

Supply Chain Conference 2024
Targeting & Special Projects Section
Reports Analysis Unit



April 30 - May 2, 2024

Little Rock, Arkansas



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Data Sources Used by the Diversion Control Division



➤ **Automation of Reports & Consolidated Orders System (ARCOS)**

- An automated, comprehensive drug reporting system that monitors the flow of controlled substances from point of manufacture to point of sale or distribution. ARCOS tracks transactions for all schedules I and II, schedule III narcotics, GHB and select schedule III and IV psychotropic drugs (manufacturers only).

➤ **Theft/Loss Reporting System (TLR)**

- Contains data generated from DEA Forms 106 and 107. Federal regulations require registrants to notify DEA field offices of thefts or losses of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft.

➤ **Suspicious Orders Reporting System (SORS)**

- DEA registrants that distribute controlled substances to other DEA registrants are required to report any suspicious orders to DEAs SORS centralized data system. Suspicious orders may include, but are not limited to: an order of controlled substance of unusual size; an order of deviating substantially from a normal pattern or orders of unusual frequency.



ARCOS



- ❖ **Audits and Scheduled Investigations**
- ❖ **Identifying Outliers and/or New Drugs Trending**



ARCOS - Audits & Scheduled Investigations

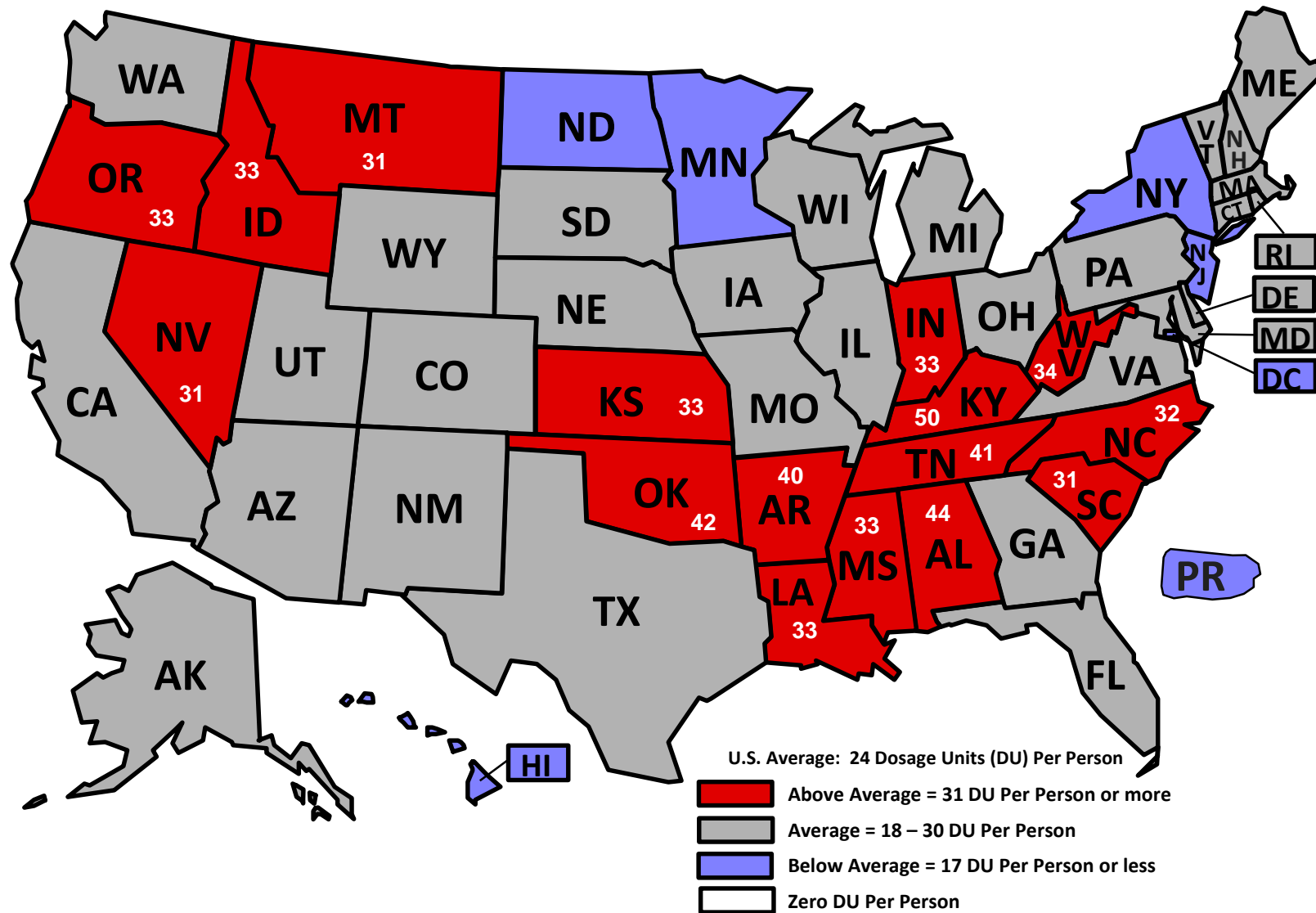
TRADE NAME	DRUG STRENGTH	PACKAGE SIZE	PACKAGE MEASURE	2021	2022	2023	JAN - FEB 2024	TOTAL DOSAGE UNITS
GENERIC HYDROCODONE	10MG	100	18 - TABLET (TAB)	30,300	70,300	49,200	6,900	156,700
		1000	18 - TABLET (TAB)	63,000	0	4,000	1,000	68,000
		500	18 - TABLET (TAB)	0	0	8,000	2,000	10,000
		60	19 - CAPSULE (CAP)	480	0	0	0	480
	5MG	100	18 - TABLET (TAB)	11,700	9,600	9,000	2,000	32,300
		473	5 - MILLILITER (ML)	0	0	0	0	0
	7.5MG	100	18 - TABLET (TAB)	7,300	6,900	4,800	1,700	20,700
		500	18 - TABLET (TAB)	0	0	500	0	500
		473	5 - MILLILITER (ML)	0	0	0	0	0
GENERIC HYDROCODONE TOTAL				112,780	86,800	75,500	13,600	288,680
HYCODAN	5MG	473	5 - MILLILITER (ML)	0	0	0	0	0
HYCODAN TOTAL				0	0	0	0	0
				112,780	86,800	75,500	13,600	288,680
GENERIC OXYCODONE	10MG	100	18 - TABLET (TAB)	16,100	15,300	20,100	2,700	54,200
		500	18 - TABLET (TAB)	0	0	500	1,000	1,500
	5MG	100	18 - TABLET (TAB)	8,200	6,800	8,300	1,200	24,500
		500	18 - TABLET (TAB)	0	1,500	500	500	2,500
	15MG	100	18 - TABLET (TAB)	9,500	4,800	2,400	600	17,300
	7.5MG	100	18 - TABLET (TAB)	2,900	4,100	3,900	200	11,100
	20MG	100	18 - TABLET (TAB)	600	0	0	0	600
	1MG	500	5 - MILLILITER (ML)	0	0	0	0	0
GENERIC OXYCODONE TOTAL				37,300	32,500	35,700	6,200	111,700
OXYCONTIN	20MG	100	18 - TABLET (TAB)	0	400	700	100	1,200
	10MG	100	18 - TABLET (TAB)	100	0	0	0	100

ARCOS - Audits & Scheduled Investigations



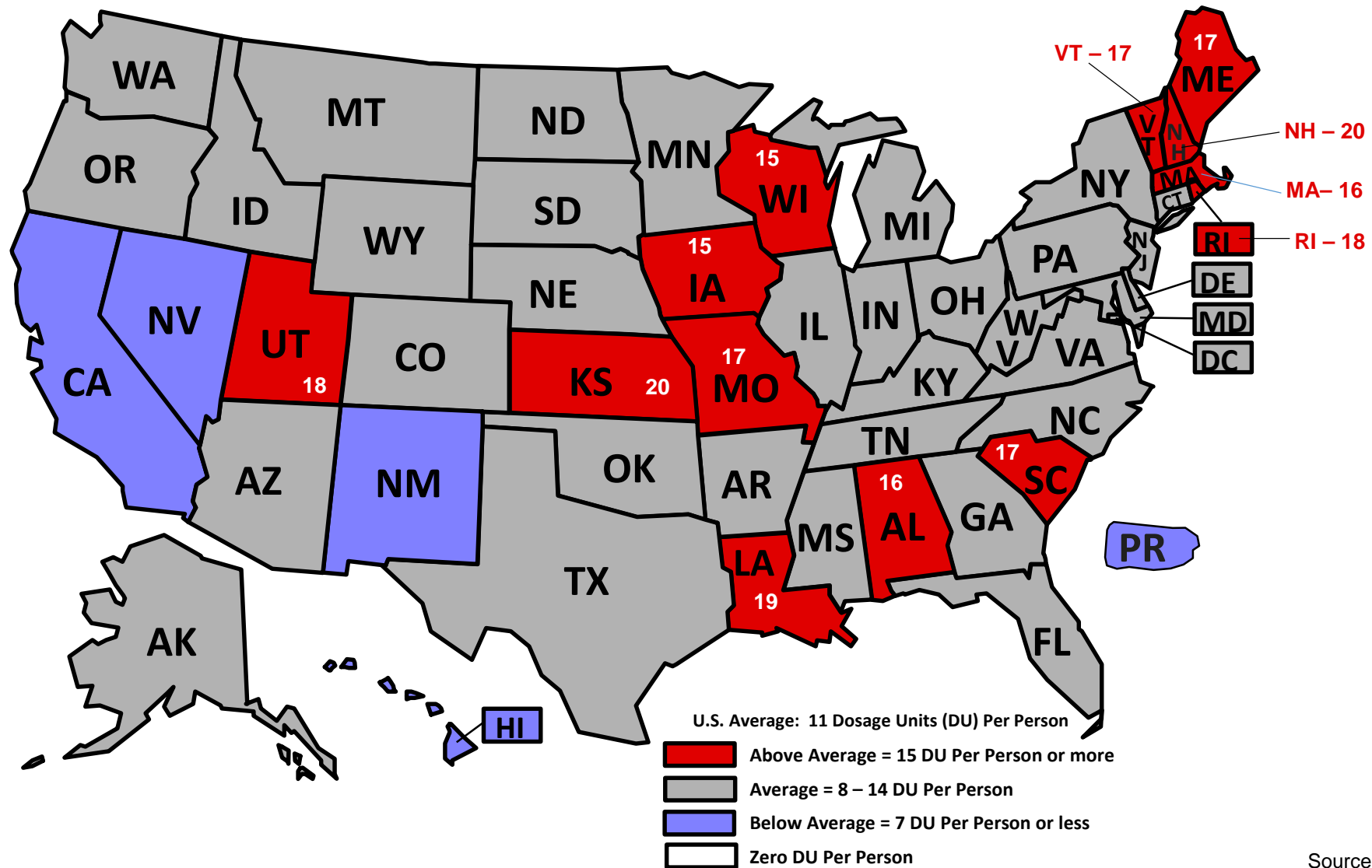
REPORTED SALES								
REPORTER'S DEA NO: AA1111111 REPORTER'S NAME: REGISTRANT #1 REPORTER'S BUSINESS ACTIVITY: DISTRIBUTOR REGISTRANT'S REPORTING FREQUENCY: QUARTERLY								
REGISTRANT'S DEA NUMBER	REGISTRANT'S NAME	STATE	BUSINESS ACTIVITY	FIELD OFFICE	DRUG	TOTAL DOSAGES REGISTRANT #1 REPORTED SALES - TRANS CODE (S)	TOTAL DOSAGES REGISTRANTS REPORTED as PURCHASING from REGISTRANT #1. - TRANS CODE (P)	DIFFERENCE
BB2222222	REGISTRANT #2	PA	REVERSE DISTRIB	PHILADELPHIA	FENTANYL	637,172	752,600	115,428
BB2222222 - Total						637,172	752,600	115,428
CC3333333	REGISTRANT #3	PA	DISTRIBUTOR	HARRISBURG	METHADONE	38,273,840	0	38,273,840
CC3333333 - Total						38,273,840	0	38,273,840
Overall - Total						38,911,012	752,600	38,158,412

Opioid Sales to Retail Registrants Nationwide January - December 2023



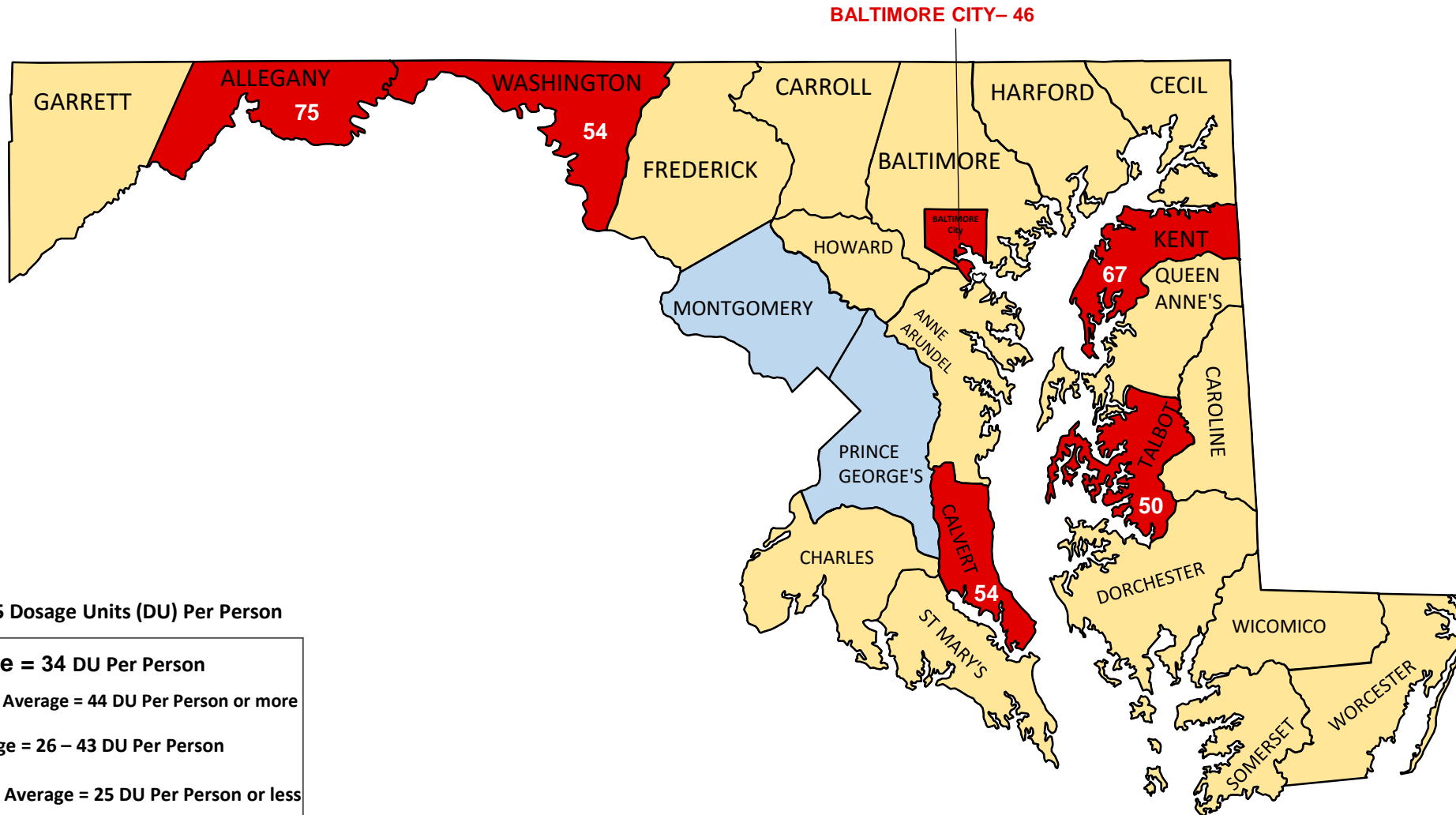
Source: ARCOS
Date Prepared: 03/18/2024

Stimulant Sales to Retail Registrants Nationwide January - December 2023

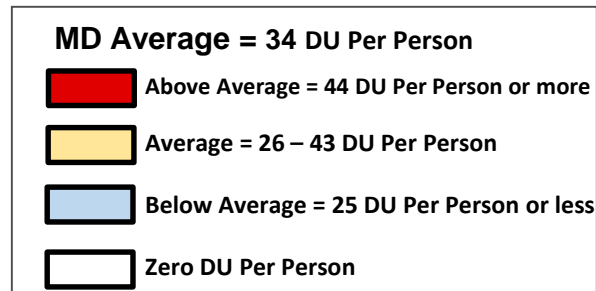


Source: ARCOS
Date Prepared: 03/18/2024

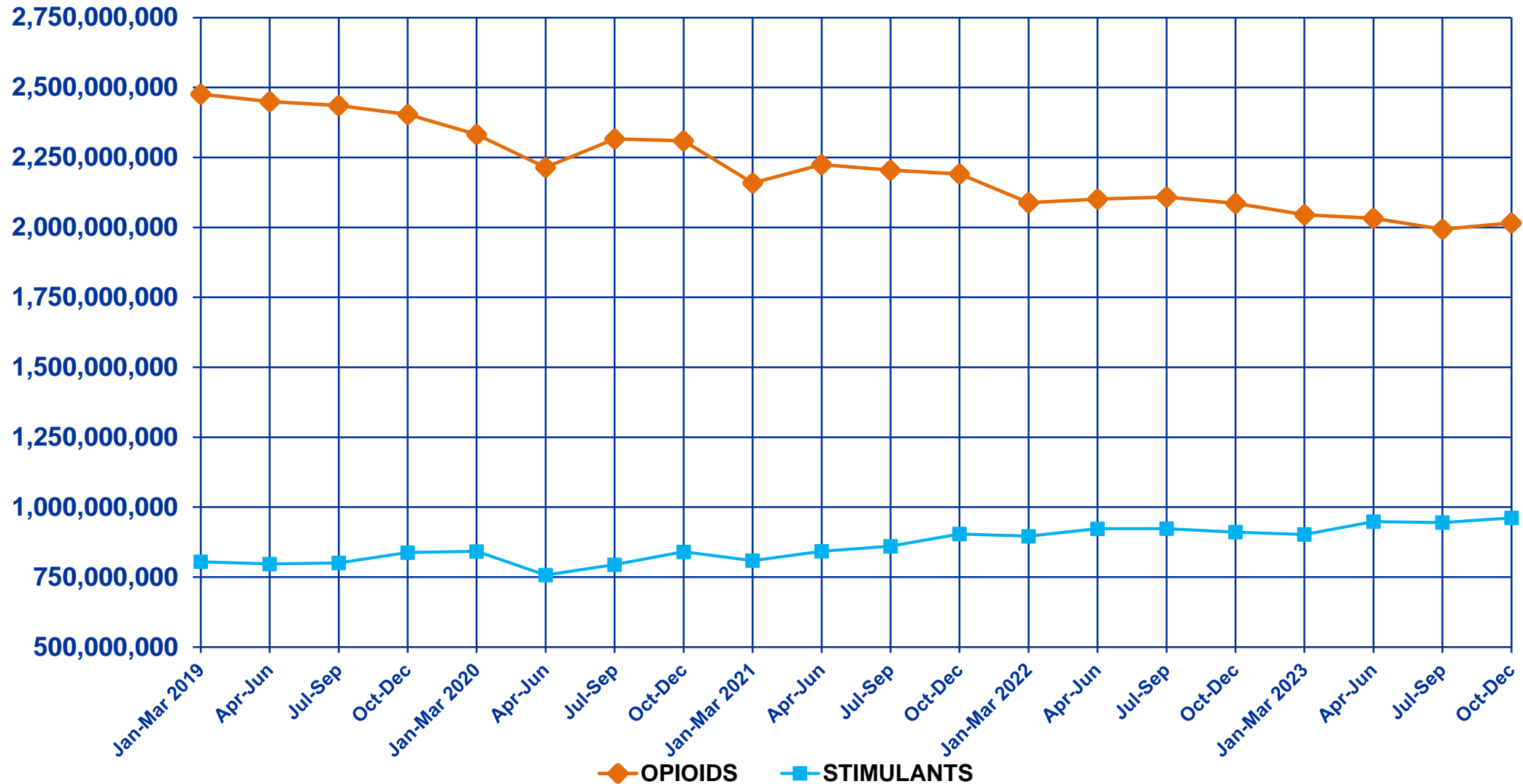
State of Maryland by County Controlled Substance Sales to Retail Registrants January - December 2023



U.S. Average = 35 Dosage Units (DU) Per Person

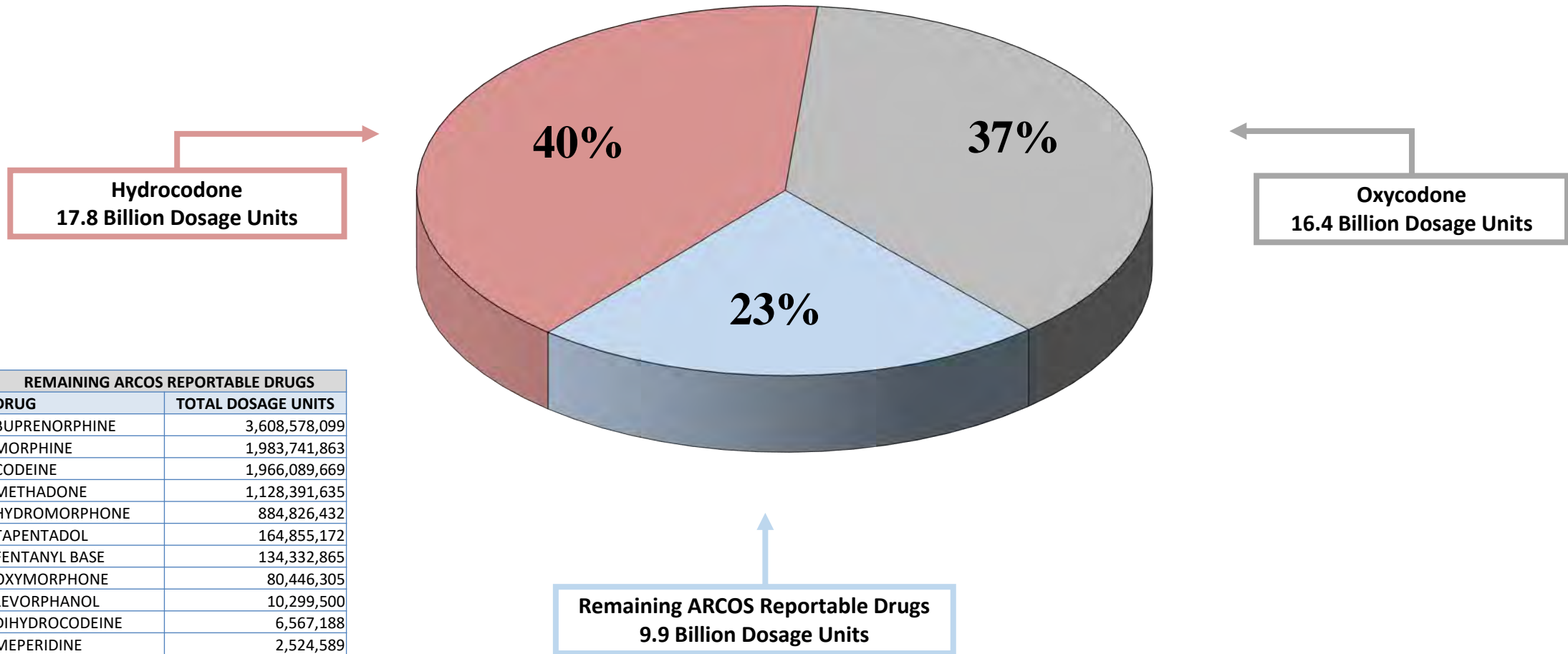


Quarterly Sales to Retail Registrants Nationwide January 2019 – December 2023



Sales of Opioids to Retail Registrants by Drug

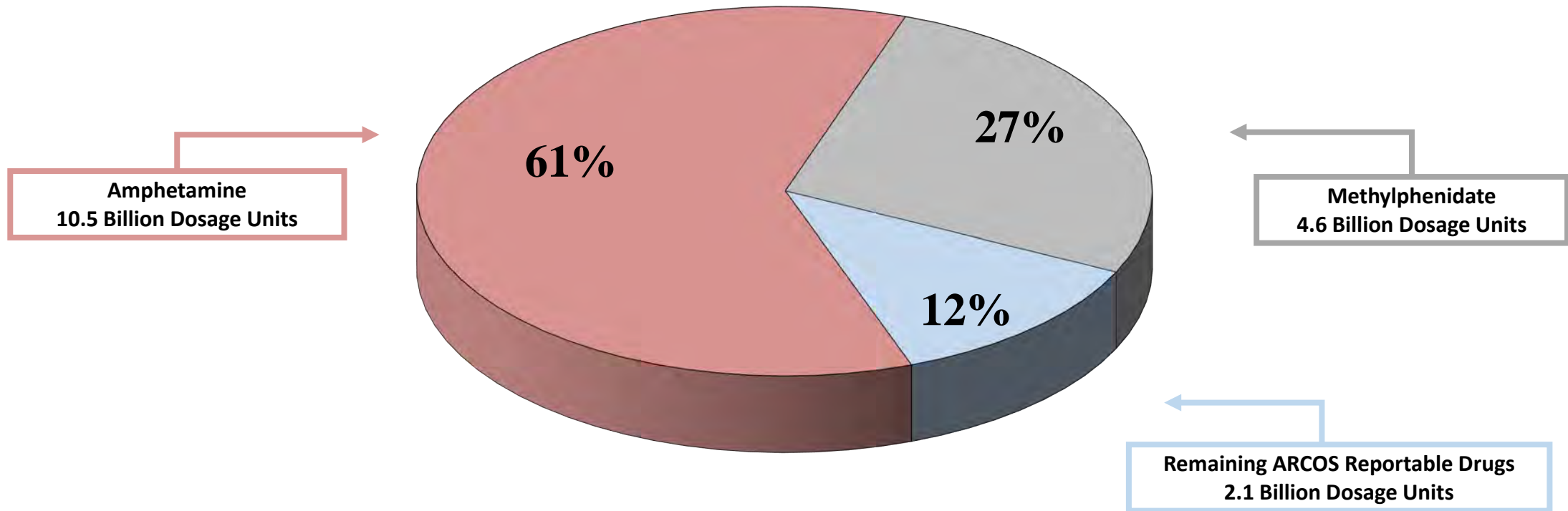
January 2019 – December 2023



REMAINING ARCOS REPORTABLE DRUGS	
DRUG	TOTAL DOSAGE UNITS
BUPRENORPHINE	3,608,578,099
MORPHINE	1,983,741,863
CODEINE	1,966,089,669
METHADONE	1,128,391,635
HYDROMORPHONE	884,826,432
TAPENTADOL	164,855,172
FENTANYL BASE	134,332,865
OXYMORPHONE	80,446,305
LEVORPHANOL	10,299,500
DIHYDROCODEINE	6,567,188
MEPERIDINE	2,524,589
OPIUM POWDERED	2,078,246
NOROXYMORPHONE	152,460
SUFENTANIL BASE	59,812
THEBAINE	38,640

Sales of Stimulants to Retail Registrants by Drug

January 2019 – December 2023



REMAINING ARCOS REPORTABLE DRUGS	
DRUG	TOTAL DOSAGE UNITS
LISDEXAMFETAMINE	2,110,916,107
METHAMPHETAMINE	5,188,300



Identifying Outliers and/or New Drugs Trending January – December 2023



DRUG	DRUG STRENGTH	DRUG TYPE	TOTAL DOSAGE UNITS
HYDROCODONE W/ACETAMINOPHEN	10MG/325MG	OPIOID	1,535,365,331
OXYCODONE	10MG	OPIOID	1,211,782,285
OXYCODONE	5MG	OPIOID	1,094,996,248
HYDROCODONE W/ACETAMINOPHEN	5MG/325MG	OPIOID	917,989,555
AMPHETAMINE	20MG	STIMULANT	762,153,267
HYDROCODONE W/ACETAMINOPHEN	7.5MG/325MG	OPIOID	618,225,430
AMPHETAMINE	10MG	STIMULANT	525,404,628
BUPRENORPHINE W/NALOXONE	8MG/2MG	OPIOID	508,488,723
AMPHETAMINE	30MG	STIMULANT	464,374,116
OXYCODONE	15MG	OPIOID	243,913,071
METHYLPHENIDATE	10MG	STIMULANT	240,008,512
AMPHETAMINE	15MG	STIMULANT	228,432,508
OXYCODONE	7.5MG	OPIOID	223,666,991
CODEINE	30MG	OPIOID	218,734,313
METHYLPHENIDATE	20MG	STIMULANT	195,351,129
MORPHINE	15MG	OPIOID	192,394,484
OXYCODONE	30MG	OPIOID	154,968,857
AMPHETAMINE	5MG	STIMULANT	138,320,477
METHYLPHENIDATE	5MG	STIMULANT	124,493,270
BUPRENORPHINE	8MG	OPIOID	117,048,191



Theft Loss Reporting (TLR)



Theft/Loss Types

- LOSSES IN TRANSIT
- PACKAGING DISCREPANCY
- EMPLOYEE THEFT (OR SUSPECTED)
- CUSTOMER THEFT (OR NON EMPLOYEE)
- BREAK-IN/BURGLARY
- ROBBERY
- DISASTER (FIRE, WEATHER, ETC.)
- HIJACKING OF TRANSPORT VEHICLE

Business Activities

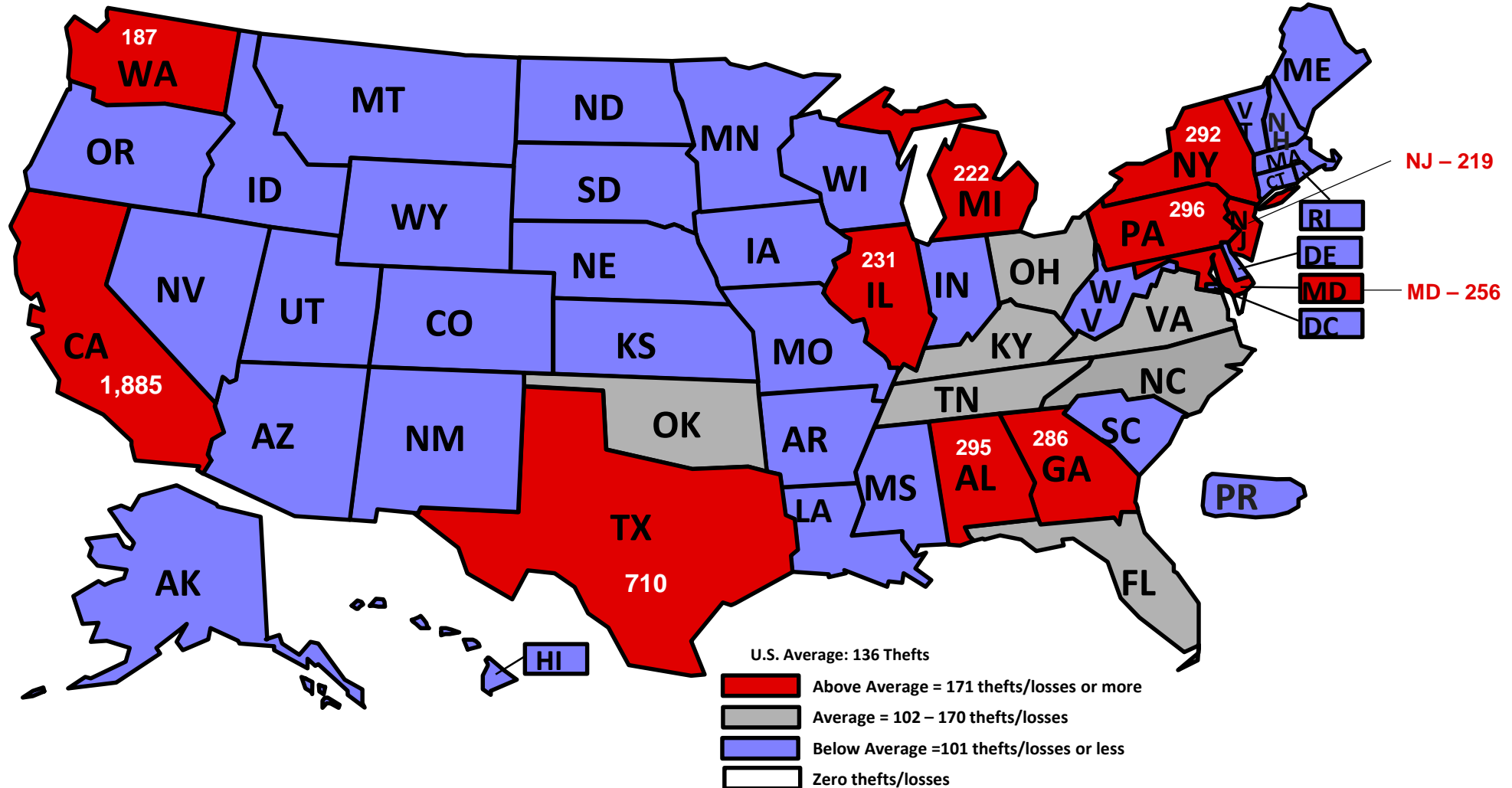
- PHARMACY
- HOSPITAL
- PRACTITIONER
- MID LEVEL PRACTITIONER
- TEACHING INSTITUTION
- NARCOTIC TREATMENT PROGRAM
- ANALYTICAL LAB
- CANINE HANDLER
- REVERSE DISTRIBUTOR
- DISTRIBUTOR
- MANUFACTURER
- IMPORTER
- EXPORTER



Reported Break-Ins & Robberies Nationwide by Number of Thefts/Losses

2019 – 2023

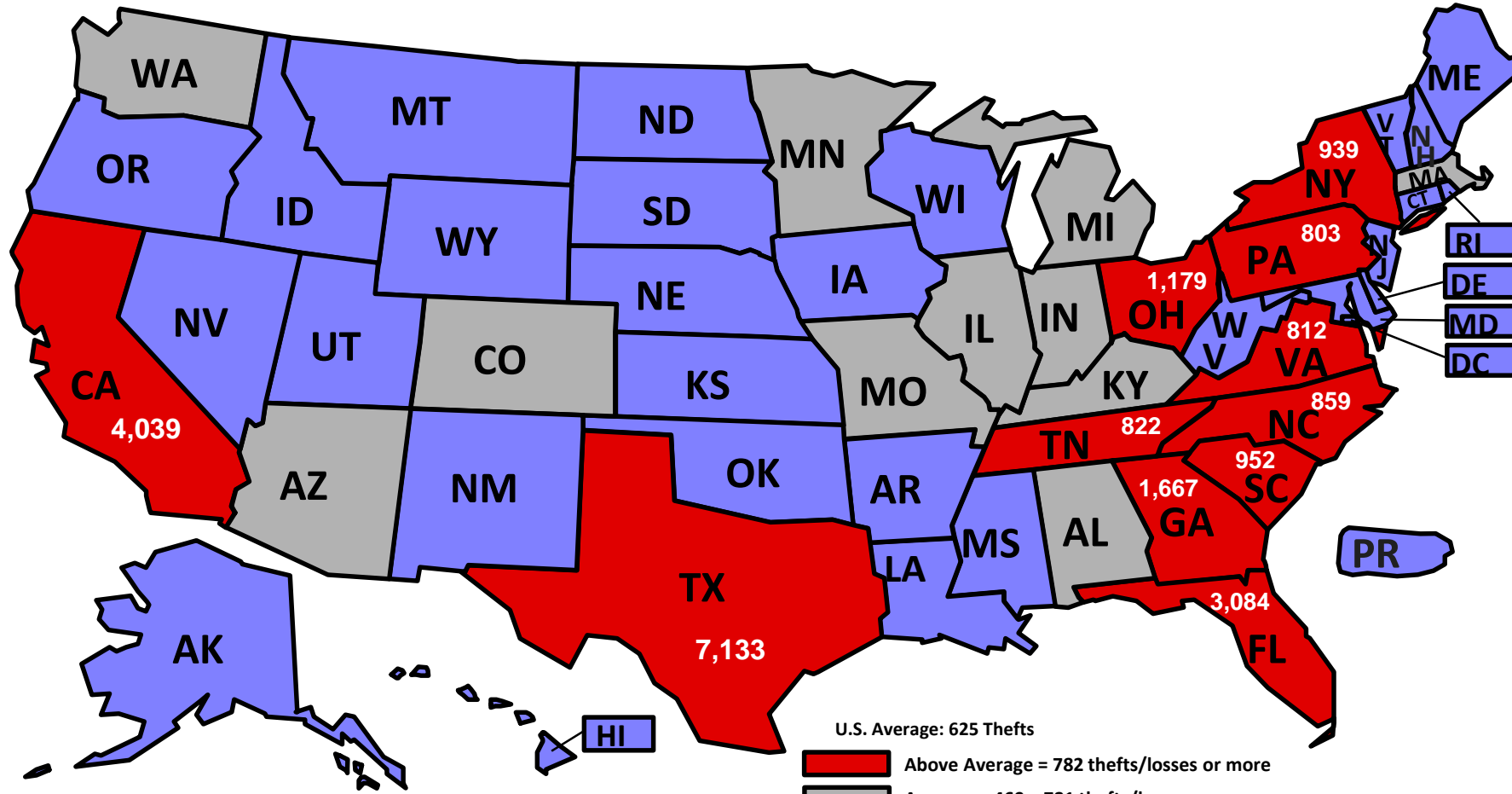
All Business Activities - All Drugs



Reported Customer & Employee Thefts Nationwide by Number of Thefts

2019 – 2023

All Business Activities - All Drugs



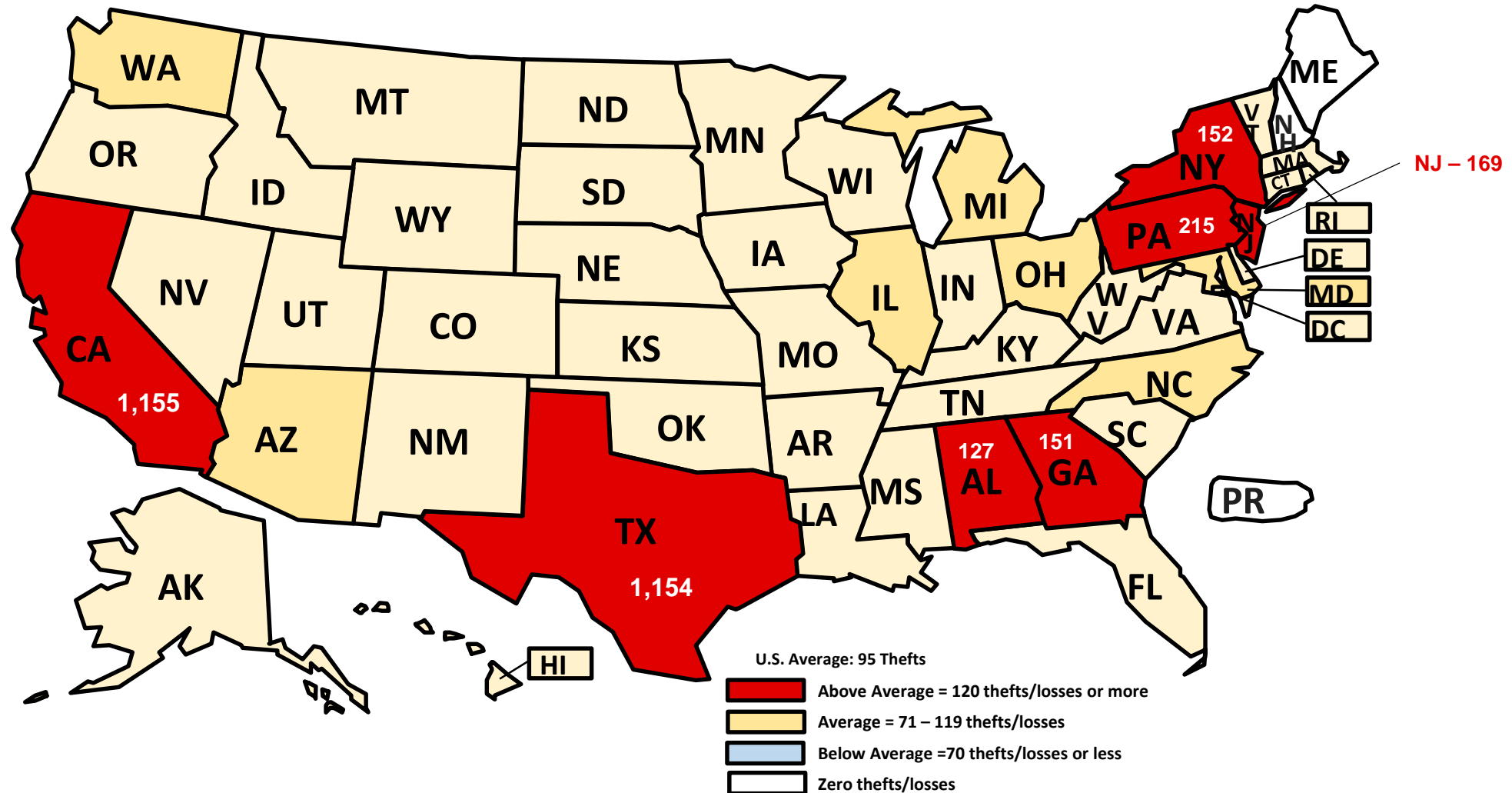
U.S. Average: 625 Thefts

- Above Average = 782 thefts/losses or more
- Average = 469 – 781 thefts/losses
- Below Average = 468 thefts/losses or less
- Zero thefts/losses

Promethazine with Codeine Thefts/Losses Nationwide

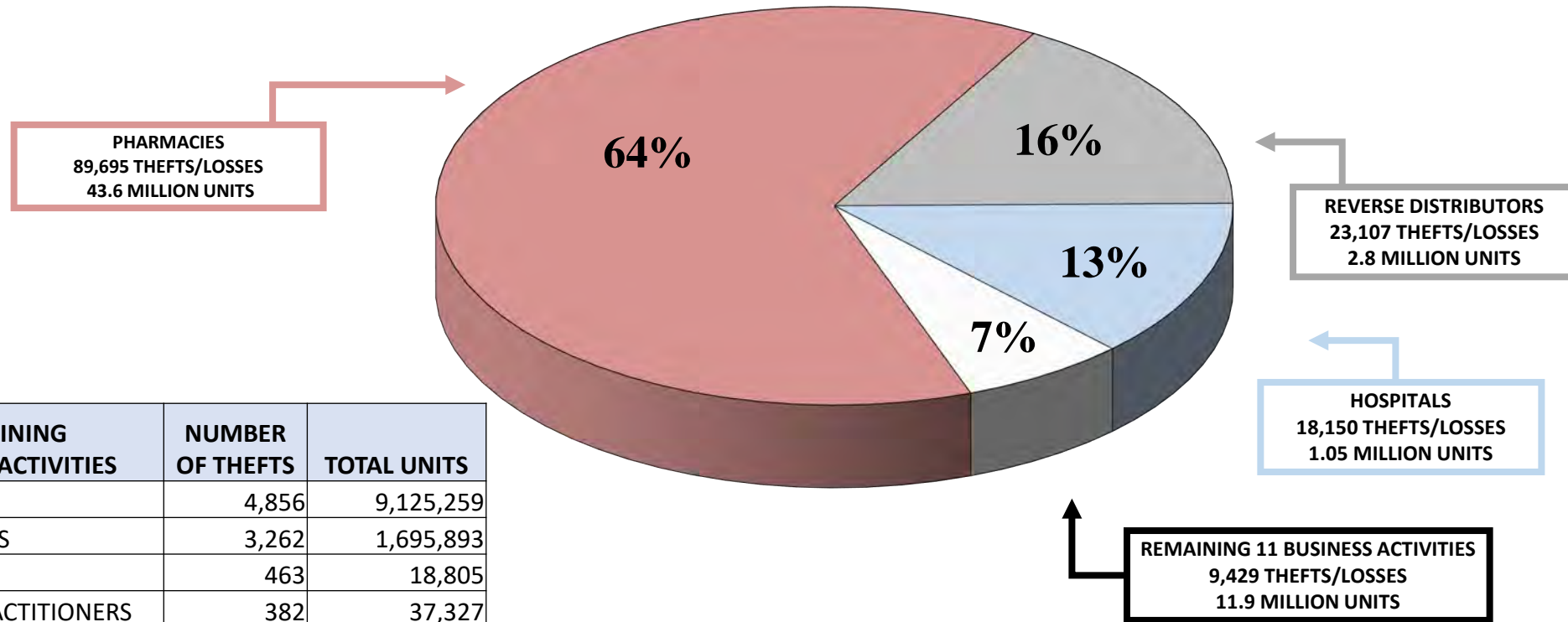
2019 – 2023

All Business Activities – All Theft Types



Reported Thefts/Losses by Business Activity Nationwide 2019 – 2023

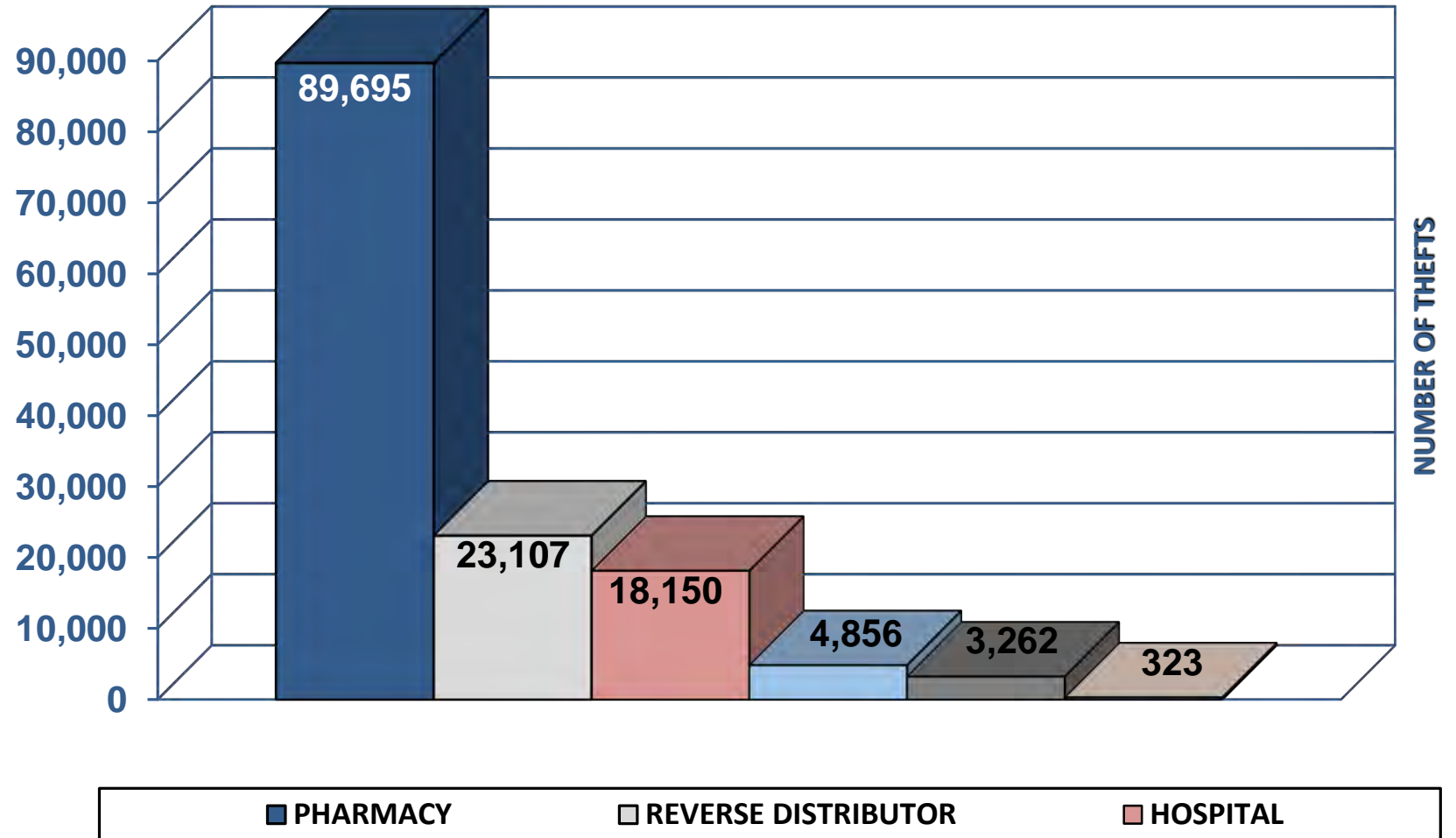
All Business Activities – All Drugs – All Theft Types



REMAINING BUSINESS ACTIVITIES	NUMBER OF THEFTS	TOTAL UNITS
DISTRIBUTORS	4,856	9,125,259
PRACTITIONERS	3,262	1,695,893
NTPS	463	18,805
MID LEVEL PRACTITIONERS	382	37,327
MANUFACTURERS	323	1,092,509
RESEARCHERS	83	289
ANALYTICAL LABS	24	77
CANINE HANDLERS	13	2
TEACHING INSTITUTIONS	9	160
IMPORTERS	9	634
EXPORTERS	5	1,280

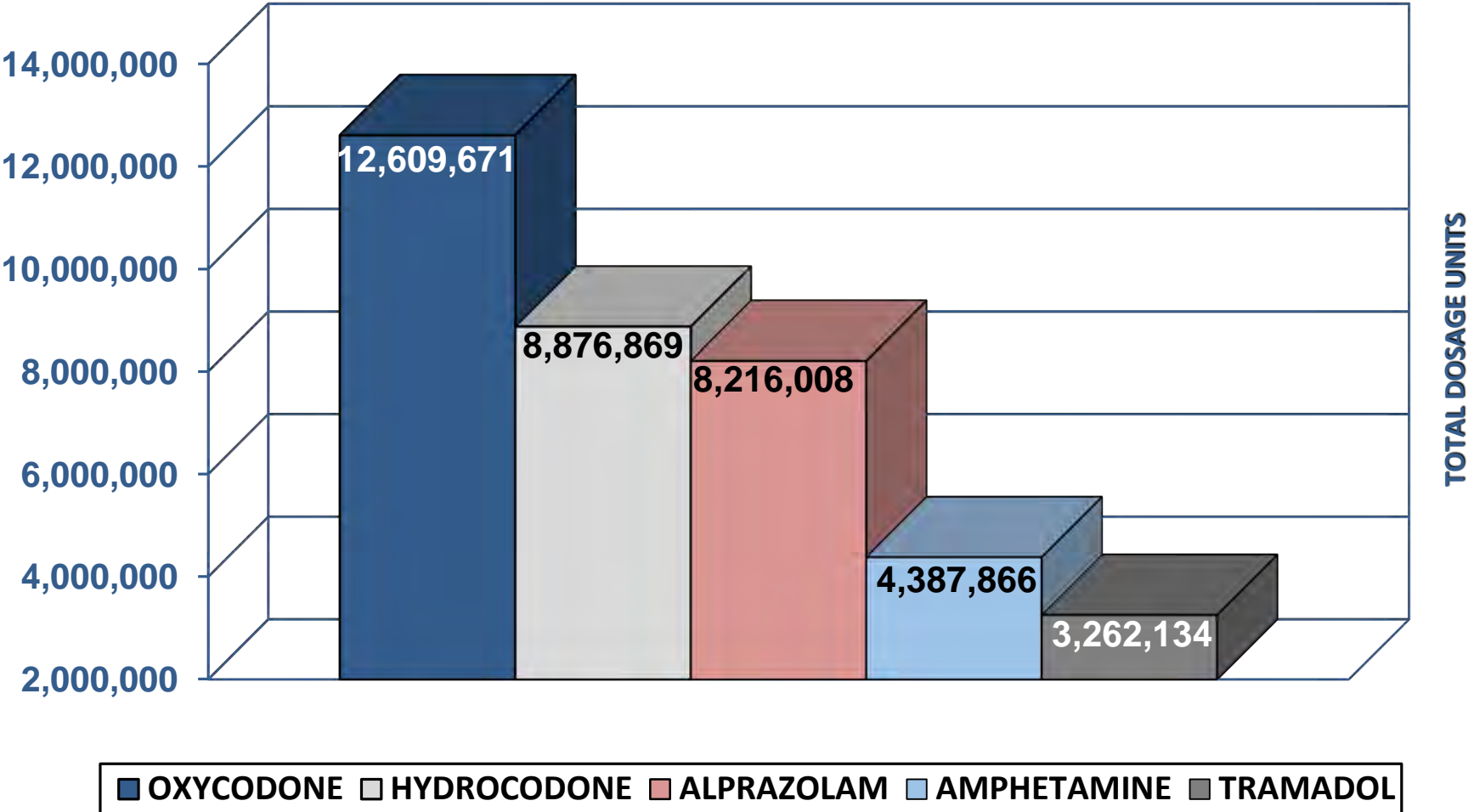


PHARMACY	PACKAGING DISCREPANCY
	EMPLOYEE THEFT
REVERSE DISTRIBUTOR	CUSTOMER THEFT
	LOSS IN TRANSIT
HOSPITAL	LOSS IN TRANSIT
	PACKAGING DISCREPANCY
DISTRIBUTOR	PACKAGING DISCREPANCY
	HIJACKING OF TRANSPORT VEHICLE
PRACTITIONER	PACKAGING DISCREPANCY
	LOSS IN TRANSIT
MANUFACTURER	PACKAGING DISCREPANCY
	EMPLOYEE THEFT



Top 5 Drugs Reported as a Theft/Loss by All Business Activities 2019 – 2023

All Theft Types



Total Dosages by Theft/Loss and Drug Type Nationwide

2019 – 2023

All Business Activities – All Drugs



THEFT/LOSS TYPE	TOTAL UNITS
BREAK-IN/BURGLARY	21,086,456
LOSS IN TRANSIT	13,965,600
EMPLOYEE THEFT (OR SUSPECTED)	11,584,678
PACKAGING DISCREPANCY	4,775,867
ROBBERY	4,517,590
CUSTOMER THEFT (OR NON EMPLOYEE)	2,076,323
DISASTER (FIRE, WEATHER, ETC.)	833,460
HIJACKING OF TRANSPORT VEHICLE	416,271

DRUG TYPE	NUMBER OF THEFTS	TOTAL UNITS
OPIOIDS	61,850	30,937,524
BENZODIAZEPINES	30,855	13,888,209
STIMULANTS	19,305	7,598,459
GRAND TOTAL	112,010	52,424,193



Suspicious Orders Reporting System (SORS)



- What is a Suspicious Order
- Who is Required to Report a Suspicious Order
- What are the SORS Reporting Requirements





What is a Suspicious Order? 21 CFR § 1301.74(b)

The term 'suspicious order' may include, but is not limited to:

- an order of a controlled substance of unusual size;
- an order of a controlled substance deviating substantially from a normal pattern, and;
- orders of controlled substances of unusual frequency as per 21 U.S.C. 802(57) and 21 C.F.R. 1301.74
- reports can be for multiple reasons or a reason not listed





Who is required to report Suspicious Orders?



Title 21 Code of Federal Regulation (21 CFR) requires all DEA registrants that sell or distribute controlled substances to another DEA registrant to report suspicious orders to DEA





What are the Suspicious Orders Reporting Requirements?

- 1) design and operate a system to identify suspicious orders
- 2) ensure that the system complies with applicable Federal and State privacy laws;
- 3) upon discovering a suspicious order or series of orders, notify DEA


Suspicious orders may include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 21 U.S.C. 802(57).

All registrants must maintain effective controls and procedures to guard against theft and diversion. 21 CFR 1301.71(a).




The Evolution of SORS Reporting



- **1970:** CSA becomes law
 - **1971:** CSA contains provisions regarding suspicious orders – DOJ promulgated regulations.
 - **2006-2007:** DEA sends letters to manufacturers and distributors informing them of their due diligence requirements.
 - **June 2018:** PDDA Bill (Preventing Drug Diversion Act) introduced – This bill would establish a new requirement to help drug manufacturers and distributors identify and prevent suspicious orders of opioids and reduce diversion rates. Ultimately incorporated into the SUPPORT Act.
 - **October 2018:** SUPPORT Act (Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities).
 - **October 2019:** DEA launches SORS online, a centralized database.
 - **2021:** DEA publishes Notice of Proposed Rulemaking to amend SORS regulations
- 

Suspicious Orders Reporting System (SORS)

- ❑ Quarterly mass email is sent to all DEA Registrants as a reminder of SORS Reporting Requirements.
- ❑ Emails are sent in an effort to increase reporting requirement responses.



U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
DIVERSION CONTROL DIVISION
Suspicious Orders Report System (SORS) (October 11, 2023)

Suspicious Orders Report System (SORS)

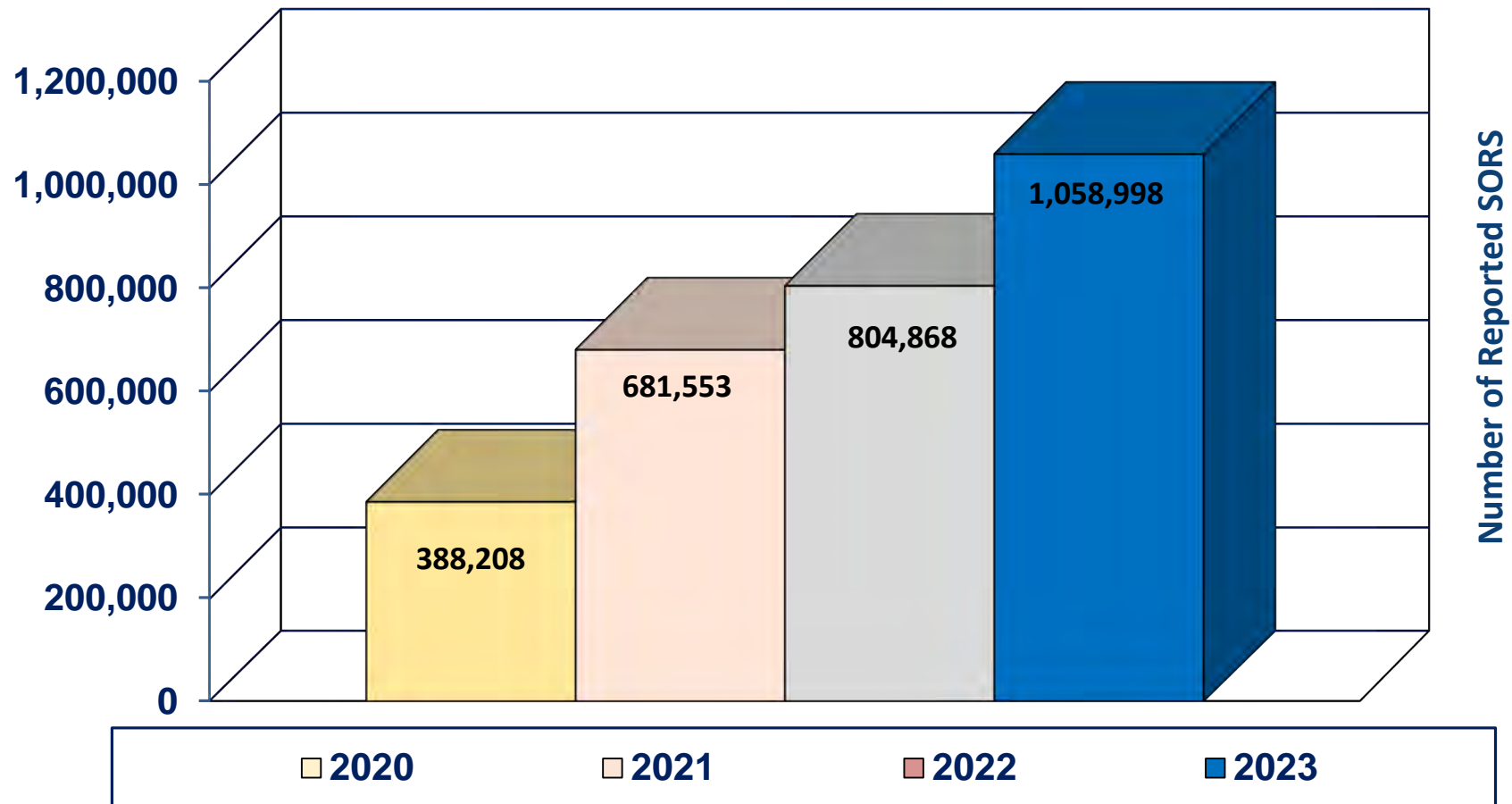
Centralized database required by the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act

On October 23, 2019, DEA launched the Suspicious Orders Report System (SORS) Online, a new centralized database required by the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (**SUPPORT Act, Pub. L. 115-271**). Reporting a suspicious order to the centralized database established by DEA (SORS Online) constitutes compliance with the reporting requirement under [21 U.S.C. 832\(a\)\(3\)](#). All registrants who distribute controlled substances (within the meaning of [21 U.S.C. 802\(11\)](#)) are required to design and operate a system to identify suspicious orders and notify DEA of suspicious orders. 21 U.S.C. 832(a). This obligation applies to all registrants ***if they distribute controlled substances***, including the following:

- Distributor
- Manufacturer
- Importer
- Pharmacy
- Hospital/Clinic
- Teaching Institution
- Practitioner
- Mid-Level Practitioner
- Mid-Level Practitioner-Ambulance Service
- Researcher
- Analytical Lab
- Narcotic Treatment Program (NTP)

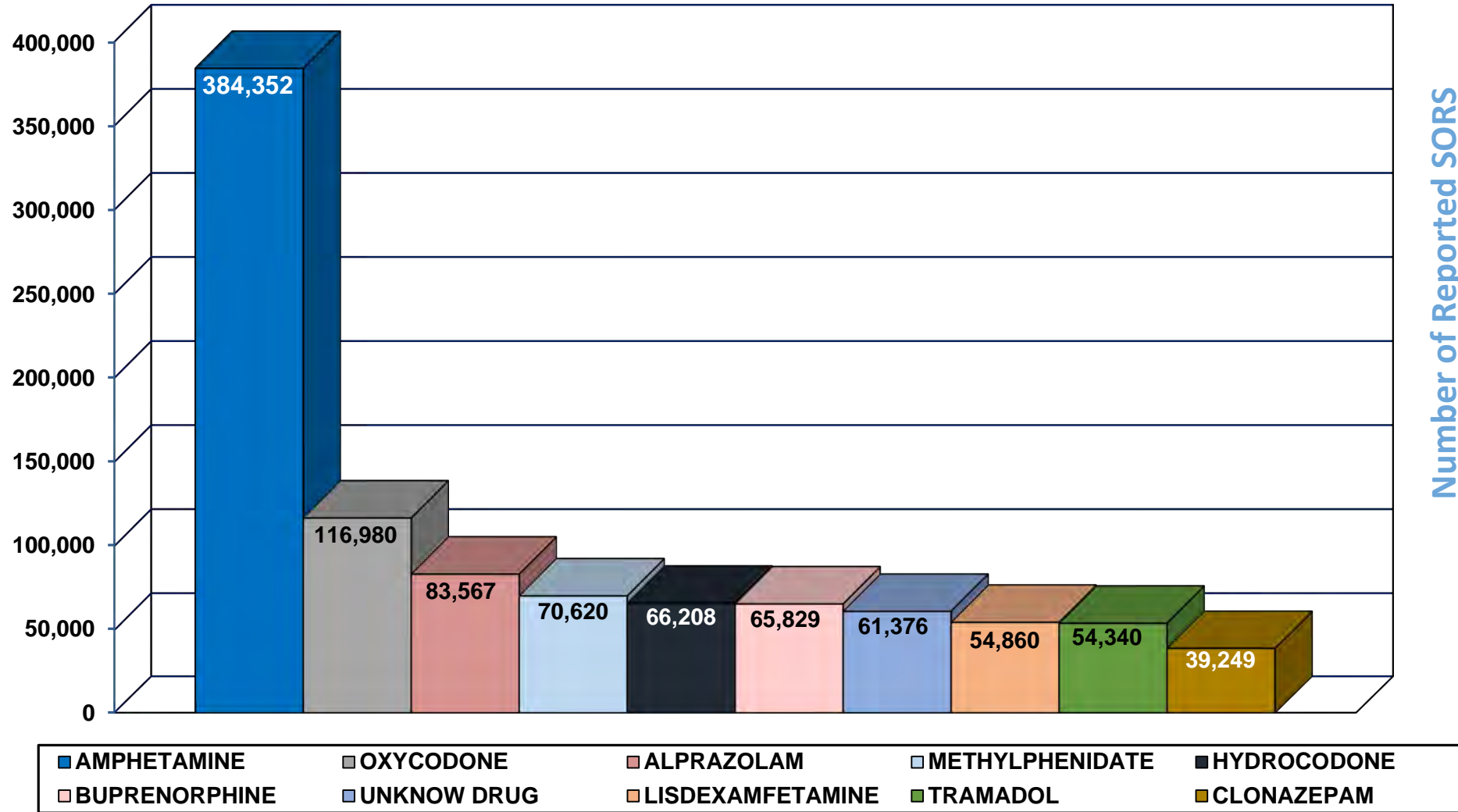
The SUPPORT Act states the term “suspicious order” may include, but is not limited to: an order of a controlled substance of unusual size; an order of a controlled substance deviating substantially from a normal pattern, and; orders of

Reported Suspicious Orders 2020 – 2023



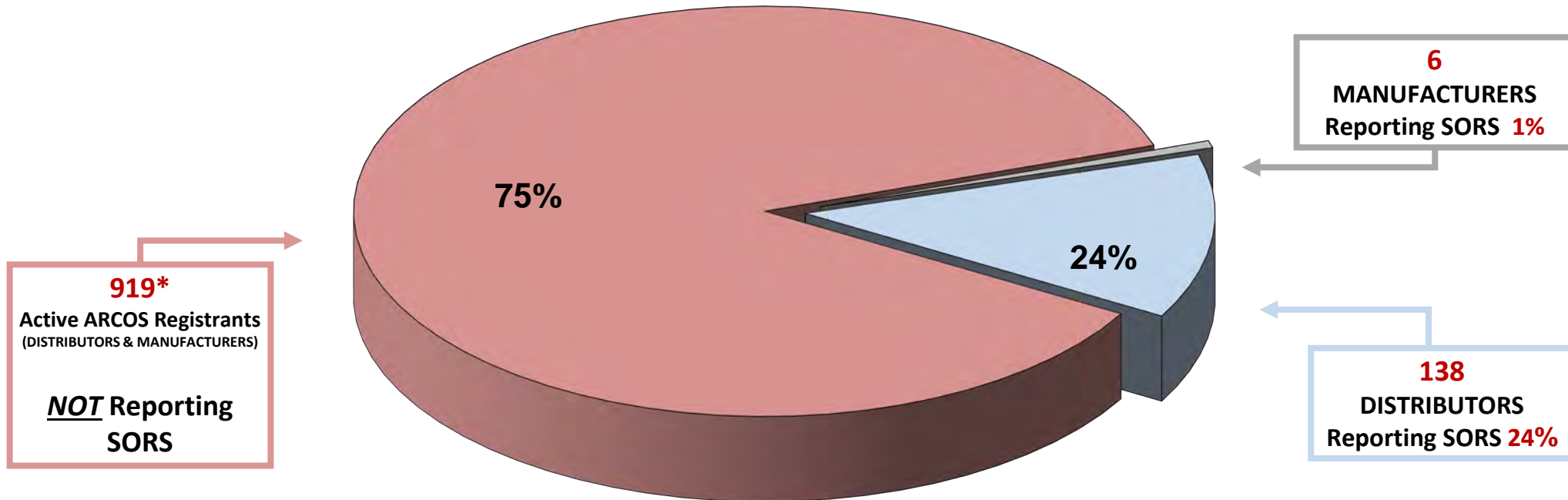
Suspicious Orders Reporting System (SORS)

Top 10 Reported SORS in 2023 - by Drug



Suspicious Orders Reporting System (SORS)

Current Reported SORS by Business Activity



*approximate total



SORS

U.S. TOTAL	
TOTAL ACTIVE ARCOS DISTRIBUTORS	586
TOTAL DISTRIBUTORS WITH SORS ACTIVITY	138
REGISTRANTS WITH DRUG ACTIVITY & NO REPORTED SORS	448
% OF ACTIVE ARCOS DISTRIBUTORS & NO REPORTED SORS	76.45%
U.S. TOTAL	
TOTAL ACTIVE ARCOS MANUFACTURERS	477
TOTAL MANUFACTURERS WITH SORS ACTIVITY	6
REGISTRANTS WITH DRUG ACTIVITY & NO REPORTED SORS	471
% OF ACTIVE ARCOS MANUFACTURERS & NO REPORTED SORS	98.74%



SORS

SORS TRANSACTION STATUS					
DEA ACTION	COUNT BY CALENDAR YEAR				
	Jan-Dec 2020	Jan-Dec 2021	Jan-Dec 2022	Jan-Dec 2023	Jan-Mar 2024
EXISTING INVESTIGATION	7,020	8,555	12,664	10,867	950
INVESTIGATION	7,886	4,882	5,039	4,564	990
NO FURTHER ACTION	338,959	525,904	596,102	708,263	124,021
PENDING	34,620	142,376	191,931	337,009	87,370
TOTAL	388,485	681,717	805,736	1,060,703	213,331