



Global Clinical Risk Management & Regulatory Policy

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The Supply Chain of Controlled Substances

- Wholesale Drug Diversion
- The Problem and DEA's New Strategy

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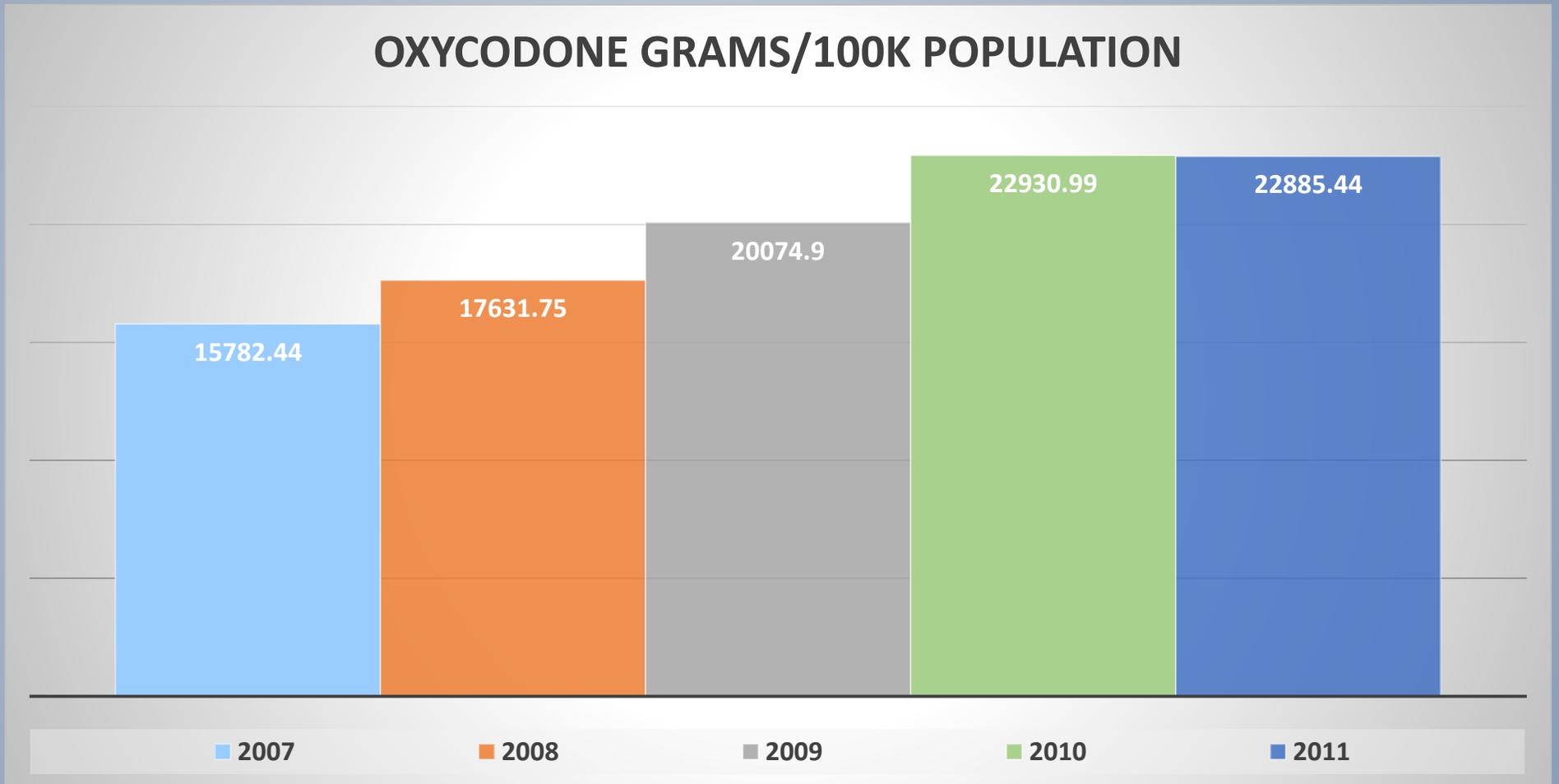
U.S. Drug Enforcement Administration



Outline

- Recent trends in medical use distribution of prescription opioids
- Relationship between increases in medical use of prescription opioids and abuse-related morbidity and mortality
- DEA Responds to prescription drug abuse “epidemic” with *Distributor Initiative Program*
- DEA cases against wholesale drug distributors 2006-2013
- Anatomy of DEA Regulatory Investigation (vs. Distributor)
- Future Warning Signs for the Industry
- Conclusions

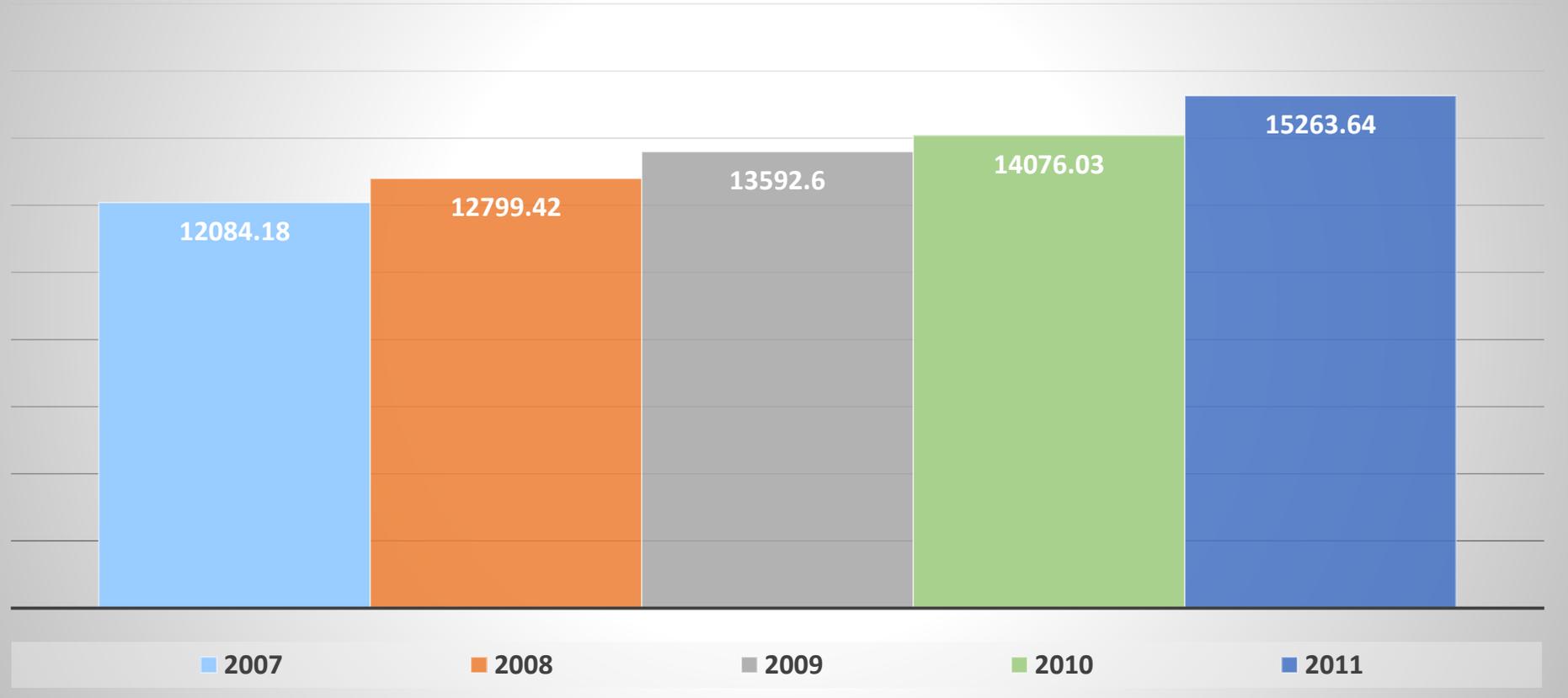
Distribution of Prescription Opioids for Medical Use



Source: DEA: Automation of Records and Consolidated Orders System (ARCOS); unpublished data, obtained by author via Freedom of Information Act, Aug. 2012.

Distribution of Prescription Opioids for Medical Use

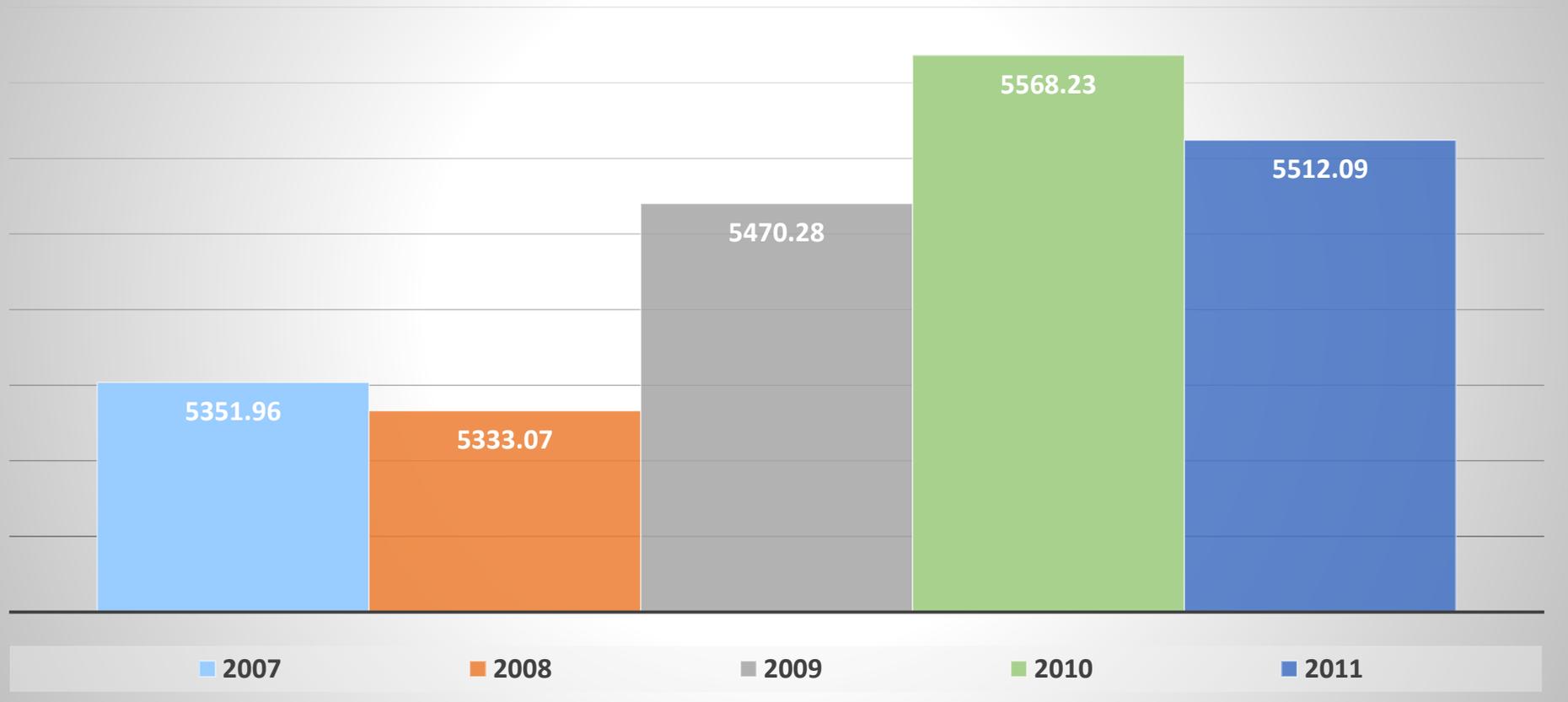
HYDROCODONE GRAMS/100K POPULATION



Source: DEA: Automation of Records and Consolidated Orders System (ARCOS); unpublished data, obtained by author via Freedom of Information Act, Aug. 2012.

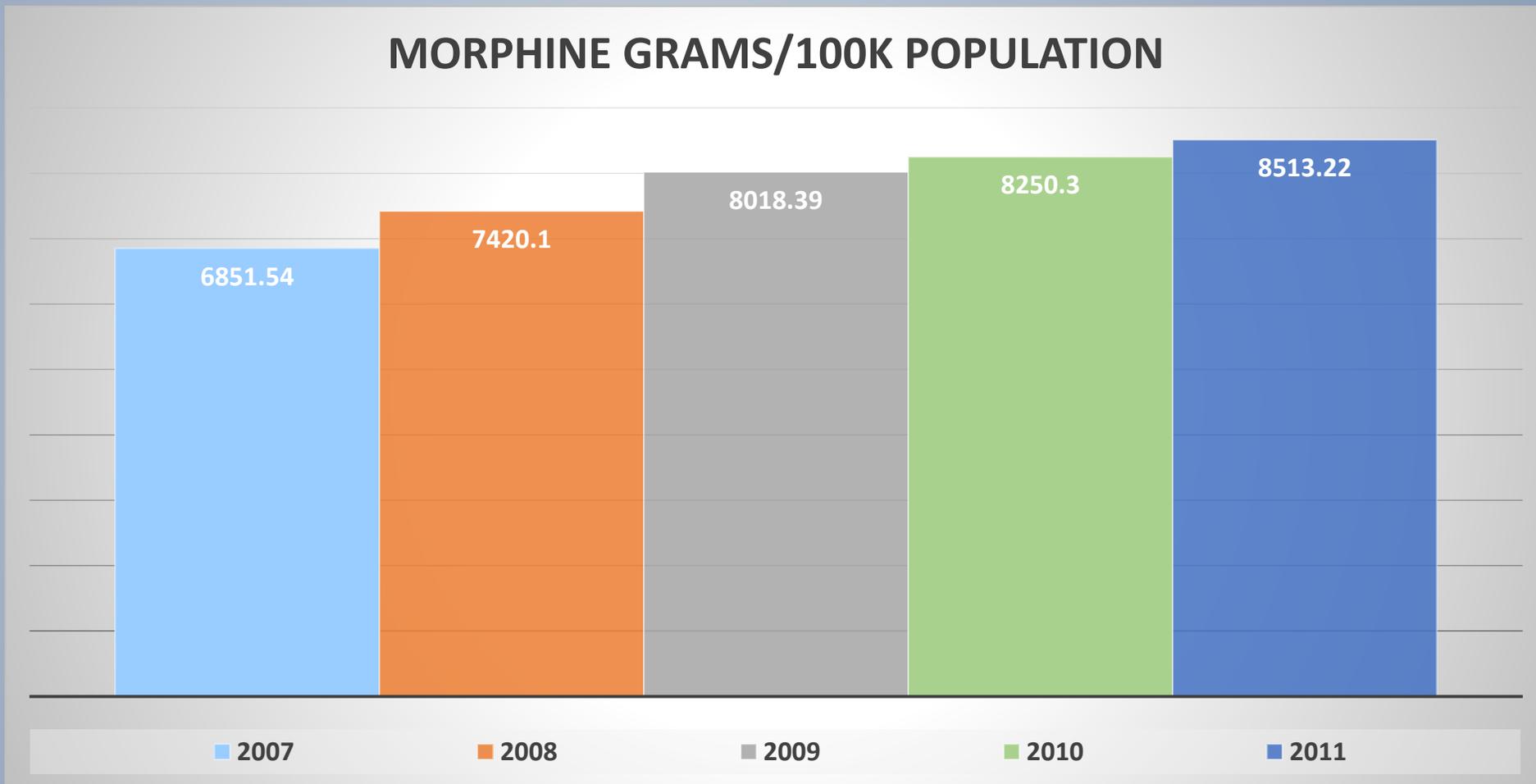
Distribution of Prescription Opioids for Medical Use

METHADONE GRAMS/100K POPULATION



Source: DEA: Automation of Records and Consolidated Orders System (ARCOS); unpublished data, obtained by author via Freedom of Information Act, Aug. 2012.

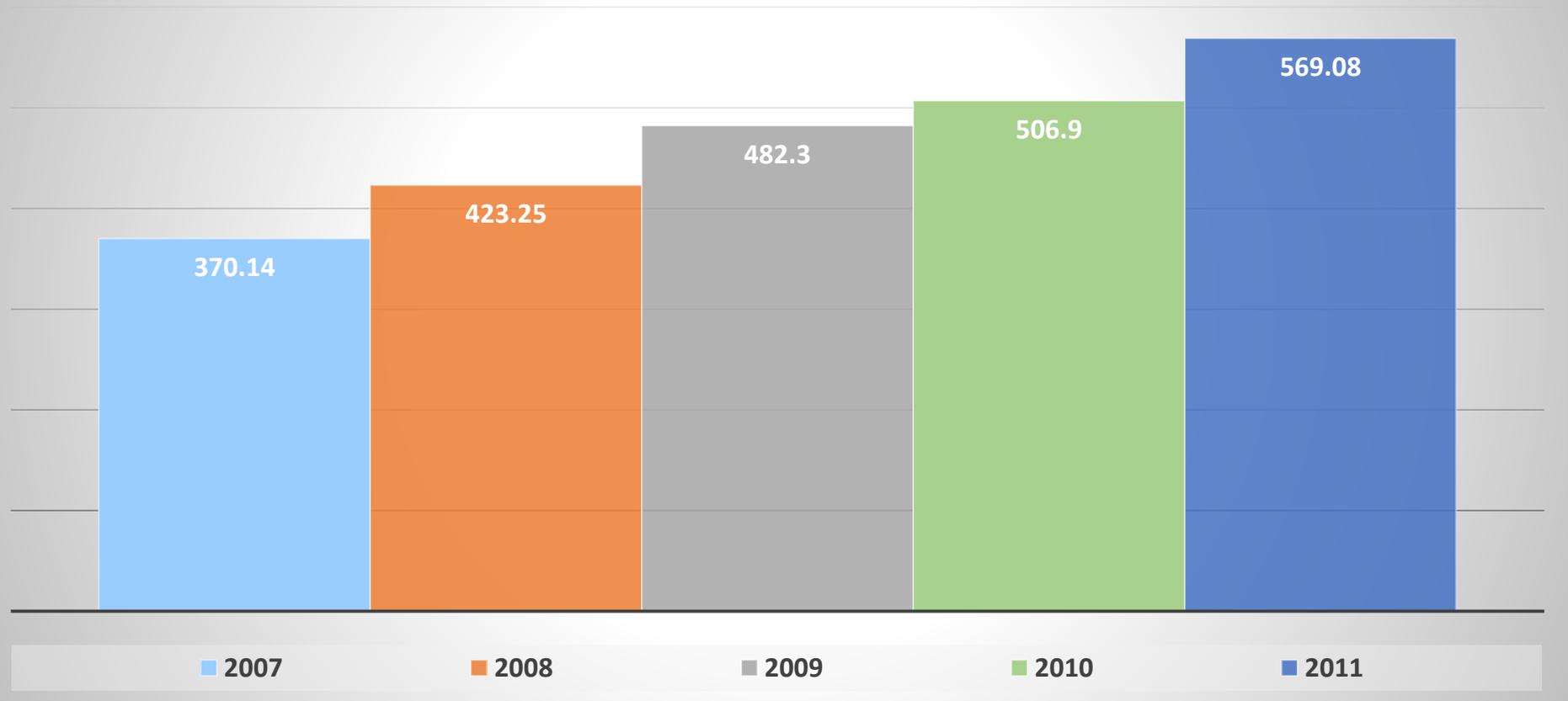
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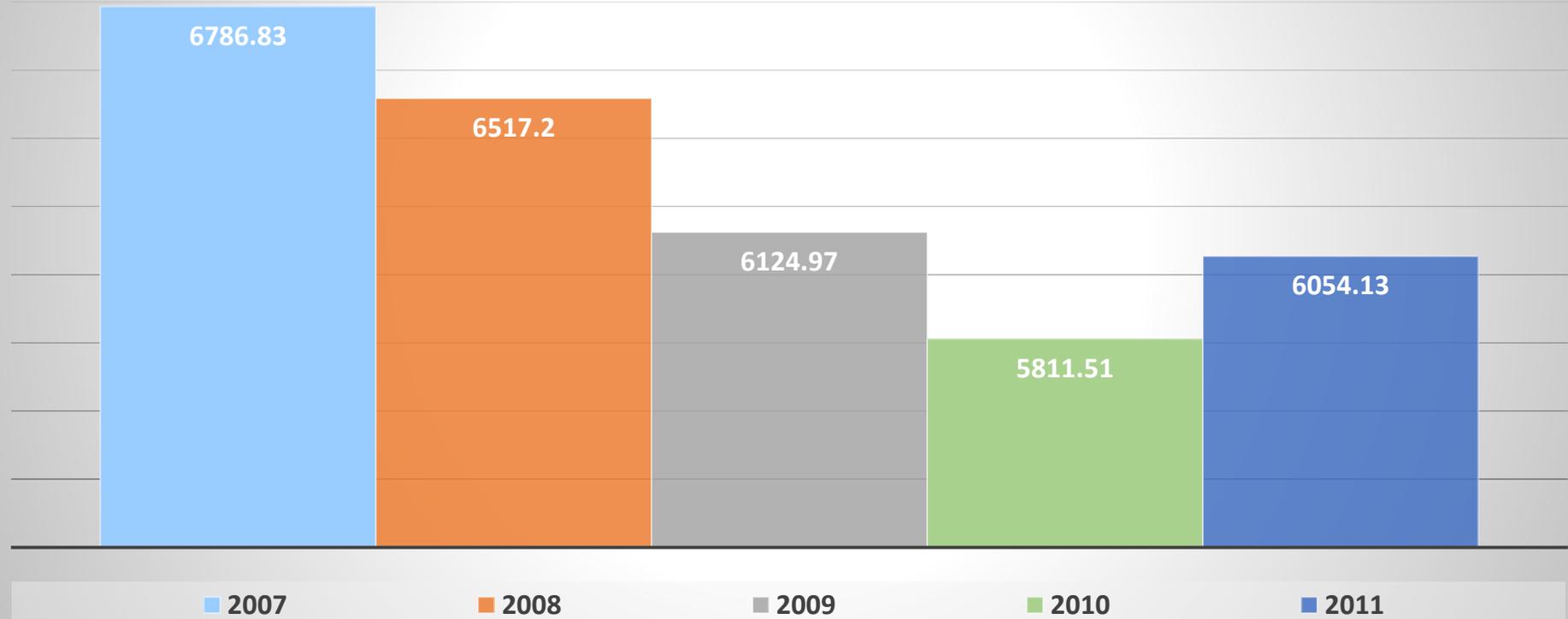
HYDROMORPHONE GRAMS/100K POPULATION



Source: DEA: Automation of Records and Consolidated Orders System (ARCOS); unpublished data, obtained by author via Freedom of Information Act, Aug. 2012.

Distribution of Prescription Opioids for Medical Use

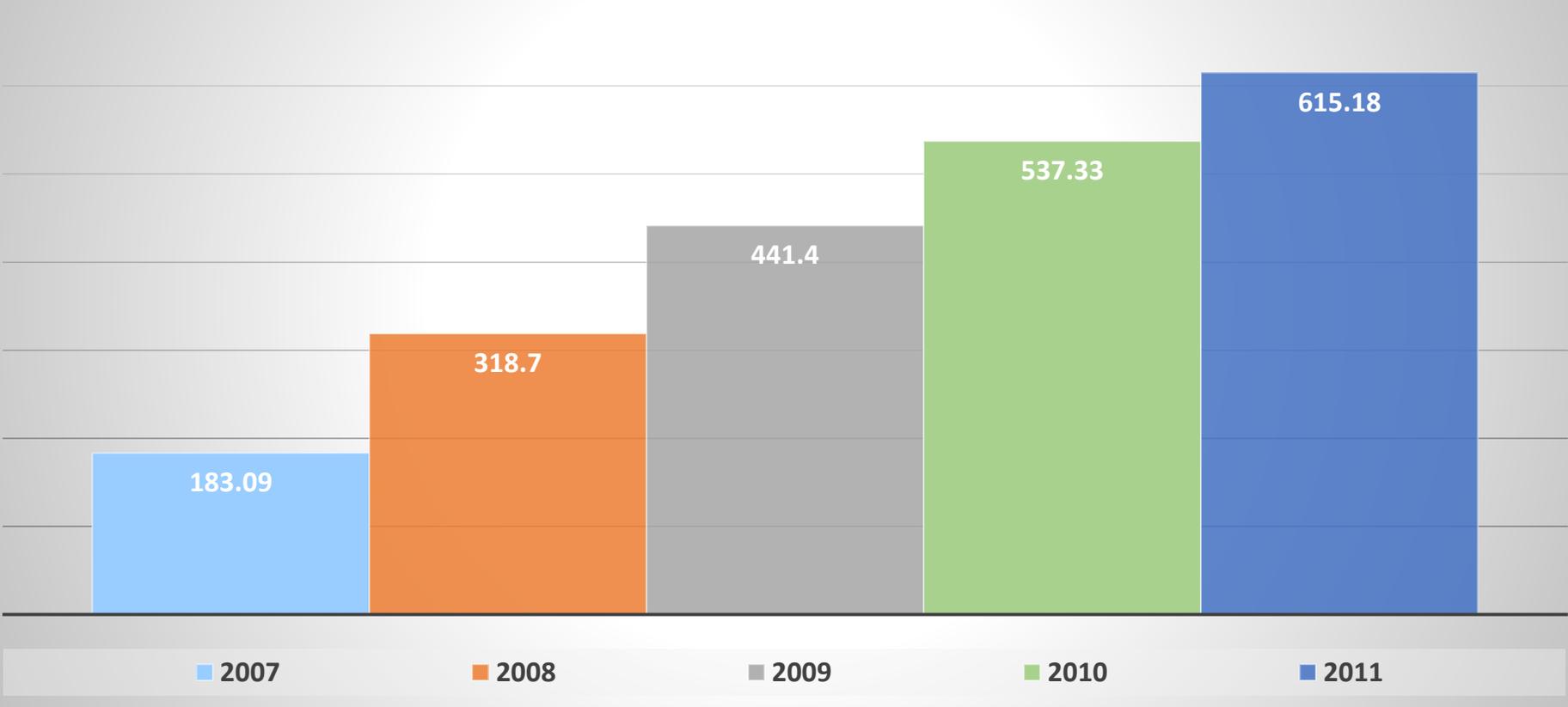
CODEINE GRAMS/100K POPULATION



Source: DEA: Automation of Records and Consolidated Orders System (ARCOS); unpublished data, obtained by author via Freedom of Information Act, Aug. 2012.

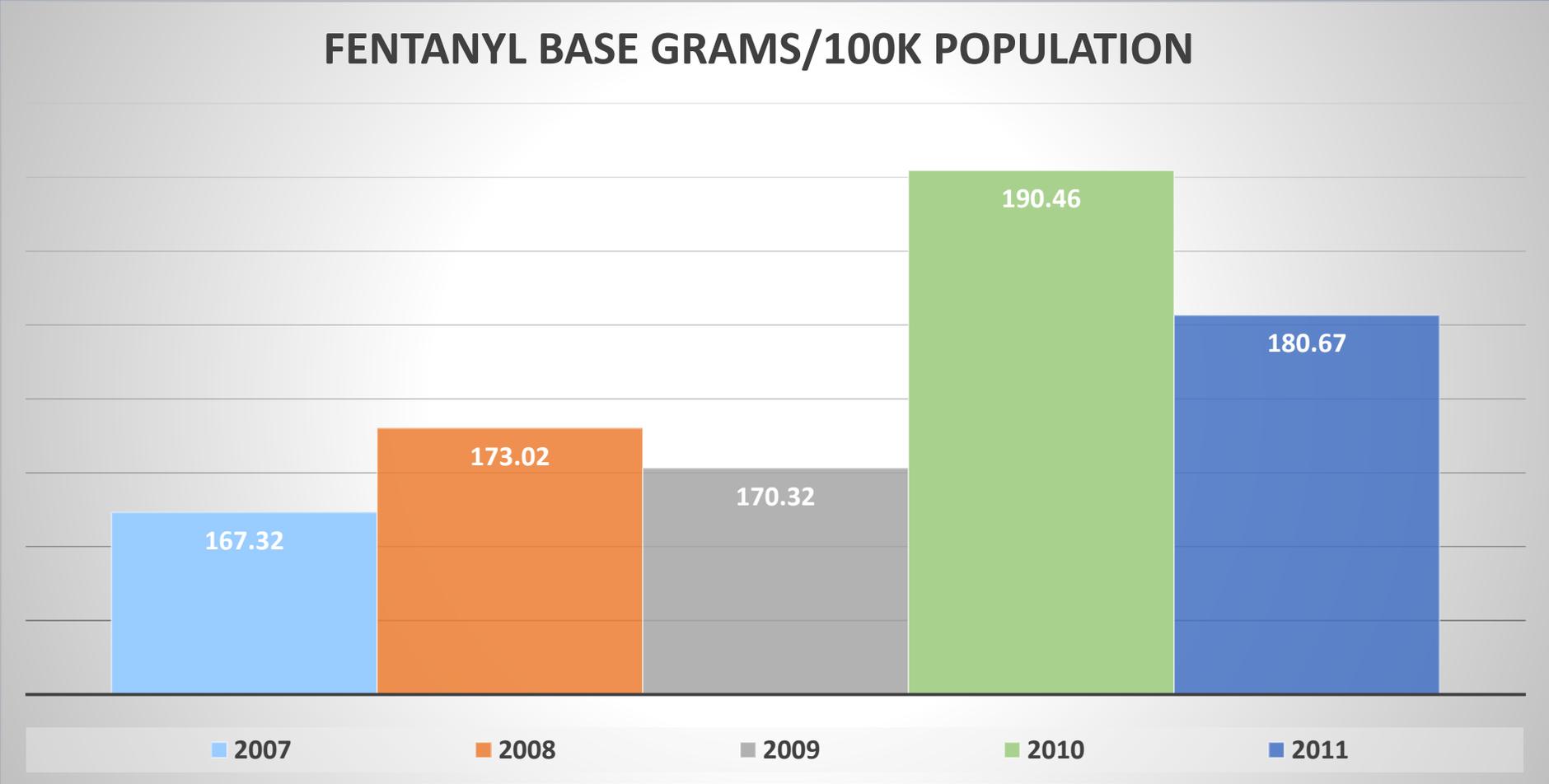
Distribution of Prescription Opioids for Medical Use

BUPRENORPHINE GRAMS/100K POPULATION



Source: DEA: Automation of Records and Consolidated Orders System (ARCOS); unpublished data, obtained by author via Freedom of Information Act, Aug. 2012.

Distribution of Prescription Opioids for Medical Use



Source: DEA: Automation of Records and Consolidated Orders System (ARCOS); unpublished data, obtained by author via Freedom of Information Act, Aug. 2012.

Distribution of Prescription Opioids for Medical Use

DRUG	2007 GM/100K	2011 GM/100K	DELTA (Δ)
OXYCODONE	15,782.44	22,885.44	+45%
HYDROCODONE	12,084.18	15,263.64	+26.3%
METHADONE	5,351.96	5,512.09	+3%
MORPHINE	6,851.54	8,513.22	+24.3%
HYDROMORPHONE	370.14	569.08	+53.7
CODEINE	6,517.20	6,054.13	-10.8%
BUPRENORPHINE	183.09	615.18	+236%
FENTANYL BASE	167.32	180.67	+8%

Source: DEA: Automation of Records and Consolidated Orders System (ARCOS); unpublished data, obtained by author via Freedom of Information Act, Aug. 2012.



Prescription Drug Abuse & Mortality

- The Centers for Disease Control and Prevention reports that 38,329 people in the U.S. died from a drug overdose in 2010. Nearly 60 percent of these overdose deaths (22,134) involved prescription drugs. Opioid analgesics, such as oxycodone, hydrocodone, and methadone, were involved in about 3 of every 4 prescription drug overdose deaths (16,651), confirming the dominant role opioid analgesics play in prescription drug abuse and mortality.¹

¹ Drug Enforcement Administration. (2013). "Statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, DEA; Presented before the Committee on Homeland Security and Governmental Affairs, U.S. Senate, June 24, 2013." (<http://www.justice.gov/dea/pr/speeches-testimony/2013t/062413-rannazzisi-testimony.pdf>.)



Medical Distribution of Oxycodone in U.S. in Gms/100K Population, Compared with Hospital Emergency Department Admissions for Misuse/Abuse of Oxycodone, 2004-2011



$r = 0.9796$ $p = > 0.001$

OXY GMS/100K ED ADMISSIONS

Sources: Gms/100k Pop = DEA, Automation of Reports and Consolidated Orders System (ARCOS), published: 2004 to 2006, unpublished: 2007-2011, obtained by author Aug 2012 via FOIA; ED visits: DHHS: Substance Abuse and Mental Health Services Administration; Drug Abuse Warning Network.



Medical Distribution of Hydrocodone in U.S. in Gms/100K Population, Compared with Hospital Emergency Department Admissions for Misuse/Abuse of Hydrocodone, 2004-2011



$r = 0.9123$ $p > 0.001$

■ HYDROCODONE GMS/100K
 — ED ADMISSIONS

Sources: Gms/100k Pop = DEA, Automation of Reports and Consolidated Orders System (ARCOS), published: 2004 to 2006, unpublished: 2007-2011, obtained by author Aug 2012 via FOIA; ED visits: DHHS: Substance Abuse and Mental Health Services Administration; Drug Abuse Warning Network.



DEA Responds With *Distributor Initiative Program* Aimed at Supply Chain Drug Diverters

- In 2005, DEA initiated a special operation (*Distributor Initiative Program*) to enforce provisions of the Controlled Substances Act requiring registrants authorized to distribute controlled substances to prevent diversion by designing and operating a system to identify *suspicious orders* and report them to DEA.¹
- The law defines *suspicious orders* as “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”²

¹ DEA, Statement by J.T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, June 24, 2013, U.S. Senate, Comm. on Homeland Security and Governmental Affairs; (available: <http://www.justice.gov/dea/pr/speeches-testimony/2013t/062413-rannazzisi-testimony.pdf>).

² Title 21, United States Code, Sect. 823(b); Title 21, Code of Federal Regulations, Sect. 1301(b).



Automation of Reports and Consolidated Orders System (ARCOS) – DEA's **Secret Weapon** Against Diversion

- Mandated by law, ARCOS is a DEA database that monitors controlled substances from their point of manufacture through wholesale distribution channels to point of sale or distribution at the dispensing/retail pharmacy level.
- ARCOS tracks transactions for: Schedule I and Schedule II drugs (manufacturers/distributors); Schedule III narcotics, and gamma-hydroxybutyric acid (GHB) (manufacturers/distributors); and selected Schedule III and Schedule IV psychotropic drugs (manufacturers only).
- DEA analysts review ARCOS data for signals of diversion (e.g., distributors who fill *suspicious orders* and do not report them to the nearest DEA field office, as required by law). ARCOS information is used by DEA to enforce civil and criminal provisions of the law.¹

¹. Drug Enforcement Administration, ARCOS Background (www.dea diversion.usdoj.gov)

DEA's *Distributor Initiative Program* pays dividends...

DEA Regulatory Actions Against Distributor-Registrants Between 2006 and 2Q2013

Distributor	Date	Drug	Amount	Disposition	DEA Registration(s)
Cardinal Health	2007	Hydrocodone	>8m d.u.	\$34m Fine/MOA	3 Restored
AmerisourceBergen	2007	Hydrocodone	3.8m d.u.	MOA	1 Restored
McKesson	2008	Hydrocodone	~3m d.u.	\$13.25m Fine/MOA	6 Restored
Cardinal Health	2012	Oxycodone	>3m d.u.	2-Yr Reg. Suspension	1 Suspended
Southwood Pharm.	2006	Hydrocodone	8.7m d.u.	MOA	1 Restored
Masters Pharm.	2009	Hydrocodone	>4m d.u.	\$0.5m Fine	1 Restored
Sunrise Wholesale	2010	Oxycodone	n/a	n/a	Surrendered
Harvard Med. Grp.	2010	Oxycodone	>13m d.u.	\$8m Fine/MOA	1 Restored
KeySource Med.	2010	Oxycodone	~48m d.u.	\$0.32m Fine/MOA	1 Restored
Omnicare	2012	Various CS	Unk.	\$50m Fine	Unaffected
CVS	2012	Various CS	Unk.	\$11m Fine	Unaffected
Walgreens	2013	Various CS	Unk.	\$80m Fine/MOA	7 Susp. 12-16 Mos.
UPS	2013	Various CS	Unk.	\$40m Fine	Unaffected

Source: Coleman, J. J. (2012). "The supply chain of medicinal controlled substances: addressing the Achilles heel of drug diversion." *J Pain Palliat Care Pharmacother* 26(3): 233-250. (Updated June 2013)





Warning Signs for Distributor-Registrants

1. A review of court documents for several major cases reveals cavalier approach by industry to legal requirements for preventing drug diversion by identifying and reporting suspicious orders
2. Fines and individual suspensions may not have the intended effect of deterring repeat violations (e.g., Cardinal Health 2007 & 2012)
3. In opposing Cardinal Health's motion for a preliminary injunction to halt DEA's ISO on the grounds of economic hardship, DEA advised the court:
"The most that will occur is that Plaintiff [i.e., Cardinal Health] may have to re-route controlled substances through Plaintiff's other distribution facilities."¹
4. Cardinal Health, like many other wholesale distributors of controlled substances, has multiple distribution facilities throughout the U.S., each with a separate DEA registration to distribute controlled substances.

¹ *Cardinal Health v. Eric Holder, Attorney General, et al.* U.S. District Court, District of Columbia, Case 1:12-cv-00185-RBW; Document #14-2, filed 2/10/12 at p. 39. Washington, D.C.

Warning Signs for Distributor-Registrants

5. Critics of “checkbook justice” claim that large corporations may not be deterred from committing regulatory infractions by the threat of fines.¹
6. Fines, they claim, may be spread across the company’s numerous profit centers so that the overall bottom line effect is minimal.
7. Or, the financial impact of a fine may simply be passed along to the consumer in the cost of the company’s goods and services.
8. Policy experts recommend, if warranted, that regulatory agencies consider using criminal provisions to ensure compliance.
9. A key penalty statute used in DEA’s *Distributor Initiative Program* has both civil and criminal provisions, the difference being that a criminal charge requires a showing of “knowledge” on the part of the person(s) whose action has allegedly violated the law.²

¹ Coglianesi C, Healey TJ, Keating EK and Michael ML. "The Role of Government in Corporate Governance." Regulatory Policy Program Report RPP-08 (2004). JFK School of Government, Harvard University." (available: <http://www.hks.harvard.edu/m-rcbg/research/rpp/reports/RPPREPORT8.pdf>). ² See 21 USC 842(c).



Warning Signs for Distributor-Registrants

10. A review of court filings in several DEA distributor cases revealed documentation and evidence of “knowledge” on the part of company officials who allegedly and knowingly failed to prevent drug diversion by intentionally not reporting identified suspicious orders to the nearest DEA office and, instead, filled them.
11. In one case, according to evidence obtained by DEA pursuant to an administrative inspection warrant and presented in court, company officials identified numerous suspicious orders and filled them despite written recommendations by company investigators to their superiors that the orders were suspicious and needed to be reported to DEA.
12. How long the government will continue to handle these cases as civil law infractions is unknown.
13. Much will depend on whether the current prescription drug abuse epidemic continues to increase or is reduced or otherwise affected positively by the DEA’s strategy as it is now being pursued.



Conclusions

1. The nation's problem of prescription drug abuse is serious and increasing at alarming proportions.
2. Wholesale drug distributors, registered by DEA to sell controlled substances, are required by law to prevent drug diversion by designing/implementing a program to identify suspicious orders so that they can be referred to the nearest DEA office.
3. Distributors may have inherent conflict of interest between complying with the law and pursuing the business of selling drugs.
4. DEA's *Distributor Initiative Program* will continue to focus on excessive (i.e., unlawful) sales of controlled substances.
5. Because system is "closed," whenever DEA enters a supply chain case at the distributor level, it often leads to investigations of customers (e.g., pharmacies, pill mills, etc.) of the distributor, as well as investigations of the prescribers and dispensers of controlled substances affiliated in some way with the customers.
6. If the current DEA strategy does not accomplish its goal of reducing prescription drug abuse, we may expect the agency to begin pursuing criminal law violations against some distributors.





Thank You!

John J. Coleman, PhD