

Supply Chain Conference May 3, 2023 Houston, Texas



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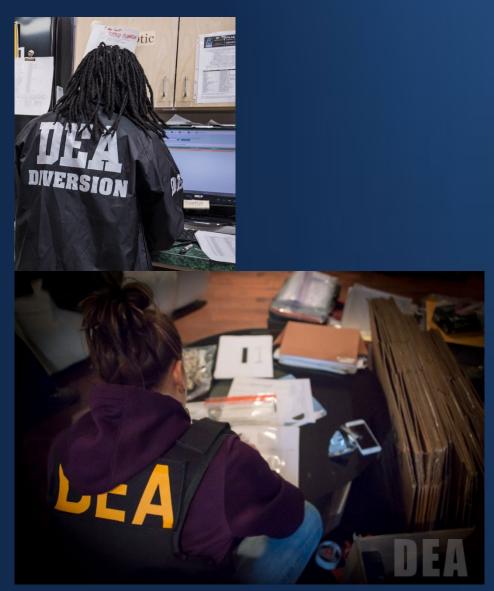
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Drug Enforcement Administration's **Diversion Control Division**

Prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources.

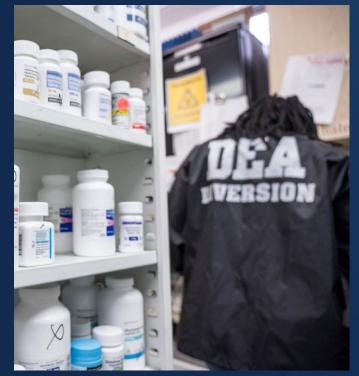
Ensure an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.



Drug Enforcement Administration's **Diversion Control Program**



- DEA registration required to handle controlled substances and listed chemicals
- Registrants must pay fees to DEA these fees fund the Diversion Control Program
- There are over 2 million DEA registrants





DEA works with domestic and international partners to:



Deny precursor chemicals to drug trafficking organizations



Ensure an adequate supply for legitimate needs

Chemical Investigations Section (DOC) – What We Do

- Support domestic and foreign chemical investigations
- Serve as the Competent National Authority for the United States regarding precursor chemicals
 International treaties, bilateral and multinational matters
- Subject matter experts on precursor chemicals and pill presses to DEA field elements, interagency partners, and international organizations
- Review and make final approval of new chemical applications
- Provide reachback support to Diversion Investigators in overseas positions





DEA's Industry Liaison Project

- Provide educational outreach to e-commerce outlets and shipping industry to increase awareness of:
 - Equipment used to make counterfeit pills
 - Alternate uses of listed chemicals
 - Mismanifested cargo hazards of transporting precursor chemicals
 - Regulations and record keeping requirements
 - "Know Your Customer" provision
- Conduct chemical industry outreach

Amazon.com banned all sales of encapsulating machines, pill presses, punches, and dies



The Problem

Staggering number of drug overdose deaths 107,735

An average of 1 overdose death every 5 minutes

*Centers for Disease Control and Prevention data for a 12-month period ending 7/2022.





THE THREAT: FENTANYL

Deadly Fentanyl-Laced Fake Pills

Fake pills made to look like OxyContin, Xanax, Adderall, and other pharmaceuticals.

Most fentanyl is trafficked by the Sinaloa and the Cartel de Jalisco Nueva Generacion (CJNG) cartels and mass-produced at factories in Mexico with chemicals sourced largely from China.

> Over 57.9 million fentanyl-laced fake pills seized in 2022



2-3 milligrams of FENTANYL considered a LETHAL dose







DEA Reports Widespread Threat of Fentanyl Mixed with Xylazine



FOR IMMEDIATE RELEASE Contact: DEA Public Affairs (202) 307-7977

Public Safety Alert

DEA Reports Widespread Threat of Fentanyl Mixed with Xylazine

WASHINGTON – The U.S. Drug Enforcement Administration is warning the American public of a sharp increase in the trafficking of fentanyl mixed with xylazine. Xylazine, also known as "Tranq," is a powerful sedative that the U.S. Food and Drug Administration has approved for veterinary use.

"Xylazine is making the deadliest drug threat our country has every faced, fentanyl, even deadlier," said Administrator Milgram. "DEA has seized xylazine and fentanyl mixtures in 48 of 50 States. The DEA Laboratory System is reporting that in 2022 approximately 23% of fentanyl powder and 7% of fentanyl pills seized by the DEA contained xylazine."

Xylazine and fentanyl drug mixtures place users at a higher risk of suffering a fatal drug poisoning. Because xylazine is not an opioid, naloxone (Narcan) does not reverse its effects. Still, experts always recommend administering naloxone if someone might be suffering a drug poisoning. People who inject drug mixtures containing xylazine also can develop severe wounds, including necrosis—the rotting of human tissue—that may lead to amputation.

According to the CDC, 107,735 Americans died between August 2021 and August 2022 from drug poisonings, with 66 percent of those deaths involving synthetic opioids like fentanyl. The Sinaloa Cartel and Jalisco Cartel in Mexico, using chemicals largely sourced from China, are primarily responsible for the vast majority of the fentanyl that is being trafficked in communities across the United States.



Drug Trends

- Two Mexican drug cartels are primarily responsible for mass producing fake prescription pills containing fentanyl for exportation to the U.S.
- Mexico continues to import chemicals from the U.S. for illicit drug production via "front" companies
- So far in 2023, DEA has seized over 16,300,000 fentanyl pills and over 2,700 pounds of fentanyl powder

In 2022, DEA seized over 57.9 million fentanyl-lace fake pills & over 13,400 pounds of fentanyl powder: equivalent to over 400 million lethal doses of fentanyl.



DEA List I Chemicals

- 1) 1-Boc-4-AP
- 2) 4-Anilinopiperidine
- 3) N-Acetylanthranilic acid
- 4) Alpha-phenylacetoacetamide (APAA)
- 5) Alpha-Phenylacetoacetonitrile (APAAN)
- 6) Anthranilic acid
- 7) Benzaldehyde
- 8) Benzyl cyanide
- 9) Benzylfentanyl
- 10) Ephedrine
- 11) Ergocristine
- 12) Ergonovine
- 13) Ergotamine
- 14) Ethylamine
- 15) Gamma-Butyrolactone (GBL)
- 16) Hydriodic acid
- 17) Hypophosphorous acid
- 18) Iodine
- 19) Isosafrole

- 20) Methyl alpha-phenylacetoacetate (MAPA)
- 21) Methylamine
- 22) 3,4-Methylenedioxyphenyl-2-propanone
- 23) N-Methylephedrine
- 24) N-Methylpseudoephedrine
- 25) N-phenethyl-4-piperidone (NPP)
- 26) Nitroethane
- 27) Norpseudoephedrine
- 28) Phenylacetic acid
- 29) Phenylpropanolamine
- 30) Phosphorus (red)
- 31) Phosphorus (white or yellow)
- 32) Piperidine
- 33) Piperonal (heliotropin)
- 34) PMK glycidate
- 35) PMK glycidic acid
- 36) Propionic anhydride
- 37) Pseudoephedrine
- 38) Safrole



DEA List I Chemicals

- ► Have legitimate uses
- Also used to manufacture controlled substances/drugs
- Often labeled as "precursors"
- Become part of the end product/drug
- DEA registration required
 - Requires record keeping and suspicious order reporting for *importers, exporters, distributors* and *manufacturers that distribute*
 - Persons required to register: 21 CFR 1309.21

DEA List II Chemicals

- 1) Acetic anhydride
- 2) Acetone
- 3) Benzyl chloride
- 4) Ethyl ether
- 5) Hydrochloric acid
- 5a) Hydrogen chloride gas
- 6) Methyl ethyl ketone (2-Butanone)
- 7) Methyl isobutyl ketone
- 8) Potassium permanganate
- 9) Sodium permanganate
- 10) Sulfuric acid
- 11) Toluene



DEA List II Chemicals

- ► Have legitimate uses
- Used in everyday products
- Usually classified as <u>solvents</u> and <u>reagents</u>
- No DEA registration required
 - Requires record keeping and suspicious order reporting
 - Persons required to register: 21 CFR 1309.21
 - Persons required to keep records and file reports: 21 CFR 1310.03
 - Maintenance of records: 21 CFR 1310.04
 - Reports: 21 CFR 1310.05





Listed Chemicals Regulated Under the Controlled Substances Act



https://www.deadiversion.usdoj.gov/schedules/orangebook/j_chemlist_ regulated.pdf

ш	ite	d Chemicals Regulated Under the							CC	DNT	ROLL	ED S	UBS	FAN	CE PR	OD	JCED)				
		rolled Substances Act				ine																
						N,N-Dimethylamphetamine		s.														
50	a 71	L C.F.R. §§ 1309, 1310, 1313 and 1314				phe	e	& analogues							ine			Xa	(d)	Phenyl-2-propanone		
		tails		e		/lam	ami	nalo							tam	ne	ane	-Methylaminorex	e (P	nedo	i	^
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	+ 11	pdate: Jan 5, 2023 Precursor 🔺	Chemical Code	heta	ine	Dim	a m	hue		Ę				AA	mer	Jaqu	Icat	thy	cycl	vl-2		Ĥ
- 4	51.0	Solvent	Number	Amphetamine	Cocaine	z,	Ethylamphetamine	Fentanyl	GHB	Heroin	S	MDA	MDE	MDMA	Methamphetamine	Methaqualone	Methcathinone	-We	Phencyclidine (PCP)	hen		Ě
	1	, 1-Boc-4-AP ¹	8336		<u> </u>	~			0	-		2	~	~	~	~	~	4	•	<u> </u>	0	
	2	4-Anilinopiperidine ⁸	8335																		0	
	3	N-Acetylanthranilic acid ²	8522																		0	
	4	Alpha-Phenylacetoacetamide ⁹ (APAA)	8515																		0	
	5	Alpha-Phenylacetoacetonitrile ³ (APAAN)	8512																		0	
	e	Anthranilic acid ²	8530																		30	
	7	. Benzaldehyde	8256			1]		4)
	8	. Benzyl cyanide	8735																		1	
		9 Benzylfentanyl ¹	8334																		0	
	10	Ephedrine ^{3&7}	8113																		0	
	11	. Ergocristine ¹	8612																		0	
	12	Ergonovine ¹	8675																		0.010	0.01
	13	Ergotamine ¹	8676																		0.020	0.03
	14	. Ethylamine ¹	8678																		1	
	15	. gamma-Butyrolactone (GBL)	2011																		0	
	16	. Hydriodic acid	6695																		1.7	1
	17	. Hypophosphorous acid ¹	6797																		0	
	18	. lodine	6699																		0	
Ē	19	. Isosafrole	8704)													4)
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	21	. Methylamine ¹	8520																		1	
	22	. 3,4-Methylenedioxyphenyl-2-propanone	8502																		4	
	23	N-Methylephedrine ³	8115																		1	
	24	N-Methylpseudoephedrine ³	8119																		1	
	25	N-phenethyl-4-piperidone (NPP)	8332																		0	
	26	. Nitroethane	6724																	۲	2.5	2
	27	Norpseudoephedrine ³	8317															•			2.5	2
	28	Phenylacetic acid ²	8791																	-	1	
	25	Phenylpropanolamine ^{3&7}	1225																		0	
	30	. Phosphorus (red)	6795																		0	
	31		6796																		0	
	32	Piperidine ¹	2704																		0.500	0.50
	33		8750																		4	
	34	Contraction and Contraction Contraction	8535																		0	
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	43	Hydrochloric acid ⁵⁸⁶	6545																		N/C	222
LIST		Hydrogen chloride gas	6545			-											_				0	-
Ë	44		6714							•		•	•		•						145	1,4
	45	25 36 AS 00	6715		-	L				•											N/C	-
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	49		6594		•														•	•	159	1,5
	2 an	d its salts d its salts and esters																				
	4 Ex	d its salts, optical isomers, and salts of optical isomers ports only, to all Western Hemisphere except Canada																			DOMESTIC	IMPORTS &
⁵ Exports to all South American countries & Panama - Domestic for HCI gas ⁶ Threshold for HCI acid and sulfuric acid is 50 gallons, the equivalent weight in killograms is shown																			DME	b0		
	* Threshold for HCI acid and sulfuric acid is 50 gallons, the equivalent weight in klagrams is shown ? For osculoebedrine, phywhyroanalrawine and enderkrie dall pur products, see 22 USC & 802(45)(A) and 21. C.F.R. Part 1314												S I	Σ								
	7 Fc	⁸ Including its amides, its carbamates, and its salts																				
	7 Fc 8 In 9 an	cluding its amides, its carbamates, and its salts d its optical isomers	ducts, see 21 USC	9 802(4	o i(A) ar	id 21 C.I	F.R. Par	t 1314														
	7 Fc 8 In 9 an 10 a	cluding its amides, its carbamates, and its salts			o ji ki ar	ia 21 C.I	F.R. Par	t 1314													KILOG	



Precursor Controls

Methamphetamine



Controlled

- Methylamine
- Benzaldehyde
- Nitroethane
- Phenylacetic Acid

Not Controlled

- Benzyl alcohol
- N-methyl formamide
- Tartaric acid
- Azobisisobutyronitrile (AIBN)
- Methyl thioglycolate

Cocaine



<u>Controlled</u>

- Potassium permanganate
- Methyl ethyl ketone
- Methyl isobutyl ketone
- Toluene

Not Controlled

- Ethyl acetate
- N-propyl acetate
- Calcium chloride
- Ammonium hydroxide

Fentanyl



Controlled

- 1-Boc-4-AP
- 4-anilino-N-phenethyl-4-piperidine (ANPP)
- 4-anilinopiperidine (4-AP)
- N-phenethyl-4-piperidone (NPP)
- Propionic anhydride

Not Controlled

- 4-piperidone (pending control)
- Propionyl chloride
- 2-phenethyl bromide

Heroin



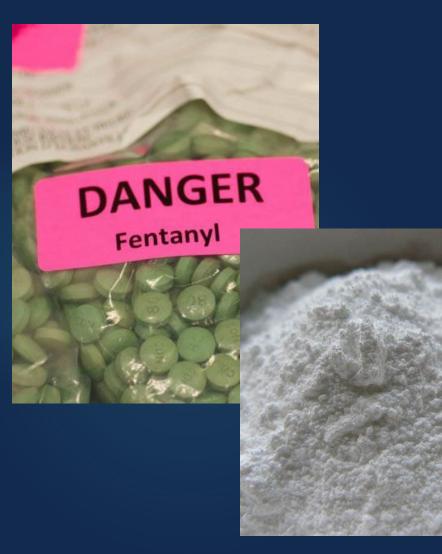
Controlled

- Acetone
- Acetic anhydride
- Hydrochloric acid
- Methyl ethyl ketone

Not Controlled

- Ethyl acetate
- Sodium carbonate
- Ammonium chloride

Chemicals of Interest: Fentanyl 🕨



► 4-ANPP

- 4-anilinopiperidine (4-AP)
- ► NPP
- 4-Piperidone
- 1-Benzyl-4-piperidone (N-benzyl-4-piperidone)
- Benzyl fentanyl
- Norfentanyl
- 4-ANBP (4-anilino-1-benzylpiperidine)
- Aniline
- Propionyl chloride (Reagent)
- Phenethyl Bromide / Phenethyl Chloride
- Sodium triacetoxyborohydride (STAB)
- Propionyl Chloride
- Acetic acid in large quantities

Methamphetamine

- Remains an extremely serious problem in the United States
- Mexican Transnational Criminal Organizations are the primary producers/suppliers – low cost, high purity
- Precursors are often transported via maritime shipments from China and India
- Mexican TCOs use various methods:
 - Phenyl-2-propanone (P2P) instead of pseudoephedrine
 - P2P = Benzaldehyde and nitroethane to produce nitrostyrene (NTS)
 - P2P = Ethyl phenylacetate (EtPA) to make phenylacetic acid (PAA)
 - PAA = Benzyl chloride and sodium cyanide to make benzylnitrile oil



Methamphetamine

- Finished methamphetamine commonly trafficked across the Southwest border
- Can be dissolved in a variety of liquids, including vehicle fluids, fuels, water, and alcoholic beverages
 - Requires a conversion laboratory to extract the methamphetamine from the solution
 - Easily smuggled, more difficult to detect can be less expensive than powder or crystal forms





\$80.7 million of liquid meth concealed in canola oil bottles shipped from Mexico

Chemicals of Interest: Methamphetamine

- Methylamine HCl or methylamine as a 40% solution
- Sodium or potassium cyanide
- Benzyl chloride or benzyl alcohol
- Lead acetate
- Tartaric acid
- Phenylacetic acid
- Ammonium chloride
- Formaldehyde (formylin)
- Benzyl cyanide (benzyl nitrite)
- Sulfuric acid
- Benzaldehyde
- Nitroethane
- Ephedrine / Pseudoephedrine





DEA's Chemical Regulation Code of Federal Regulations (CFR)

<u>Regulatory Authority</u>

- Controls 49 listed chemicals (21 CFR 1310.02)
 - 38 List I chemicals
 - ▶ 11 List II chemicals
- Registration of List I chemical companies (21 CFR 1309)
 - Pre-registration investigations
 - Cyclical investigations

Reporting Requirements

- Suspicious orders, losses, thefts (21 CFR 1310.05)
- Imports, exports, broker, transshipment (21 CFR 1313)
- Mail order reporting for sales of pseudoephedrine and ephedrine (21 CFR 1314.110)
- Record keeping requirements (2 years) (21 CFR 1310.03 and 1310.04)



Part 1310 - Records and Reports Of Listed Chemicals and Certain Machines; Importation and Exportation Of Certain Machines

§1310.05 Reports

(a)(1) Each regulated person *must report* to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located any regulated transaction involving *an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this part.*

The regulated person will *orally report* to the Special Agent in Charge of the DEA Divisional Office at the earliest practicable opportunity after the regulated person *becomes aware* of the circumstances involved and as much in advance of the conclusion of the transaction as possible.

The regulated person must file a *written report* of the transaction(s) with the Special Agent in Charge of the DEA Divisional Office as set forth in §1310.06 *within 15 calendar days* after the regulated person becomes aware of the circumstances of the event.

Chemical Unusual Order Reporting: CORT@dea.gov

Chemical Broker Requirements

Transactions involving the shipment of a listed chemical across an international border (other than the United States) in which a broker or trader located in the United States participates require a **DEA Form 486** be submitted to DEA, not later than **15 calendar days prior** to the international transaction.



U.S. Department of Justice	Import / Export I for List I and List			Drug	g Enforcement Administra			
SEE REVER	SE INSTRUCTIONS FOR PRIV	VACY A	CT	0'	MB Approval No. 1117-002			
			ype of Submission ORIGINAL		ENDED WITHDRAWA			
WARNING! 15-day advance notice require customer status. Or regular customer status. Or incertify I have met the c	ired for initial shipment or for co See 21 C.F.R. Part 1313 for fu conditions for the weiver of 15-d	ompanyl	that has lost regular importer	DEA Tran	saction Number			
2a. U.S. IMPORTER/U.S. EXPORTER / U.S. F (Name, address, telephone, and fax no.)		<u> </u>	b. IF IMPORT, LIST FOREIGN C INTERNATIONAL TRANSAC (Name, address, telephone, a	TION, LIST	T FOREIGN TRANSFEREE			
DEA Registration Number (for List I only):								
Purchase/Invoice no.		Fo	reign permit no. (if applicable)					
	3. Listed Chemicals to be l	importe	d / Exported / Brokered					
3a. Name and Description of chemical appearing on label or container. For drug products, show dosage strength and dosage size.	3b. Name of chemicals as designated by Title 21 C. 1310.02	.F.R.	3c. Number of containers, size net weight of each chemics (kg). For drug products, show number of dosage units. Show net total weigh per chemical.	al IN A Di ht (2	DATE OF ACTUAL MPORT/EXPORT AND CCTUAL QUANTITY (To be completed by person named 2a).) If same as 3c, write same as 3c."			
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SIGNATURE OF AUTHORIZED INDIVIDUAL (8 Signature) Print Name:	Print or Type Name below	DATI	E:					
DEA form - 486 (Previous version obsolete.)					Co			

Applicable Laws and Regulations

United States Code

- ► 21 U.S.C. § 802(45)(A) Scheduled Listed Chemical Product Definition
- ▶ 21 U.S.C. § 830(a); (b) Recordkeeping and Reports of Regulated Transactions
- ► 21 U.S.C. § 830(e)(2) Mail-Order Sales Reporting Requirements
- ▶ 21 U.S.C. § 843(a)(5) Punches & Dies Trademarks
 - ▶ (6) Possession of Punches & Dies
 - (7) Manufacture, Distribution, Import, & Export of Punches, Dies, Machinery, and chemical products.



Code of Federal Regulations

- 21 C.F.R. § 1310.05(b)(2) Reports of Machines Domestic Transactions (DEA Form 452)
- 21 C.F.R. § 1310.05(c) Reports of Machines Imports & Exports (DEA Form 452)
- > 21 C.F.R. § 1310.07 Records & Reporting of Listed Chemicals and Machines Proof of Identity
- 21 C.F.R. § 1314.40 Self-Certification



Chemical Handler's Manual



To find the Chemical Handler's Manual, click:

- ► Resources
- Publications & Manuals
- Manuals

United States Department of Justice Drug Enforcement Administration Office of Diversion Control



www.DEAdiversion.usdoj.gov

Chemical Handler's Manual

A Guide to Chemical Control Regulations

Revised 20221

¹ This manual replaces all previous editions of the Chemical Handler's Manual issued by the Drug Enforcement Administration, both hard copy and electronic.





Have a link to Diversion's website
Have customers acknowledge they understand and will comply with

reporting requirements

www.deadiversion.usdoj.gov

Medical Missions

Controlled Substances Export Reform Act of 2005



What Industry Can Do

- See something, say something
- Report suspicious orders, or suspicious orders declined, to your local DEA office
- Review and/or revise order screening processes
- This will help us provide data to help you screen for suspicious orders
- ► Tell us how we can help you

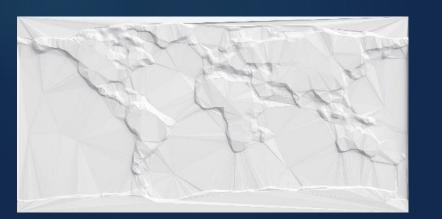




Teaming with industry to combat precursor chemical diversion and trafficking on a global scale



NO CHEMICALS...NO DRUGS











Chemical Unusual Order Reporting: <u>CORT@dea.gov</u> Mail Order Distribution Reports: Mail-Ordersales@dea.gov