate trademarked drugs within the pill presses. Regardless of knowledge or intentionality, “[m]aking, selling, disposing of, or keeping in possession, control, or custody, or concealing” any such pill mold is unlawful if it is “designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another.”¹³ There is no ability to claim ignorance of the intended purpose of the mold to avoid criminal liability.

In recent years, bipartisan federal legislation has been offered to place stiffer penalties on possession of the pill pressing machines themselves. In 2018, Senators Bill Cassidy (R-LA) and Maggie Hassan (D-NH) and Representatives David Kustoff (R-TN) and Annie Kuster (D-NH) introduced the Substance Tableting and Encapsulating Enforcement and Registration Act, or STEER Act. Under this bill, anyone wishing to possess a tableting or encapsulating machine would need to affirmatively register it by submitting an application to the Attorney General, and possession without appropriate, regularly-updated registration would result in criminal penalties.¹⁴ As of yet, though, this legislation has not been adopted. In 2019, Rep. Kustoff, along with Rep. Abigail Spanberger (R-VA) introduced the Criminalizing Abused Substance Templates Act, which would have prohibited the knowing possession of a “pill press mold” with the intention of producing a counterfeit drug, subject to a 20-year prison sentence and fines.¹⁵ However, this bill also failed to advance in Congress.

⁹ 21 U.S.C. § 881(a)(9).

¹⁰ “Counterfeit Pills Containing Fentanyl: A Global Threat,” *DEA Intelligence Brief*, July 2016, <http://bit.ly/2Gzqnd1>.

¹¹ “Illegal Pill Presses: An Overlooked Threat to American Patients,” *The Partnership for Safe Medicines*, March 2019, <https://www.safemedicines.org/wp-content/uploads/2019/03/IllegalPillPressReport-2019-SECURE.pdf>.

¹² 21 U.S.C. § 843(a)(6).

¹³ 21 U.S.C. § 331(i)(2).

¹⁴ Substance Tableting and Encapsulating Enforcement and Registration Act, S. 3281 (2018).

¹⁵ Criminalizing Abused Substance Templates Act, H.4510 (2019).

In this survey, the Legislative Analysis and Public Policy Association (LAPPA) examines the policy response at the state level to the spread of pill presses used to create counterfeit drugs. There is relatively little policy in this area compared to federal law, and most innovation is relatively recent. In Section I, we present the status of existing law on pill presses and counterfeit pill molds in the fifty states and the District of Columbia. Findings are presented jurisdiction by jurisdiction for easy comparison among states and between current state- and federal law.

Section II features a selection of additional resources for policymakers on pill presses and counterfeit drugs in the United States. These sources explain in greater detail precisely how would-be traffickers acquire pill pressing equipment on the Internet and the Dark Web, and they provide details on dozens of law enforcement investigations in all fifty states on precisely how pill presses have been used in drug counterfeiting operations and how widely their pills have been distributed.

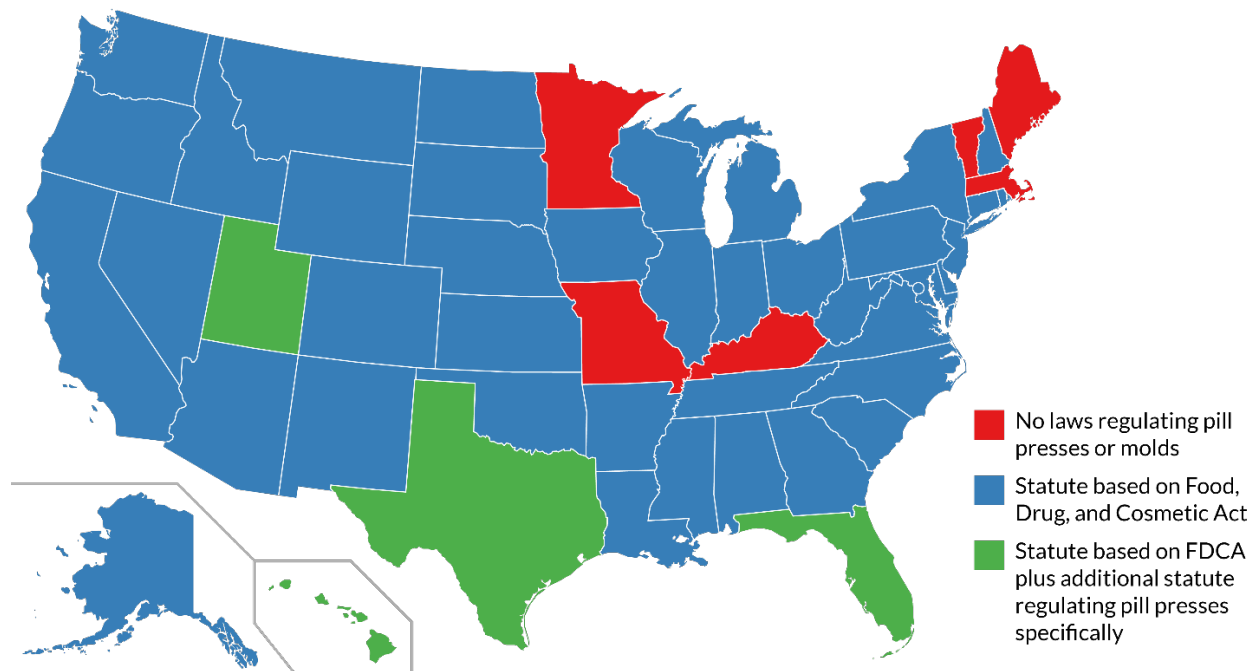


Fig. 1: Survey of state laws on pill presses and molds

As referenced above, the federal Food, Drug, and Cosmetic Act (FDCA) includes language prohibiting the “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.”¹⁶ The basic penalties for violating this section are

¹⁶ 21 U.S.C. § 331(i)(2).

imprisonment for up to one year, a fine of up to \$1,000, or both.¹⁷ But upon subsequent violations, or if the violation is committed with “the intent to defraud or mislead,” the penalty is imprisonment for up to three years, a fine of up to \$10,000, or both.¹⁸

This statute has served as a model for nearly every state and the District of Columbia. State statutes based on the FDCA constitute nearly the entirety of state-level policy on the issue, but there are novel exceptions, and not every state has passed its own FDCA equivalent. Forty-four states and the District of Columbia have laws on the books outlawing the possession or transfer of molds, punches, dies, etc., designed to reproduce counterfeit pills, using language that closely resembles that of the FDCA. Six states—Kentucky, Maine, Massachusetts, Minnesota, Missouri, and Vermont—have no such laws. Only four states—Florida, Hawaii, Texas, and Utah—have enacted laws involving pill presses (the tableting or encapsulating machines) themselves. But even among the 46 that have followed the FDCA, there is considerable variation, especially regarding the criminal penalties imposed for violation. Most state statutes call for longer prison sentences and higher fines than their federal equivalent. For a quick visual overview of the state of the states, see Figure 1, and for more details, see the tables below for each state.

¹⁷ 21 U.S.C. § 333.

¹⁸ *Id.*

<u>ALABAMA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Ala. Code § 20-2-72(a)(3).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a Class B felony, resulting in imprisonment for two to twenty years, a fine of up to \$30,000, or both. ¹⁹
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

¹⁹ Ala. Code § 20-2-72(b).

<u>ALASKA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Alaska Stat. § 11.71.040(a)(6).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a Class C felony, resulting in imprisonment for up to five years, a fine of up to \$50,000, or both. ²⁰
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

²⁰ Alaska Stat. § 11.71.040(d).

<u>ARIZONA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Ariz. Rev. Stat. § 13-3459(A).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	<p>Arizona requires the intent to “[c]ounterfeit a controlled substance, prescription-only drug or over-the-counter drug” or to “[d]uplicate substantially the physical appearance, form, package or label of a controlled substance, prescription-only drug or over-the-counter drug,” rather than possession alone.</p> <p>Violation is a class 1 misdemeanor, resulting in up to six months in jail, a fine of up to \$2,500, or both.²¹</p>
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

²¹ Ariz. Rev. Stat. § 13-3459(B).

<u>ARKANSAS</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Ark. Code § 5-64-403(a)(4).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a Class D felony, resulting in imprisonment for up to six years, a fine of up to \$10,000, or both. ²²
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

²² Ark. Code § 5-64-403(b)(1).

<u>CALIFORNIA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Cal. Health & Safety Code § 110325.
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation results in up to one year in a county jail, a fine of up to \$1000, or both. ²³
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

²³ Cal. Health & Safety Code § 111825(a).

<u>COLORADO</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Colo. Rev. Stat. § 18-18-423(2).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a level 3 drug felony, resulting in imprisonment for two to four years, a fine of \$2,000 to \$500,000, or both. ²⁴
Are there any additional state laws regulating pill presses or molds?	None
Details of additional state law	N/A

²⁴ Colo. Rev. Stat. § 18-18-423(3).

<u>CONNECTICUT</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Conn. Gen. Stat. § 21a-93(o)(3).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	For a first offense, or absent intent to defraud or mislead, violation results in imprisonment of up to six months, a fine of up to \$500, or both. ²⁵
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

²⁵ Conn. Gen. Stat. § 21a-95.

<u>DELAWARE</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Del. Code tit. 16, § 4757(a)(5).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a Class F felony, resulting in imprisonment for up to 3 years and a fine in whatever amount the court deems appropriate. ²⁶
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

²⁶ Del. Code tit. 16, § 4757(b).

<u>DISTRICT OF COLUMBIA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	D.C. Code § 48-904.03(a)(5).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation results in imprisonment for up to 4 years, a fine of up to \$12,500, or both. ²⁷
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

²⁷ D.C. Code § 48-904.03(b).

<u>FLORIDA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Fla. Stat. § 893.147(7)(a).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	The statute regulates “Controlled substance counterfeiting material,” defining this with the usual punch, die, plate, stone, etc., language of the Food, Drug, and Cosmetic Act. ²⁸ For additional differences, see below.
Are there any additional state laws regulating pill presses or molds?	Fla. Stat. § 893.147(7)(a).
Details of additional state law	<p>Unlike most states, Florida’s statute outlaws pill presses specifically, rather than drug molds alone, making it unlawful to “possess, purchase, deliver, sell, or possess with intent to sell or deliver a tableting machine, an encapsulating machine, or controlled substance counterfeiting materials...” However, it adds a higher intent threshold: it is unlawful to possess such material “knowing, intending, or having reasonable cause to believe that it will be used to manufacture a controlled substance or counterfeit controlled substance.”</p> <p>Additionally, although this is among the strongest state actions against pill presses, this statute has a blind spot. It prohibits the use of pill presses and drug molds for the creation of controlled substances, but it says nothing about counterfeiting other medicines that do not appear on the schedule of controlled substances, including some cancer treatments.²⁹</p> <p>Violation is a third degree felony, resulting in imprisonment for up to 5 years, a fine of up to \$5,000, or both, or a second degree felony if a Schedule I controlled substances is manufactured, resulting in imprisonment for up to 15 years, a fine of up to \$15,000, or both.³⁰</p>

²⁸ Fla. Stat. § 893.147(7)(c)(2).

²⁹ “Illegal Pill Presses: An Overlooked Threat to American Patients,” *The Partnership for Safe Medicines*, March 2019, <https://www.safemedicines.org/wp-content/uploads/2019/03/IllegalPillPressReport-2019-SECURE.pdf>.

³⁰ Fla. Stat. § 893.147(7)(d).

<u>GEORGIA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Ga. Code Ann. § 16-13-43(a)(5).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation results in imprisonment for up to 8 years, a fine of up to \$50,000, or both. ³¹
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

³¹ Ga. Code Ann. § 16-13-43(b).

<u>HAWAII</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Haw. Rev. Stat. § 329-42(a)(5).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a Class C felony, resulting in imprisonment for up to 5 years, a fine of up to \$10,000, or both. ³²
Are there any additional state laws regulating pill presses or molds?	Haw. Rev. Stat. § 329-63.
Details of additional state law	Hawaii has an additional statute that mimics the federal record-keeping requirements for all pill press transactions. Any person who “sells, transfers, receives, or brings in from outside the State” a tableting or encapsulating machine is required to keep records of each transaction for two years. Any such person who handles controlled substances must additionally submit reports to the state for each transaction involving a pill press. Failure to submit these reports, or knowing submission of false reports, shall result in imprisonment up to 30 days, a fine of up to \$5,000, or both; subsequent offenses result in imprisonment up to one year, a fine of up to \$100,000, or both. ³³

³² Haw. Rev. Stat. § 329-42(b).

³³ Haw. Rev. Stat. § 329-65.

<u>IDAHO</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Idaho Code Ann. § 37-2734(a)(5).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation results in imprisonment for up to 4 years, a fine of up to \$30,000, or both. ³⁴
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

³⁴ Idaho Code Ann. § 37-2734(b).

<u>ILLINOIS</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	720 Ill. Comp. Stat. 570/406(b)(5).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a Class 4 felony, resulting in imprisonment for one to three years, a fine of up to \$100,000, or both; subsequent offenses are Class 3 felonies, resulting in imprisonment for two to five years, a fine of up to \$200,000. ³⁵
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

³⁵ 720 Ill. Comp. Stat. 570/406(b).

<u>INDIANA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Ind. Code § 35-48-4-14(b)(4).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a Class 6 felony, resulting in imprisonment for six months to two and a half years, a fine of up to \$10,000, or both. ³⁶
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

³⁶ Ind. Code § 35-48-4-14(b).

<u>IOWA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Iowa Code § 126.3(12).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a serious misdemeanor, resulting in up to one year in jail, a fine of \$315 to \$1,875, or both; subsequent offenses are aggravated misdemeanors, resulting in up to two years in jail, a fine of \$625 to \$6,250, or both. ³⁷
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

³⁷ Iowa Code § 126.5.

<u>KANSAS</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Kan. Stat. Ann. § 65-657(m)(3).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation results in a civil penalty of up to \$1,000, but reckless or intentional violation is a Class A misdemeanor, resulting in up to one year in a county jail, a fine of up to \$2,500, or both. ³⁸
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

³⁸ Kan. Stat. Ann. § 65-682.

<u>KENTUCKY</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	None.
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	N/A
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

<u>LOUISIANA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	La. Stat. Ann. § 40:971(B)(1)(d).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation results in imprisonment for up to 5 years, a fine of up to \$5,000, or both. ³⁹
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

³⁹ La. Stat. Ann. § 40:971(B)(2).

<u>MAINE</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	None.
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	N/A
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

<u>MARYLAND</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Md. Code, Health-Gen. §§ 21-258(b)(7)-(b)(9).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a misdemeanor, resulting in imprisonment for up to one year, a fine of up to \$10,000, or both; subsequent violations result in imprisonment for up to three years, a fine of up to \$25,000, or both. ⁴⁰
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁴⁰ Md. Code, Health-Gen. § 21-1215(b).

<u>MASSACHUSETTS</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	None.
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	N/A
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

<u>MICHIGAN</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Mich. Comp. Laws § 333.7407(1)(e).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a felony, resulting in imprisonment for up to 4 years, a fine of up to \$30,000, or both. ⁴¹
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁴¹ Mich. Comp. Laws § 333.7407(3).

<u>MINNESOTA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	None.
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	N/A
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

<u>MISSISSIPPI</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Miss. Code. Ann. § 41-29-143(4).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	No. In addition to the similar language, Mississippi also imposes the same penalties as the FDCA. ⁴²
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁴² Miss. Code. Ann. § 41-29-143.

<u>MISSOURI</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	None.
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	N/A
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

<u>MONTANA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Mont. Code Ann. § 50-31-501(15).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a misdemeanor, resulting in imprisonment for up to 3 months, a fine of up to \$250, or both; subsequent offenses result in imprisonment for up to 6 months, a fine of up to \$500, or both. ⁴³
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁴³ Mont. Code Ann. § 50-31-506.

<u>NEBRASKA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Neb. Rev. Stat. § 28-418(1)(e).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a Class 4 felony, resulting in imprisonment for up to 2 years, a fine of up to \$10,000, or both. ⁴⁴
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁴⁴ Neb. Rev. Stat. § 28-418(2).

<u>NEVADA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Nev. Rev. Stat. § 453.331(1)(g).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a Class C felony, resulting in imprisonment for one to five years, a fine of up to \$10,000, or both. ⁴⁵
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁴⁵ Nev. Rev. Stat. § 453.331(2).

<u>NEW HAMPSHIRE</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	N.H. Rev. Stat. Ann. § 146:1(XI)(3).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	For a natural person, violation is a civil violation, resulting in a fine of up to \$1,000; subsequent offenses for natural persons and first offenses for all other persons are misdemeanors, resulting in a fine of up to \$1,200. For other persons, a subsequent offense is a felony with a fine of up to \$4,000. ⁴⁶
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁴⁶ N.H. Rev. Stat. Ann. § 146:18.

<u>NEW JERSEY</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	N.J. Rev. Stat. § 24:21-22(a)(5).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation results in imprisonment for up to 3 years, a fine of up to \$30,000, or both. ⁴⁷
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁴⁷ N.J. Rev. Stat. § 24:21-22(b).

<u>NEW MEXICO</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	N.M. Stat. § 30-31-25(A)(5).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a fourth degree felony, resulting in imprisonment for up to eighteen months, a fine of up to \$5,000, or both. ⁴⁸
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁴⁸ N.M. Stat. § 31-18-15.

<u>NEW YORK</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	N.Y. Pub. Health Law § 3383(3) (McKinney).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a Class A misdemeanor, resulting in up to 364 days in jail, a fine of up to \$1,000, or both; a subsequent violation is a Class E felony, resulting in imprisonment for up to four years, a fine of up to \$5,000, or both. ⁴⁹
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁴⁹ N.Y. Pub. Health Law § 3383(7) (McKinney).

<u>NORTH CAROLINA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	N.C. Gen. Stat. § 90-108(a)(12).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a Class 1 misdemeanor, resulting in up to 120 days in jail, a fine in an amount the court deems appropriate, or both; however, if the violation was committed intentionally, it is a Class I felony, resulting in imprisonment for three to twelve months, a fine at the court's discretion, or both. ⁵⁰
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁵⁰ N.C. Gen. Stat. § 90-108(b).

<u>NORTH DAKOTA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	N.D. Cent. Code § 19-03.1-25(1)(e).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a Class C felony, resulting in imprisonment for up to 5 years, a fine of up to \$10,000, or both. ⁵¹
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁵¹ N.D. Cent. Code § 19-03.1-25(2).

<u>OHIO</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Ohio Rev. Code § 2925.37(C).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a fifth degree felony, resulting in imprisonment for six to twelve months, a fine of up to \$2,500, or both. ⁵²
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁵² Ohio Rev. Code § 2925.37(H).

<u>OKLAHOMA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Okla. Stat. tit. 63, § 2-406(a)(5).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a felony resulting in imprisonment for up to 20 years, a fine of up to \$250,000, or both. ⁵³
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁵³ Okla. Stat. tit. 63, § 2-406(b).

<u>OREGON</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Or. Rev. Stat. § 475.916(1)(e).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a Class A misdemeanor, resulting in up to 364 days in jail, a fine of up to \$6,250, or both. ⁵⁴
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁵⁴ Or. Rev. Stat. § 475.916(2).

<u>PENNSYLVANIA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	35 Pa. Cons. Stat. § 780-113(a)(9).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation results in imprisonment for up to 3 years, a fine of up to \$5,000, or both; a subsequent violation results in imprisonment for up to 3 years, a fine of up to \$25,000, or both. ⁵⁵
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁵⁵ 35 Pa. Cons. Stat. § 780-113(b).

<u>RHODE ISLAND</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	21 R.I. Gen. Laws § 21-28-4.03(a)(5).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation results in imprisonment for up to 5 years, a fine of up to \$5,000, or both. ⁵⁶
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁵⁶ 21 R.I. Gen. Laws § 21-28-4.03(b).

<u>SOUTH CAROLINA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	S.C. Code Ann. § 44-53-390(a)(5).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a felony resulting in imprisonment for up to five years, a fine of up to \$10,000, or both; corporations are subject to civil penalties of up to \$100,000. ⁵⁷
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁵⁷ S.C. Code Ann. § 44-53-390(b).

<u>SOUTH DAKOTA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	S.D. Codified Laws § 22-42-9.
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a Class 5 felony, resulting in imprisonment for up to five years, a fine of up to \$10,000, or both.
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

<u>TENNESSEE</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Tenn. Code Ann. § 53-11-402(a)(5).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a Class D felony, resulting in imprisonment for up to 12 years, a fine of up to \$5,000, or both. ⁵⁸
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁵⁸ Tenn. Code Ann. § 53-11-402(b).

<u>TEXAS</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Tex. Health & Safety Code § 431.021(1)(2).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a Class A misdemeanor, resulting in up to one year in jail, a fine of up to \$5,000, or both; a subsequent offense is a state jail felony, resulting in imprisonment for six months to two years, a fine of up to \$10,000, or both. ⁵⁹
Are there any additional state laws regulating pill presses or molds?	Tex. Health & Safety Code § 481.002(53). Tex. Health & Safety Code § 481.080. Tex. Health & Safety Code § 481.138. Tex. Health & Safety Code § 481.139.
Details of additional state law	<p>Texas classifies tableting machines or encapsulating machines as “chemical laboratory apparatus.” Tex. Health & Safety Code § 481.002(53). Any person who “sells, transfers, or otherwise furnishes” such apparatus is required to keep and maintain records of each transaction for at least two years.⁶⁰</p> <p>Failure to maintain these records or making a false record is a state jail felony for a first offense and a subsequent offense is a third degree felony, resulting in imprisonment from two to ten years, a fine of up to \$10,000, or both.⁶¹</p> <p>Selling, transferring, or otherwise furnishing chemical laboratory apparatus, including tableting or encapsulating machines, with “the knowledge or intent that the recipient will use the apparatus to unlawfully manufacture a controlled substance or controlled substance analogue” is also a third degree felony.⁶²</p>

⁵⁹ Tex. Health & Safety Code § 431.059(a).

⁶⁰ Tex. Health & Safety Code § 481.080.

⁶¹ Tex. Health & Safety Code § 481.138.

⁶² Tex. Health & Safety Code § 481.139.

<u>UTAH</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Utah Code § 58-37-8(3)(a)(4).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a third degree felony, resulting in imprisonment for up to 5 years, a fine of up to \$5,000, or both. ⁶³
Are there any additional state laws regulating pill presses or molds?	Utah Code § 58-37d-6(2)(f).
Details of additional state law	In Utah’s Clandestine Drug Lab Act, a trier of fact may use the possession of a “pill press machine or similar device,” to draw the inference that a defendant is involved in a clandestine laboratory operation.

⁶³ Utah Code § 58-37-8(3)(b).

<u>VERMONT</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	None.
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	N/A
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

<u>VIRGINIA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Va. Code Ann. § 54.1-3457(14).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a Class 2 misdemeanor, resulting in up to six months in jail, a fine of up to \$1,000, or both. ⁶⁴
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁶⁴ Va. Code Ann. § 54.1-3458.

<u>WASHINGTON</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Wash. Rev. Code § 69.50.416(2).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a Class c felony, resulting in imprisonment for up to two years, a fine of up to \$2,000, or both. ⁶⁵
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁶⁵ Wash. Rev. Code § 69.50.416(3).

<u>WEST VIRGINIA</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	W. Va. Code § 60A-4-403(a)(5).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a felony resulting in imprisonment for up to four years, a fine of up to \$30,000, or both. ⁶⁶
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁶⁶ W. Va. Code § 60A-4-403(b).

<u>WISCONSIN</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Wis. Stat. § 961.43(1)(b).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a Class H felony, resulting in imprisonment for up to six years, a fine of up to \$10,000, or both. ⁶⁷
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁶⁷ Wis. Stat. § 961.43(1)(b).

<u>WYOMING</u>	
Does this jurisdiction have a statute modeled on the Federal Food, Drug, and Cosmetic Act?	Wyo. Stat. Ann. § 35-7-111(a)(ix).
Are there any significant differences between the state law and the Food, Drug, and Cosmetic Act?	Violation is a misdemeanor resulting in imprisonment for up to six months, a fine of up to \$750, or both; a subsequent offense results in imprisonment for up to one year, a fine of up to \$1,500, or both. ⁶⁸
Are there any additional state laws regulating pill presses or molds?	None.
Details of additional state law	N/A

⁶⁸ Wyo. Stat. Ann. § 35-7-113(a).

RESOURCES

Informing current and proposed law, government and private actors have contributed valuable research to understanding and documenting the rise of clandestine pill press operations to distribute counterfeit drugs throughout the United States. Here is a selection of additional sources that may be useful to policymakers seeking to address these challenges.

The Partnership for Safe Medicines

The Partnership for Safe Medicines has been one of the earliest, strongest voices drawing attention to the specific vulnerabilities presented by pill presses. They have been studying counterfeit drugs and pill presses for several years, producing a significant volume of valuable research and reporting.

- [Illegal Pill Presses: An Overlooked Threat to American Patients](#), a 2019 report, is perhaps the best single overview of pill presses. The report explains how the machines work, where illegal drug manufacturers buy them and how they ship them into the United States, an overview of different countries' regulations of pill presses, and some policy recommendations.
- Another report, [Forty-Three States and Counting: The Deadly Combination of Imported Fentanyl and Counterfeit Medicines](#) from 2018, gives an overview of the PSM's research tracking individual cases of counterfeit drugs containing fentanyl found in the United States. Because of how quickly the conditions on the ground are changing, the work has been updated frequently: this report is actually an updated version of [Forty States and Counting](#) from 2017, and it has since been supplemented with [new data](#) from 2019 on how counterfeit fentanyl pills have been found in all fifty states.
- [State Resources: Counterfeit Incident Summaries](#) is a collection of fact sheets for all reported counterfeit drug incidents in each states. Each case is organized by date and the variety of drug involved.

Government sources, especially those involved in law enforcement, have produced additional reference materials, focusing primarily on identifying and thwarting efforts to smuggle counterfeit drug precursor materials and equipment into the United States. Several provide detailed case studies to describe general patterns drawn from specific criminal investigations.

Department of Justice Executive Office for U.S. Attorneys

[Investigating and Prosecuting "Pill Press" Manufacturing Schemes](#). In this article in the 2018 *United States Attorneys' Bulletin*, Benjamin R. Barron and Michael G. Freedman use the recent trial *United States v. Resnik* as a representative case study of pill press operations. Walking through the facts of this case, the piece suggests effective investigative strategies in prosecuting similar cases and identifies the common modus operandi among them.

Drug Enforcement Administration

[The 2019 DEA National Drug Threat Assessment](#) gives a review of the threats of abuse and trafficking of all drugs in the United States. Included within discussion of fentanyl, pill press operations are given their own section highlighting presses' growing importance in international operations involving imported fentanyl. The DEA assessment includes several case studies highlighting specific drugs counterfeited with illegal presses.

White House Office of National Drug Control Policy

In August 2019, the Office of National Drug Control Policy (ONDCP) released a set of four “private sector advisories” to better inform businesses on the operations of opioid drug traffickers and to protect supply chains from inadvertently being used to further the drug trade. Two of them are relevant for understanding pill presses:

- [Tab A](#), the manufacturing advisory, discusses the use of pill presses at the end of the drug manufacturing process. Using information from several criminal investigations of drug mills, the advisory explains how to detect pill press operations and includes photos of actual punches and dies used to replicate trademarked drugs.
- [Tab B](#), the marketing advisory, discusses pill presses in the context of using the Dark Web to buy and sell drugs, precursor materials, and equipment. The advisory lists a number of common terms used in domain names and product listings that indicate the selling of fentanyl and pill presses or press parts.

United States Senate Committees

[Combatting the Opioid Crisis: Exploiting Vulnerabilities in International Mail](#): In 2018, Sens. Rob Portman (R-OH) and Tom Carper (D-DE) of the Senate Homeland Security and Government Affairs Committee released this report on how the U.S. Postal Service can be used to transmit foreign fentanyl and drug-manufacturing equipment, including pill presses. It describes how foreign sellers deliberately mislabel pill press equipment or send it in multiple boxes to avoid scrutiny by U.S. customs.

Proposed Federal Legislation (as discussed above)

- [Substance Tableting and Encapsulating Enforcement and Registration Act, S. 3281 \(2018\)](#).
- [Criminalizing Abused Substance Templates Act, H.4510 \(2019\)](#).

ABOUT THE LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

Based in Washington D.C., and led by and comprised of experienced attorneys, the Legislative Analysis and Public Policy Association 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 timely model laws and policies that can be used by national, state, and local public health, public safety, and substance use disorder practitioners who want the latest comprehensive information on law and policy as well as up-to-the-minute comparative analyses, publications, educational brochures, and other tools ranging from podcasts to fact sheets. Examples of topics on which LAPPA has assisted stakeholders include naloxone laws, law enforcement/community engagement, alternatives to incarceration for those with substance use disorders, medication-assisted treatment in correctional settings, and the involuntary commitment and guardianship of individuals with alcohol or substance use disorders.



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