LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

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. Proliferation of these pills accelerated rapidly, to the point that, as of October 2019, authorities found them in each of the fifty states. 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), fake pill molds and dies that mimic trademarked pharmaceuticals, and sufficient illicitly imported fentanyl to create between \$5 and \$20 million in counterfeit pills.

While controlled substances like fentanyl deservedly receive much attention, the presses and molds used to create counterfeit pills are largely 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. But counterfeit drugs are not being made with fentanyl alone: multiple counterfeiters have produced fake Adderall pills containing methamphetamine, 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 must: (1) "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 (2) provide this record to the Attorney General of the United States. When black market drug manufacturers simply ignore these requirements, the registration mandate only serves 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

 $^{25, 2019, \}underline{https://www.safemedicines.org/2019/02/fake-cancer-medicine-found-to-only-contain-acetaminophen.\underline{html}.$

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. 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 foreign sellers exacerbate the problem by advertising 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." Moreover, the 3D printing era provides a new threat: 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. Under the provides of the provides of the provides of the provides and the provides of the provid

Interestingly, at the federal level, the 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." 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." There is no ability to claim ignorance of the intended purpose of the mold to avoid criminal liability.

In recent years, legislators proposed bipartisan federal legislation 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 applying to the Attorney General, and subsequent possession of it without an appropriate, updated registration would result in criminal penalties. ¹⁴ The bill did not advance in Congress that year or when reintroduced in 2019. In 2019, Rep. Kustoff, along with Rep. Abigail Spanberger (R-VA) introduced the Criminalizing Abused Substance Templates Act, which proposed to make the knowing possession of a "pill press mold" with the intention of producing a counterfeit drug subject to a 20-year prison sentence and

⁹ 21 U.S.C. § 881(a)(9).

¹⁰ "Counterfeit Pills Containing Fentanyls: 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).

fines. 15 But this bill, too, failed to advance in Congress. Legislators reintroduced the bill in both 2021 and 2023. 16,17

In this survey, first published in 2021 and updated periodically since then, 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, District of Columbia, and U.S. territories. Findings are presented jurisdiction by jurisdiction for easy comparison among states and between current state- and federal law.

As referenced above, the federal Food, Drug, and Cosmetic Act (FDCA) includes language prohibiting the "[m]aking, 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." Congress added this provision to the FDCA in July 1965, long before present counterfeit pill problem surfaced. The basic penalties for violating this section are imprisonment for up to one year, a fine of up to \$1,000, or both. 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.

This statute serves as a model for nearly every jurisdiction. 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 its own FDCA equivalent. Forty-eight jurisdictions (44 states, the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands) 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. In eight of these 48 jurisdictions—Florida, Hawaii, Mississippi, North Carolina, Tennessee, Texas, Utah, and Washington—there are laws specifically related to pill presses in addition to the more general FDCA-based law.²² The remaining six states—Kentucky, Maine, Massachusetts, Minnesota, Missouri, and Vermont—as well as American Samoa, and the Northern Mariana Islands have no such law(s) at all. But even among the 48 jurisdictions that follow 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 the map below and for more details, see the tables below for each state.

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

¹⁶ Criminalizing Abused Substance Templates Act of 2021, H.1303 (2021).

¹⁷ Criminalizing Abused Substance Templates Act of 2023, H.1549 (2023).

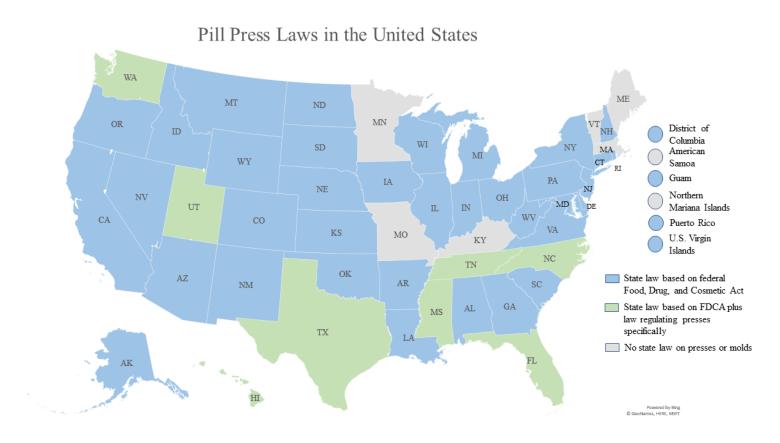
¹⁸ 21 U.S.C. § 331(i)(2).

¹⁹ Pub. L. 89-74, § 9(c) (July 15, 1965), 79 Stat. 235.

²⁰ 21 U.S.C. § 333(a)(1).

²¹ 21 U.S.C. § 333(a)(2).

²² In addition to North Carolina and Washington, whose pill-press specific laws took effect in 2023, three other states considered pill-press specific legislation during the 2023 session: Connecticut, Massachusetts, and New York.



Section II of this analysis features a selection of additional resources for policymakers on pill presses and counterfeit drugs in the United States. These sources explain in greater detail how would-be traffickers acquire pill pressing equipment on the open Internet and the Dark Web. They also contain details on dozens of law enforcement investigations related to pill presses used in drug counterfeiting operations.

<u>ALABAMA</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	ALA. CODE § 20-2-72(a)(5), (b) (West 2023)
Prohibited actions	It is illegal "[t]o make, distribute, or possess 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 the drug a counterfeit substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	A violation is a Class B felony, resulting in imprisonment for two to twenty years, a fine of up to \$30,000, or both. This penalty is more punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	None

<u>ALASKA</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	ALASKA STAT. § 11.71.040(a)(6), (d) (West 2023)
Prohibited actions	It is illegal if an individual "makes, delivers, or possesses a punch, die, plate, stone, or other thing that prints, imprints, or reproduces a trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of these on a drug, drug container, or labeling so as to render the drug a counterfeit substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	A violation is a Class C felony, resulting in imprisonment for up to five years, a fine of up to \$50,000, or both. This is more punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	None

<u>ARIZONA</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	ARIZ. REV. STAT. ANN. § 13-3459 (West 2023)
Prohibited actions	It is unlawful "for any person to make, distribute or possess 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 relating to the authorized identification of any controlled substance, prescription-only drug or over-the-counter drug or any likeness of any of the foregoing upon any drug or container to intentionally: • Counterfeit a controlled substance, prescription-only drug or over-the-counter drug [or] • Duplicate substantially the physical appearance, form, package or label of a controlled substance, prescription-only drug or over-the-counter drug."
	This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	A violation is a class 1 misdemeanor, resulting in up to six months in jail, a fine of up to \$2,500, or both. This is less punitive than the FDCA, at least in terms of potential jail time, for both first offenses and subsequent offenses.
Additional state law provision(s)	None

<u>ARKANSAS</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	ARK. CODE ANN. § 5-64-403(a)(4), (b) (West 2023)
Prohibited actions	It is unlawful to knowingly "[m]ake, distribute, or possess 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 person or any likeness of any trademark, trade name, or other identifying mark, imprint, or device of another person upon any drug or container or labeling of a drug or container so as to render the drug a counterfeit substance."
	This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation is a Class D felony, resulting in imprisonment for up to six years, a fine of up to \$10,000, or both. This penalty is more punitive than the FDCA for both first offenses and subsequent offenses.
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Additional state law provision(s)	None

<u>CALIFORNIA</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	Cal. Health & Safety Code §§ 110325, 111825 (West 2023)
Prohibited actions	It is unlawful to "possess, make, sell, dispose of, cause to be made, or conceal any punch, die, plate, or other device that may be used to render a food, drug, device, or cosmetic or its package or labeling a counterfeit." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation results in up to one year in a county jail, a fine of up to \$1,000, or both. This is consistent with first offenses under the FDCA.
Additional state law provision(s)	None

<u>COLORADO</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	Colo. Rev. Stat. Ann. § 18-18-423(2), (3) (West 2023)
Prohibited actions	It is unlawful "knowingly or intentionally to make, distribute, or possess a 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." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	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. This penalty is more punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	None

<u>CONNECTICUT</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	 CONN. GEN. STAT. ANN. § 21a-93(15)(C) (West 2023) (prohibitions) CONN. GEN. STAT. ANN. § 21a-95 (West 2023) (penalties)
Prohibited actions	"[M]aking, selling, disposing of or causing to be made, sold or disposed of or keeping in possession, control or custody, or concealing, with intent to defraud, 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 thereof upon any drug, device or container thereof" is prohibited. This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	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. This penalty is less punitive than that of the FDCA.
Additional state law provision(s)	None
Recently proposed legislation	See Recent Federal and State Legislation

<u>DELAWARE</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	DEL. CODE ANN. tit. 16, § 4757(a)(5), (b) (West 2023)
Prohibited actions	It is unlawful to knowingly or intentionally "make, distribute or possess 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 the drug a counterfeit substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation is a Class F felony, resulting in imprisonment for up to three years and a fine in whatever amount the court deems appropriate. This period imprisonment is more punitive than first offenses under the FDCA.
Additional state law provision(s)	None

	DISTRICT OF COLUMBIA
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	D.C. CODE ANN. § 48-904.03(a)(5), (b) (West 2023)
Prohibited actions	It is unlawful to knowingly or intentionally "make, distribute, or possess 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 the drug a counterfeit substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation results in imprisonment for up to four years, a fine of up to \$12,500, or both. This penalty is more punitive than the FDCA for both first offenses and subsequent offenses.
Additional jurisdiction law provision(s)	None

	<u>FLORIDA</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	FLA. STAT. ANN. § 893.147(7)(a), (b) (West 2023)	
Prohibited actions	It is unlawful to "to possess, purchase, deliver, sell, or possess with intent to sell or deliver a tableting machine, an encapsulating machine, or controlled substance counterfeiting materials knowing, intending, or having reasonable cause to believe that it will be used to manufacture a controlled substance or counterfeit controlled substance." The statute defines "controlled substance counterfeiting material" with the usual punch, die, plate, stone, etc., language of the FDCA. This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).	
Criminal penalties	Violation is a third-degree felony, resulting in imprisonment for up to five years, a fine of up to \$5,000, or both. This penalty is more punitive than the FDCA.	
Additional state law provision(s)	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." This specific provision first took effect July 1, 2018. Although this is a strong state law against pill presses, it does not cover everything. The law prohibits the use of pill presses and drug molds for the creation of controlled substances, but it says nothing about counterfeiting other non-controlled medicines, including some cancer treatments. ²³ Violation is: (1) a third-degree felony, resulting in imprisonment for up to five years, a fine of up to \$5,000, or both; or (2) 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.	

²³ "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.

<u>GEORGIA</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	GA. CODE ANN. § 16-13-43(a)(5), (b) (West 2023)
Prohibited actions	It is unlawful to "make, distribute, or possess 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 the drug a counterfeit substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation results in imprisonment for up to 8 years, a fine of up to \$50,000, or both. This penalty is more punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	None

<u>HAWAII</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	HAW. REV. STAT. ANN. § 329-42(a)(5), (b) (West 2023)
Prohibited actions	It is unlawful to "make, distribute, or possess 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 the drug a counterfeit substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation is a Class C felony, resulting in imprisonment for up to five years, a fine of up to \$10,000, or both. This penalty is more punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	Haw. Rev. Stat. Ann. § 329-63 (West 2023) Hawaii has an additional statute that mimics the federal record-keeping requirements for all pill press transactions. This provision first took effect in 1999. 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, results 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.

<u>IDAHO</u>	
Statute(s) analogous to	IDAHO CODE Ann. § 37-2734(a)(5), (b) (West 2023)
federal Food, Drug, and Cosmetic Act	
Prohibited actions	It is unlawful to "make, distribute, or possess 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 the drug a counterfeit substance."
Criminal nanalties	This is consistent with the FDCA; 21 U.S.C. § 331(i)(2). Violation results in imprisonment for up to four years, a fine
Criminal penalties	of up to \$30,000, or both. This penalty is more punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	None

	<u>ILLINOIS</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	720 ILL. COMP. STAT. ANN. 570/406(b)(5) (West 2023)	
Prohibited actions	It is unlawful to "make, distribute or possess 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 controlled substance or container or labeling thereof so as to render the drug a counterfeit substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).	
Criminal penalties	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. This penalty is more punitive than the FDCA for both first offenses and subsequent offenses.	
Additional state law provision(s)	None	

<u>INDIANA</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	IND. CODE ANN. § 35-48-4-14(b)(4) (West 2023).
Prohibited actions	Any person who "makes, distributes, or possesses a 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 a likeness of any of the foregoing on a drug or container or labeling thereof so as to render the drug a counterfeit substance" violates the statute. This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	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. This penalty can be more punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	None

	<u>IOWA</u>
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	• IOWA CODE ANN. § 126.3(12) (West 2023) (prohibitions) • IOWA CODE ANN. § 126.5 (West 2023) (penalties)
Prohibited actions	"Making, selling, disposing of, or keeping in possession, control, or custody, or concealing a 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 trademark, trade name, mark, imprint, or device or a likeness of any trademark, trade name, mark, imprint, or device upon a drug or drug container or the labeling thereof so as to render the drug a counterfeit drug" is unlawful.
	This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	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. This penalty can be either more or less punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	None

<u>KANSAS</u>	
Statute(s) analogous to federal Food, Drug, and	• KAN. STAT. ANN. § 65-657(m)(3) (West 2023) (prohibitions)
Cosmetic Act	• KAN. STAT. ANN. § 65-682 (West 2023) (penalties)
Prohibited actions	The "making, selling, disposing of or causing to be made, sold or disposed of or keeping in possession, control or custody, or concealing, with intent to defraud, any punch, die, plate, or other thing designed to print, imprint or reproduce that trade name or other identifying mark or imprint of another or any likeness of any of the foregoing upon any drug, device or container thereof" is unlawful.
	This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	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. This penalty is less punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	None

<u>KENTUCKY</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	None
Prohibited actions	N/A
Criminal penalties	N/A
Additional state law provision(s)	None

<u>LOUISIANA</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	La. Stat. Ann. § 40:971(B)(1)(d), (B)(2) (West 2023)
Prohibited actions	It is unlawful to "make, distribute, or possess 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 of any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit controlled dangerous substance."
	This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation results in imprisonment for up to five years, a fine of up to \$5,000, or both. This penalty is generally more punitive than the FDCA.
Additional state law provision(s)	None

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<u>MAINE</u>	
Statute(s) analogous to federal Food, Drug, and	None
Cosmetic Act	
Prohibited actions	N/A
Criminal penalties	N/A
Additional state law provision(s)	None

MARYLAND	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	 MD. CODE, HEALTH-GEN. § 21-258(b)(6)-(b)(9) (West 2023) (prohibitions) MD. CODE, HEALTH-GEN. § 21-1215(b) (West 2023)
Cosmette rec	(penalties)
Prohibited actions	 It is unlawful to: "Make, sell, or dispose of any counterfeit marking tool" "Cause any counterfeit marking tool to be made, sold, or disposed of" "Keep possession, control, or custody of any counterfeit marking tool" or "Conceal any counterfeit marking tool," with "counterfeit marking tool defined as "any punch, die, plate, stone, or other thing that is designed to print, imprint, or otherwise reproduce the trademark, trade name, imprint, symbol, or any other identifying mark of a drug, or a likeness of any of these markings, on a drug or on the container of a drug, other than the drug or container to which the marking belongs."
	This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	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. This penalty imposes heavier fines than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	None

<u>MASSACHUSETTS</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	None
Prohibited actions	N/A
Criminal penalties	N/A
Additional state law provision(s)	None
Recently proposed legislation	See Recent Federal and State Legislation

<u>MICHIGAN</u>	
Statute(s) analogous to federal Food, Drug, and	MICH. COMP. LAWS ANN. § 333.7407(1)(e), (3) (West 2023)
Cosmetic Act	
Prohibited actions	It is unlawful to "[m]ake, distribute, or possess a 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 a drug or container or labeling thereof so as to render the drug a counterfeit substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation is a felony, resulting in imprisonment for up to four years, a fine of up to \$30,000, or both. This penalty is more punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	None

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<u>MINNESOTA</u>		
Statute(s) analogous to	None	
federal Food, Drug, and		
Cosmetic Act		
Prohibited actions	N/A	
Criminal penalties	N/A	
Additional state law	None	
provision(s)		

<u>MISSISSIPPI</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	MISS. CODE. ANN. § 41-29-143(4) (West 2023)
Prohibited actions	It is unlawful to "make, distribute, or possess 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 the drug a counterfeit substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Mississippi imposes the same penalties as the FDCA.
Additional state law provision(s)	MISS. CODE. ANN. § 41-29-315 (West 2023) Unless authorized by the State Board of Pharmacy, it is unlawful to "possess, create, sell, barter, transfer, manufacture, or distribute a pill press, a punch, die, plate, tableting machine, encapsulating machine, or any similar pharmaceutical producing equipment, knowing, intending, or having reasonable cause to believe, that it will be used to manufacture a controlled substance or counterfeit controlled substance." This provision first took effect on July 1, 2022.
	Violation results in imprisonment for up to five years, a fine of \$5,000, or both.

<u>MISSOURI</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	None
Prohibited actions	N/A
Criminal penalties	N/A
Additional state law provision(s)	None

<u>MONTANA</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	 MONT. CODE ANN. § 50-31-501(15) (West 2023) (prohibitions) MONT. CODE ANN. § 50-31-506 (West 2023) (penalties)
Prohibited actions	The "making, selling, disposing of, or causing to be made, sold, or disposed of or keeping in possession, control, or custody or concealing, with intent to defraud, any punch, die, plate, or other thing designed to print, imprint, or reproduce a trade name, other identifying mark, or imprint of another or any likeness of the name, mark, or imprint upon any drug, device, or container of the drug or device" is prohibited.
Criminal penalties	This is consistent with the FDCA; 21 U.S.C. § 331(i)(2). 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. This penalty is less punitive than the
Additional state law provision(s)	FDCA for both first offenses and subsequent offenses. None

<u>NEBRASKA</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	NEB. REV. STAT. ANN. § 28-418(1)(e), (2) (West 2023)
Prohibited actions	It is unlawful to "make, distribute, or possess 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 controlled substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation is a Class 4 felony, resulting in imprisonment for up to two years, a fine of up to \$10,000, or both. This penalty is more punitive than the FDCA for first offenses.
Additional state law provision(s)	None

<u>NEVADA</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	NEV. REV. STAT. ANN. § 453.331(1)(g), (2) (West 2023)
Prohibited actions	It is unlawful to "[m]ake, distribute or possess 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 the drug a counterfeit substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation is a Class C felony, resulting in imprisonment for one to five years, a fine of up to \$10,000, or both. This penalty can be more punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	None

NEW HAMPSHIRE	
Statute(s) analogous to federal Food, Drug, and	• N.H. REV. STAT. ANN. § 146:1(XI)(3) (West 2023) (prohibitions)
Cosmetic Act	• N.H. REV. STAT. ANN. § 146:18 (West 2023) (penalties)
Prohibited actions	"Making, selling, disposing of or causing to be made, sold or disposed of or keeping in possession, control or custody, or concealing, with intent to defraud, any punch, die, plate, or other thing designed to print, imprint, or reproduce that trade name or other identifying mark or imprint of another of any likeness of any of the foregoing upon any drug, device or container thereof" is prohibited. This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	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. This penalty is generally less punitive than the FDCA.
Additional state law provision(s)	None

NEW JERSEY	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	N.J. STAT. ANN. § 24:21-22(a)(5), (b) (West 2023)
Prohibited actions	It is unlawful to "make, distribute, or possess 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 controlled dangerous substance."
	This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation results in imprisonment for up to three years, a fine of up to \$30,000, or both. This penalty is more punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	None

NEW MEXICO	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	 N.M. STAT. ANN. § 30-31-25(A)(5) (West 2023) (prohibitions) N.M. STAT. ANN. § 31-18-15 (West 2023) (penalties)
Prohibited actions	It is unlawful "to intentionally make, distribute or possess 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 the drug a counterfeit substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation is a fourth-degree felony, resulting in imprisonment for up to 18 months, a fine of up to \$5,000, or both. This penalty is more punitive than the FDCA for first offenses.
Additional state law provision(s)	None

<u>NEW YORK</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	N.Y. Pub. Health Law § 3383(3), (7) (McKinney 2023)
Prohibited actions	It is unlawful "to possess or use any punch, die, plate, stone or any other equipment in order 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 substance or container or labeling thereof with intent to manufacture an imitation controlled substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	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. This penalty is more punitive than the FDCA for subsequent offenses.
Additional state law provision(s)	None
Recently proposed legislation	See Recent Federal and State Legislation

NORTH CAROLINA	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	N.C. GEN. STAT. ANN. § 90-108(a)(12), (b) (West 2023)
Prohibited actions	It is unlawful to "make, distribute, or possess 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 controlled substance, knowing, intending, or having reasonable cause to believe that it will be used to create a counterfeit controlled substance."
	This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	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. This penalty is less punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	N.C. GEN. STAT. ANN. § 90-108(a)(12)(a) (West 2023). It is a Class D felony to "possess, manufacture, distribute, export, or import any three-neck round-bottom flask, tableting machine, encapsulating machine, or gelatin capsule, or any equipment, chemical, product, or material which may be used to create a counterfeit controlled substance, knowing, intending, or having reasonable cause to believe that it will be used to create a counterfeit controlled substance." This provision first took effect on December 1, 2023.

NORTH DAKOTA	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	N.D. CENT. CODE ANN. § 19-03.1-25(1)(e), (2) (West 2023)
Prohibited actions	It is unlawful to "make, distribute, or possess 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 the drug a counterfeit substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation is a Class C felony, resulting in imprisonment for up to five years, a fine of up to \$10,000, or both. This penalty is more punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	None

<u>OHIO</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	OHIO REV. CODE ANN. § 2925.37(C), (H) (West 2023)
Prohibited actions	No person "shall make, possess, sell, offer to sell, or deliver any punch, die, plate, stone, or other device knowing or having reason to know that it will be used to print or reproduce a trademark, trade name, or other identifying mark upon a counterfeit controlled substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation is a fifth-degree felony, resulting in imprisonment for six to twelve months, a fine of up to \$2,500, or both. This penalty is more punitive than the FDCA for first offenses.
Additional state law provision(s)	None

<u>OKLAHOMA</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	OKLA. STAT. ANN. tit. 63, § 2-406(a)(5), (b) (West 2023)
Prohibited actions	It is unlawful to "make, distribute, or possess 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 controlled dangerous substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation is a felony resulting in imprisonment for up to 20 years, a fine of up to \$250,000, or both. This penalty is more punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	None

<u>OREGON</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	OR. REV. STAT. ANN. § 475.916(1)(e), (2) (West 2023)
Prohibited actions	It is unlawful to "make, deliver or possess 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 the drug a counterfeit substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation is a Class A misdemeanor, resulting in up to 364 days in jail, a fine of up to \$6,250, or both. This penalty can be either more or less punitive than the FDCA.
Additional state law provision(s)	None

<u>PENNSYLVANIA</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	35 PA. STAT. AND CONS. STAT. ANN. § 780-113(a)(9), (b) (West 2023)
Prohibited actions	The "[m]aking, selling, disposing of or causing to be made, sold, or disposed of, or keeping in possession, control or custody, or concealing with intent to defraud, any punch, die, plate, stone or other thing designed to print, imprint or reproduce the trademark, trade name or other identifying mark, imprint or symbol of another or any likeness of any of the foregoing upon any controlled substance, other drug, device or cosmetic or container thereof" is prohibited. This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation results in imprisonment for up to three years, a fine of up to \$5,000, or both; a subsequent violation results in imprisonment for up to three years, a fine of up to \$25,000, or both. This penalty is more punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	None

RHODE ISLAND	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	21 R.I. GEN. LAWS ANN. § 21-28-4.03(a)(5), (b) (West 2023)
Prohibited actions	It is unlawful to "make, distribute, or possess 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 these upon any drug or container or labeling of the drug or container so as to render the drug a counterfeit substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation results in imprisonment for up to five years, a fine of up to \$5,000, or both. This penalty is more punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	None

SOUTH CAROLINA	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	S.C. CODE ANN. § 44-53-390(a)(5), (b) (West 2023)
Prohibited actions	It is unlawful to "make, distribute, or possess 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 so as to render the drug a counterfeit substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	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. This penalty is more punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	None

SOUTH DAKOTA	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	S.D. Codified Laws § 22-42-9 (West 2023)
Prohibited actions	It is unlawful to "make[], distribute[], or possess[] any punch, die, plate, or other thing designed to print or reproduce the trademark, trade name, or other identifying mark of another on any drug, or container or label thereof so as to make such drug a counterfeit controlled drug or substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation is a Class 5 felony, resulting in imprisonment for up to five years, a fine of up to \$10,000, or both. This penalty is more punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	None

<u>TENNESSEE</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	TENN. CODE ANN. § 53-11-402(a)(5), (b) (West 2023)
Prohibited actions	It is unlawful to "[m]ake, distribute or possess 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 the trademark, trade name, or other identifying mark, imprint or device of another upon any drug or container or labeling of any drug or container so as to render the drug a counterfeit substance."
	This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation is a Class D felony, resulting in imprisonment for up to 12 years, a fine of up to \$5,000, or both. This penalty is more punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	Tenn. Code Ann. § 39-17-402(12)(D) (West 2023) Tennessee classifies "[p]ill press devices and pieces of a pill press device" as drug paraphernalia unless the person possesses them in the course of legitimate business activity, such as licensed pharmacy or drug manufacturer. This provision first took effect on July 1, 2022.

Statute(s) analogous to federal Food, Drug, and Cosmetic Act Prohibited actions The "making, selling, disposing of, or keeping control, or custody, or concealing any punch, or other thing designed to print, imprint, or reptrademark, trade name, or other identifying madevice of another or any likeness of any of the any drug or container or labeling thereof so as drug a counterfeit drug" is prohibited. This is consistent with the FDCA; 21 U.S.C. § Violation is a Class A misdemeanor, resulting year in jail, a fine of up to \$5,000, or both; a soffense is a state jail felony, resulting in imprimonths to two years, a fine of up to \$10,000, or penalty is more punitive than the FDCA for fine Additional state law provision(s) Additional state law provision(s) Tex. Health & Safety Code Ann. § 481.0 (record-keeping requirements) Tex. Health & Safety Code Ann. § 481.1 (record-keeping penalties) Tex. Health & Safety Code Ann. § 481.1 (prohibitions and penalties for transferring particular of transferring particular descriptions and penalties for transferring particular descriptions.	(in possession, die, plate, stone, produce the
Cosmetic Act 2023) (prohibitions) Tex. Health & Safety Code Ann. § 431.05 2023) (penalties) Prohibited actions The "making, selling, disposing of, or keeping control, or custody, or concealing any punch, or other thing designed to print, imprint, or repetrademark, trade name, or other identifying madevice of another or any likeness of any of the any drug or container or labeling thereof so as drug a counterfeit drug" is prohibited. This is consistent with the FDCA; 21 U.S.C. §	(in possession, die, plate, stone, produce the
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as "chemical laboratory apparatus." This dates 2001. Any person who "sells, transfers, or oth furnishes" such apparatus is required to keep a records of each transaction for at least two year to maintain these records or making a false recipial felony for a first offense and a subsequent third-degree felony, resulting in imprisonment ten years, a fine of up to \$10,000, or both. Selling, transferring, or otherwise furnishing or laboratory apparatus, including tableting or en machines, with "the knowledge or intent that the will use the apparatus to unlawfully manufacture."	38 (West 2023) 39 (West 2023) ill presses) illating machines back to at least erwise and maintain ars. The failure cord is a state offense is a from two to hemical capsulating he recipient

	<u>UTAH</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	UTAH CODE ANN. § 58-37-8(3)(a)(iv), (b) (West 2023)	
Prohibited actions	It is unlawful to "make, distribute, or possess a 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 so as to render a drug a counterfeit controlled substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).	
Criminal penalties	Violation is a third-degree felony, resulting in imprisonment for up to five years, a fine of up to \$5,000, or both. This penalty is more punitive than the FDCA for both first offenses and subsequent offenses.	
Additional state law provision(s)	UTAH CODE ANN. § 58-37d-6(2)(f) (West 2023) 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. This provision first took effect on May 13, 2019.	

<u>VERMONT</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	None
Prohibited actions	N/A
Criminal penalties	N/A
Additional state law provision(s)	None

<u>VIRGINIA</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	 VA. CODE ANN. § 54.1-3457(14) (West 2023) (prohibitions) VA. CODE ANN. § 54.1-3458 (West 2023) (penalties)
Prohibited actions	The "making, selling, disposing of, or causing to be made, sold, or disposed 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" is prohibited. This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation is a Class 2 misdemeanor, resulting in up to six months in jail, a fine of up to \$1,000, or both. This penalty is less punitive than the FDCA.
Additional state law provision(s)	None

<u>WASHINGTON</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	WASH. REV. CODE ANN. § 69.50.416(2), (3) (West 2023)
Prohibited actions	It is unlawful "to make, distribute, or possess a 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." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation is a class C felony, resulting in imprisonment for up to two years, a fine of up to \$2,000, or both. This penalty is more punitive than the FDCA for first offenses.
Additional state law provision(s)	WASH. REV. CODE ANN. § 69.50.418 (West 2023) It is unlawful to "possess, purchase, deliver, sell, or possess with intent to sell a tableting machine or encapsulating machine knowing, or under circumstances where one reasonably should know, that it will be used to manufacture, compound, convert, produce, process, prepare, or otherwise introduce into the human body a controlled substance, other than cannabis." Violation is a class C felony. This provision first took effect on July 23, 2023.

WEST VIRGINIA	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	W. VA. CODE ANN. § 60A-4-403(a)(5), (b) (West 2023)
Prohibited actions	It is unlawful to "make, distribute, or possess 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 the drug a counterfeit substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation is a felony resulting in imprisonment for up to four years, a fine of up to \$30,000, or both. This penalty is more punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	None

WISCONSIN	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	WIS. STAT. ANN. § 961.43(1)(b), (2) (West 2023)
Prohibited actions	Without authorization, is it unlawful to "to make, distribute or possess 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: 1. To make a counterfeit substance; or 2. To duplicate substantially the physical appearance, form, package or label of a controlled substance."
Criminal penalties	This is consistent with the FDCA; 21 U.S.C. § 331(i)(2). Violation is a Class H felony, resulting in imprisonment for up to six years, a fine of up to \$10,000, or both. This penalty is more punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	None

<u>WYOMING</u>	
Statute(s) analogous to federal Food, Drug, and	• WYO. STAT. ANN. § 35-7-111(a)(ix) (West 2023) (prohibitions)
Cosmetic Act	• WYO. STAT. ANN. § 35-7-113(a) (West 2023) (penalties)
Prohibited actions	No person shall "[m]ake, sell or possess 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 drugs a counterfeit drug."
Criminal penalties	This is consistent with the FDCA; 21 U.S.C. § 331(i)(2). 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. This penalty is less punitive than the FDCA for both first offenses and subsequent offenses.
Additional state law provision(s)	None

AMERICAN SAMOA	
Statute(s) analogous to	None
federal Food, Drug, and	
Cosmetic Act	
Prohibited actions	N/A
Criminal penalties	N/A
Additional territorial law	None
provision(s)	

<u>GUAM</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	• 10 G.C.A. § 40103 (West 2023) (prohibitions) • 10 G.C.A. § 40105 (West 2023) (penalties)
Prohibited actions	"Making, selling or disposing of, causing to be made, sold or disposed of, 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" is prohibited. This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation is a misdemeanor.
Additional territorial law provision(s)	None

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NORTHERN MARIANA ISLANDS	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	None
Prohibited actions	N/A
Criminal penalties	N/A
Additional territorial law provision(s)	None

<u>PUERTO RICO</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	24 L.P.R.A. § 2403(a)(5), (c) (West 2023)
Prohibited actions	It is unlawful "to make, distribute, or possess 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 substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation results in imprisonment for two years and six months.
Additional territorial law provision(s)	None

<u>U.S. VIRGIN ISLANDS</u>	
Statute(s) analogous to federal Food, Drug, and Cosmetic Act	VI ST tit. 19, § 606(a)(5), (c) (West 2023)
Prohibited actions	It is unlawful "to make, distribute, or possess 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 substance." This is consistent with the FDCA; 21 U.S.C. § 331(i)(2).
Criminal penalties	Violation for a first offense results in imprisonment for up to four years, a fine of up to \$30,000, or both; a subsequent offense results in imprisonment for up to eight years, a fine of up to \$60,000, or both. This penalty is more punitive than the FDCA for both first offenses and subsequent offenses.
Additional territorial law provision(s)	None

RECENT FEDERAL AND STATE LEGISLATION	
State/Bill Number/Status	<u>Description</u>
Congress H.R.1549 (2023) (introduced and referred to House committee Mar. 10, 2023)	This is the "Criminalizing Abused Substance Templates Act of 2023." This bill proposes to make it a crime to knowingly possess a pill press mold with the intent to manufacture a counterfeit substance in schedule I or II of the Controlled Substances Act. A violator is subject to criminal penalties—a prison term of not more than 20 years and a fine.
Connecticut H.B. 6352 (2023) (died upon legislature's adjournment)	This bill proposed to categorize pill presses as drug paraphernalia.
Massachusetts H.B. 1808 (2023) (hearing on bill held June 6, 2023)	This bill proposes to make it felony for any person to possess or transfer a tableting or encapsulating machine knowing, intending, or having cause to believe it will be used to manufacture a controlled substance or counterfeit controlled substance.
New York A.B. 7490 (2023) (referred to Assembly committee May 25, 2023)	This bill proposes to make the possession or sale of a pill press, tableting machine, or encapsulating machine to manufacture an imitation drug a new class A misdemeanor called "unlawful possession or sale of imitation drug paraphernalia."

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.

- <u>Illegal Pill Presses: An Overlooked Threat to American Patients</u>, 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.
- <u>State Resources: Counterfeit Incident Summaries</u> 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

<u>Investigating and Prosecuting "Pill Press" Manufacturing Schemes</u>. 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.
- <u>Tab B</u>, 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 of 2023, H.1549 (2023).

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-theminute 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.

