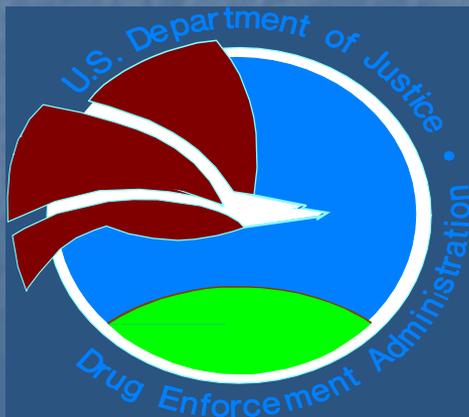


*Drug Enforcement Administration  
Office of Diversion Control  
ODG/Regulatory Section*

*Effective Controls Against Diversion*



**“I’m not a Doctor.”**

**“I’m not the Doctor.”**

**“I’m not a Pharmacist.”**

**“It’s not my responsibility”**

**“We can’t check every prescription.”**

**“They have a DEA registration number”**

**“We are too busy to look at every customer order.”**

**“We are only a link (one link) in  
the supply chain”**

**“We are not the police.”**

# **Comprehensive Drug Abuse Prevention and Control Act**

October 27, 1970

**Public Law 91-513**



# Background of Current Drug Control Legislation

- **In response to:**
  - **Single Convention on Narcotic Drugs 1961 (Ratified by the U.S. in 1967)**
  - **“The growing menace of drug abuse in the United States”**
  - **Need for unified legislation and more effective drug control efforts**

# Report on S. 3246

- **“It ...provides for records and reports, for order forms and for prescriptions as required by the Attorney General to help regulate the manufacture, distribution, and dispensing of controlled dangerous substances.”**

December 16, 1969

# Report on S. 3246

- **“...vests the Attorney General with authority to establish any rules, regulations, and other procedures to help him carry out the provisions of this bill.”**

December 16, 1969

# Report on H.R. 18583

- **“This bill is designed to improve the administration and regulation of the manufacturing, distribution, and dispensing of controlled substances by providing for a “closed system” of drug distribution for legitimate handlers of these drugs.”**

September 10, 1970

# Report on H.R. 18583

- **“... provide(s) authority for the Department of Justice to keep track of all drugs subject to abuse manufactured or distributed in the United States in order to prevent diversion of these drugs from legitimate channels of commerce.”**

September 10, 1970

# “Controlled Substances Act”

- Created a system of controls for the legitimate manufacture, distribution, import, export, dispensing, and prescribing of controlled substances for legitimate medical, commercial, scientific, and research needs.

# 21 U.S.C. § 822 (a)(1)

- Persons Required to Register:
- “Every person who manufactures or distributes any Controlled Substance or List I Chemical ...”

# 21 U.S.C. § 822 (a)(2)

- Persons Required to Register:
- “Every person who dispenses ... any Controlled Substance ...”

# 21 U.S.C. § 957 (a)(1)

- Persons Required to Register:

No person may

(1) import into the customs territory of the United States ... any controlled substance or list I chemical, or

# 21 U.S.C. § 957 (a)(2)

**(2) export from the United States any controlled substance or list I chemical, unless there is in effect with respect to such person a registration issued by the Attorney General ...**

# 21 U.S.C. § 827

## All DEA Registrants Must:

- Take and Keep Inventories
- Make and Keep Records
- Make and Keep Reports

# 21 U.S.C. § 827

- **Inventories, Records, And Reports Must Be:**
  - **In a Form as Required By Regulation**
  - **Readily Retrievable**
  - **Complete and Accurate**
  - **Kept for (at least) Two Years**

Importers/Exporters 465

Manufacturers 542

**Distributors 950**

69,407	1,156,508	15,890	226,011
Pharmacies	Practitioners	Hospitals	Mid-Level

Research/Analytical Labs 11,219

Narcotic Treatment Programs 1,316

U.S. Population 310,300,000

# Mission

- The Office of Diversion Control's Mission is to Prevent, Detect, and Investigate the Diversion of Pharmaceutical Controlled Substances and Listed Chemicals from Legitimate Channels ...
- While Ensuring an Adequate and Uninterrupted Supply of ...Controlled Substances to Meet Legitimate Medical, Commercial, and Scientific Needs.

# Closed System

- DEA is responsible for
  - the oversight of the system
  - the integrity of the system,
  - the protection of the public health and safety.

# Closed System

- **All registrants** have certain legal responsibilities for helping to maintain this closed system and to assist DEA in helping to protect the public health and safety.

# Types of Registrants:

<b>Practitioners</b>	<b>Non-Practitioners</b>
<b>Physician</b>	<b>Manufacturer</b>
<b>Retail Pharmacy</b>	<b>Distributor</b>
<b>Hospital Clinic</b>	<b>Reverse Distributor</b>
<b>Teaching Institution</b>	<b>Importer</b>
<b>Researcher</b>	<b>Exporter</b>
<b>Analytical Laboratory</b>	<b>Narcotic Treatment Program</b>
<b>Mid-level Practitioner</b>	

# Effective Controls

- **21 C.F.R. § 1301.71 (a):**

All applicants and registrants shall provide **effective controls** and procedures to guard against theft and diversion of controlled substances.

# Effective Controls

- **21 C.F.R. § 1301.71 (a):**

**In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72-1301.76 as standards for physical security controls and operating procedures necessary to prevent diversion.**

# Reports: Non-Practitioners

- 21 C.F.R. § 1301.74 (b)
- The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances.
- The registrant shall inform the Field Division Office ...in his area of suspicious orders when discovered by the registrant.

# Suspicious Orders Include

- Orders of Unusual Size
- Orders Deviating Substantially From a Normal pattern
- Orders of Unusual Frequency
- These criteria are **disjunctive**  
(They can stand alone or together)

# Reports: Practitioners

- **21 C.F.R. § 1301.76 (c)**
- **Whenever the registrant distributes a controlled substance (without being registered as a distributor, as permitted in ...) he/she shall comply with the requirements imposed on non-practitioners in Sec. 1301.74 (a), (b), and (e).**

# Additional Responsibilities Practitioners

- **21 CFR 1306.04 (a)**
- A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.

# Additional Responsibilities: Practitioner

- **21 CFR 1306.04 (a)**
- The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner...

# Additional Responsibilities: Pharmacies

- **21 CFR 1306.04 (a)**
- ...but a corresponding responsibility rests with the pharmacist who fills the prescription .

# Reports: Chemical Handlers

- **-Section 1310.05 Reports.**
- (a) Each regulated person shall 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, as follows:

# Suspicious Chemical Orders

- (1) 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.

# Suspicious Orders

- DEA will no longer accept Excessive Purchase Reports.
- **Excessive purchases were reported after the order had been filled.**

# Suspicious Orders

- The responsibility for making the decision to ship or not to ship rests with the supplier.
- Once a Suspicious Order is identified by the supplier the order must not Be shipped.

# Suspicious Orders

- The Registrant must **KNOW THEIR CUSTOMERS.**
- What are the “**RED**” flags?

# **“Know Your Customers”**

## **Some Factors to Consider:**

- Where is it going?**
- Who is it going to?**
- How many other distributors are involved?**
- Who are the Down Stream customers?**

# **“Know Your Customers”**

## **Some Factors to Consider:**

- **What do the news reports say about the state or geographical area where the controlled substances are being sold to?**
- **Is there a problem with controlled substances in that particular state?**
- **What is the problem? What are the controlled substances involved?**

# “Know Your Customers”

## Some Factors to Consider:

- Range and Quantity of Products Being Purchased,
- Location and hours of operation,
- Methods of Payment Utilized (cash, credit card, insurance).
- % Controlled vs. % Non-Controlled,

# **“Know Your Customers”**

## **Some Factors to Consider:**

- **What is the average monthly purchase for an average type of registrant for a particular controlled substance? For a particular geographical area?**
- **Does the requested purchase represent a quantity that far exceeds that average monthly purchase? Why?**

# “Know Your Customers”

## Some Factors to Consider:

- Are a large portion of the prescriptions being filled at a pharmacy for large quantities of controlled substances and are being paid for in cash or by credit card?
- Are the prescriptions mostly for oxycodone, hydrocodone, and/or benzodiazepines (Ativan, Lorazepam, Diazepam) ?

LEAVE PRESCRIPTIONS  
HERE

NO INSURANCE  
FOR ANY  
ROXICODONE

FREE SODA OR  
WATER WHILE YOU  
WAIT FOR YOUR  
RX'S

NO CELL PHONE  
USE IN PHARMACY

WE DO NOT  
ACCEPT ANY  
INSURANCE ON :  
OXYCODONE

All new patients must have  
their MRI report or else have  
your doctor fax us a copy of  
the report. 561-588-8562



OXYCONTIN,  
OXYCODONE ORAL  
SOLUTION,  
OXYCODONE ER  
OR LA PRODUCTS



# **“Know Your Customers”**

## **Some Factors to Consider:**

- Are there security guards on the premises? Why?**
- Is there a line of people waiting to get into the place?**
- Are there pain clinics in the area? How many? Is the pharmacy inside a pain clinic?**





PHARMAC

Grand 3D White  
3D White  
Grand 3D White  
Grand 3D White

OPEN

FASHION

30%



Pharmacy

458 W. ...

... 33441 P...

4749C2-0

Dr. [REDACTED]

IRVING

**RICHARD**

RD, LEXINGTON, KY 40515

TAKE 1 CAPSULE BY MOUTH EVERY  
HOURS

**OXYCODONE 30MG CMPD**

12/SM

Qty: 180, CA 10/20/2010 Expiration Date: 10/20/2010

0 refills / Dr. Approval Required

Manuf. CO

# Average Prescription

- Oxycodone 30mg
- 180-220 Tablets
- Cash/Credit Card Only
- Prescription is always from a Pain Clinic
- Pharmacy is Charging \$4.00-\$6.00 Per Tablet
- \$720.00 to \$1,320.00 Cash at Counter

SHARP ELECTRONIC CASH REGISTER

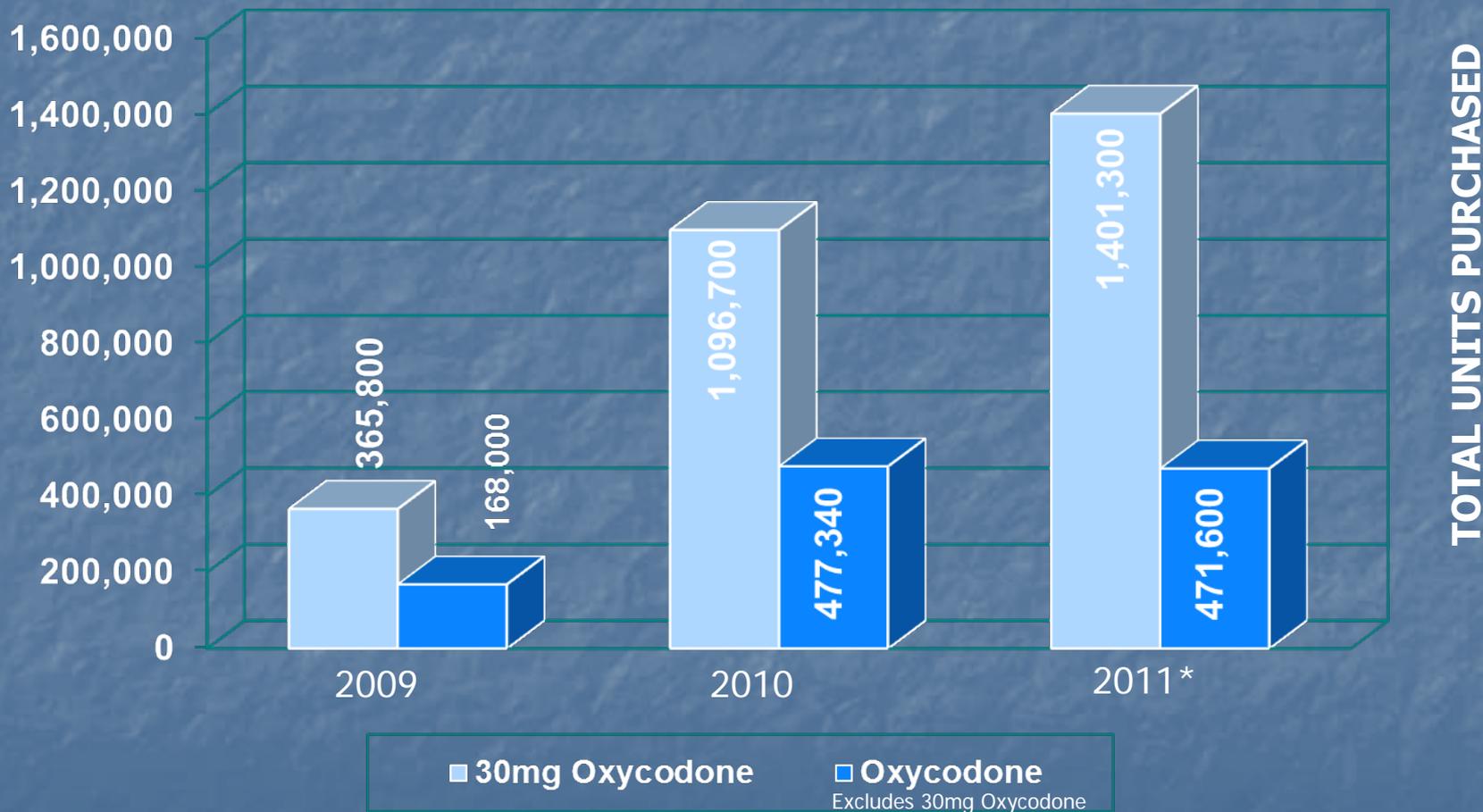
F 1115.00

XE-A106

OFF ON / Flash / Z / PGM  
VOID

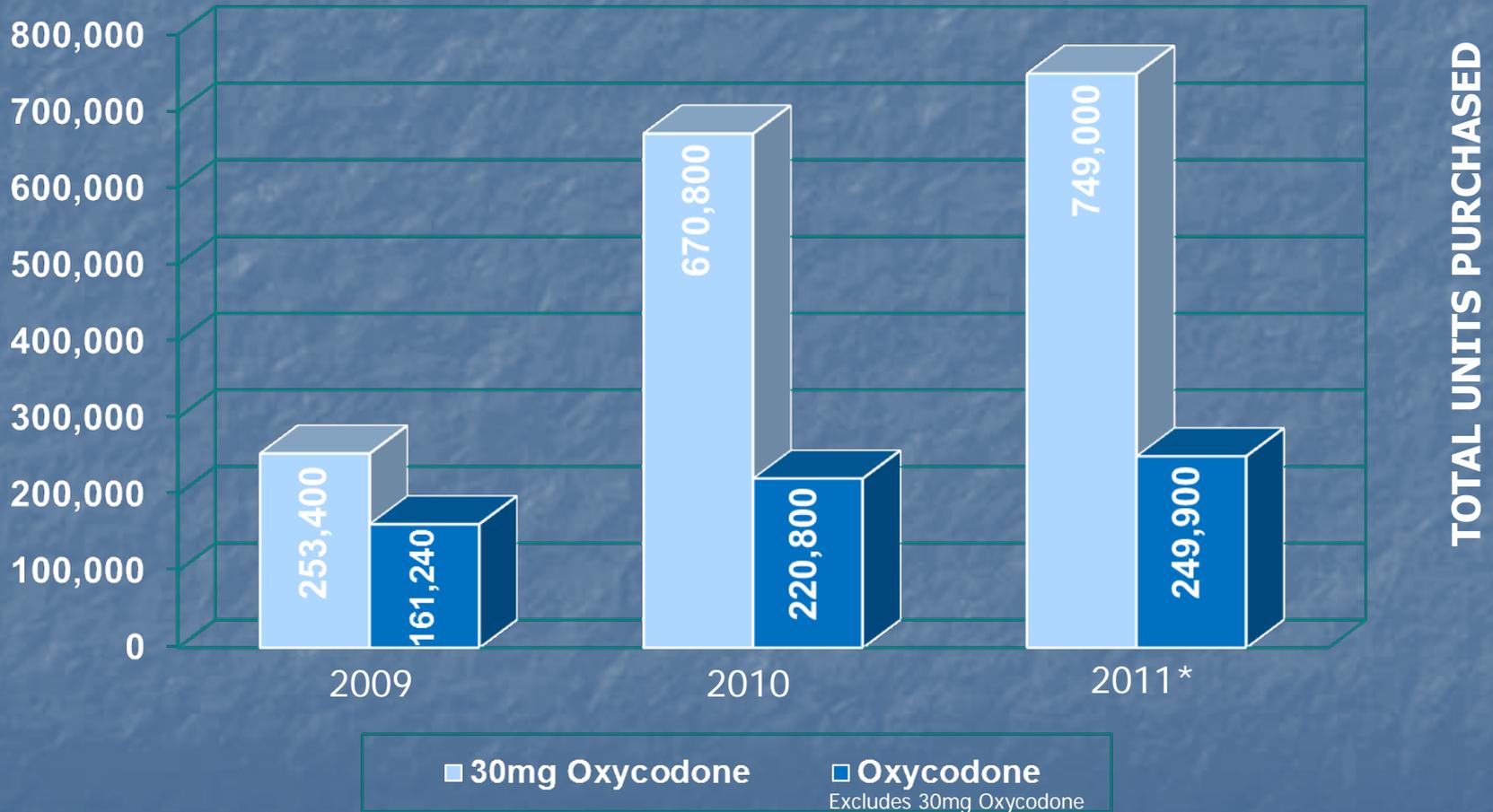
# 2009 – (August 2011)\*

## Comparison of Oxycodone Purchases by a Pharmacy



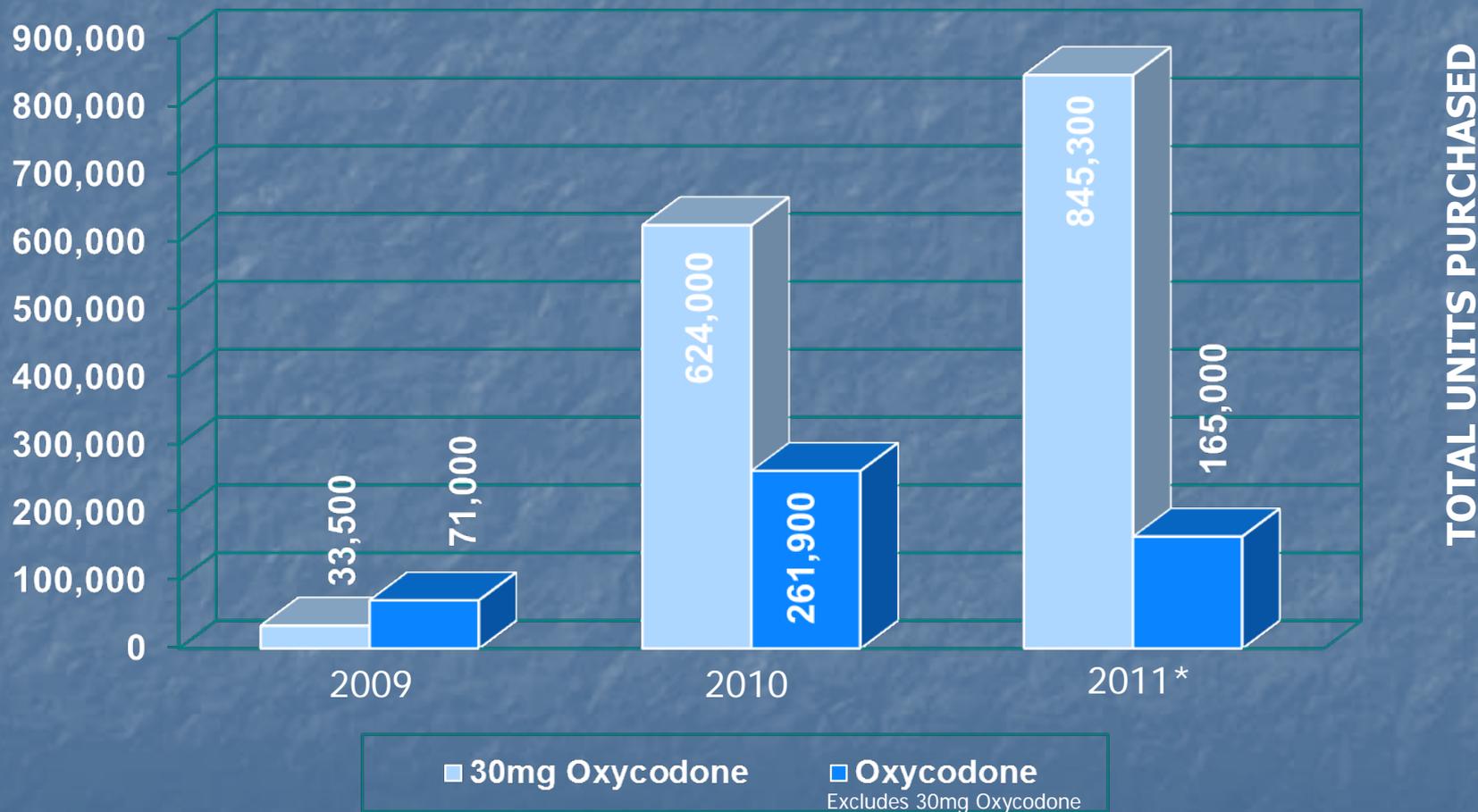
# 2009 – (August 2011)\*

## Comparison of Oxycodone Purchases by a Pharmacy



# 2009 – (August 2011)\*

## Comparison of Oxycodone Purchases by a Pharmacy



# IMS Prescription Data (U.S.)

CY	Total Prescriptions	Controlled Substance Prescriptions	% of Controlled Substance Prescriptions
2009	3.949 Billion	510.3 Million	13.00%
2010	3.993 Billion	521.4 Million	13.06%
2011	4.024 Billion	525.96 Million	13.07%

According to DEA/ARCOS data:

-Average Purchase of All Oxycodone Products for All Pharmacies in U.S.

2009                    63,289 total dosage units.

2010                    70,395 total dosage units.

2011                    74,706 total dosage units.

2012                    73,434 total dosage units

# **Is it a Duck?**

**If it looks like a duck, quacks  
like a duck, (it might be ...)**



**It's Not ...**



# RESPONSIBILITY

- 21 U.S.C. 823 (a), (b), (d), (e)
- **Maintenance of effective controls**  
against diversion of particular controlled substances into other than legitimate medical channels
- Has the registrant failed to maintain effective controls? Yes? No?  
Is the registration in the public interest?

# Failure to Report Suspicious Orders

- 21 U.S.C. § 824 (4):

(The registrant) has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.

# Failure to Report Suspicious Orders

- Immediate Suspension Order
- Order to Show Cause
- Possible Civil Action

# Actions Taken by DEA

Southwood Pharmaceuticals, Inc.

- 72 FR 36,487 (2007)
  - Immediate Suspension Order
  - Revocation of Registration
    - Failure to maintain effective controls against diversion
    - Supplied millions of dosage units of controlled substances to Internet pharmacies
    - Failure to exercise due diligence (21 USC 823)

# Actions Taken by DEA

## United Prescription Services

- 72 FR 50397 (2007)
  - Immediate Suspension Order and revocation of registration.
  - United Prescription Services operated several Internet sites.
  - Between Oct 2005 – Jan 2006, distributed 1,808,693 D.U. More than 1,275,000 were written by one practitioner.
  - Mostly written for hydrocodone and alprazolam.

# Actions Taken by DEA

Ladapo O. Shyngle, M.D.

- 72 FR 6056 (2009)
  - Revocation of Application to renew registration
  - Dr. Shyngle prescribed C/S's via an Internet questionnaire and telephone interviews.
  - Prescribed over 500,000 D.U.'s to patients in 41 states.
  - Issued prescriptions primarily for hydrocodone.

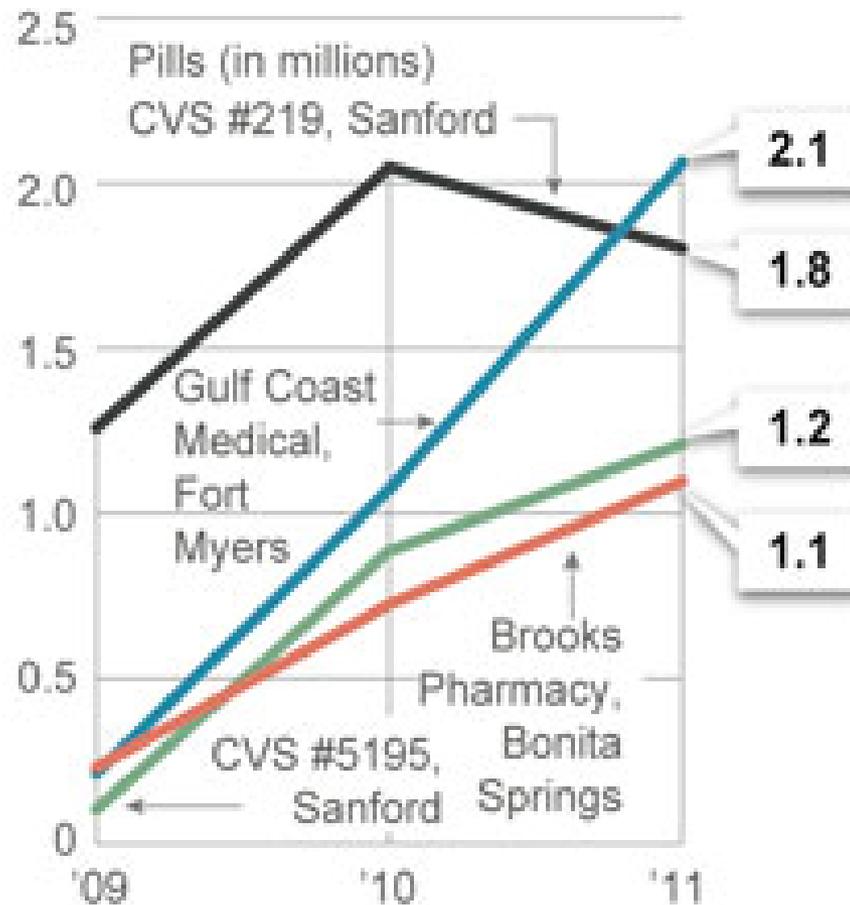
# Actions Taken by DEA

## Bob's Pharmacy & Diabetic Supplies

- 74 FR 19599 (2009)
  - Immediate Suspension Order and Revocation of Registration.
  - Between Apr – Dec 2007, ordered 2.3 million dosage units of hydrocodone products.
  - Prescriptions were approved via an on-line questionnaire.

## Oxycodone purchases

The DEA suspended the licenses of four Florida pharmacies for buying escalating or unusually high numbers of oxycodone pills from Cardinal Health.



Source: Drug Enforcement Administration  
By Julie Snider, USA TODAY

ers' Comp  
IONS FILLED  
ient  
cket Expense

# BROOKS PHARMACY

at Bonita Community Health Center

A Friendly Home Town Pharmacy  
3501 Health Center  
239-992-76

Where We Care About You, Your Health  
Blvd., Bonita Springs  
3 • Fax: 239-992

Your Medicines."  
L 34135  
896



## Federal agents raid Fort Myers pharmacy

### WINK News

A Fort Myers pharmacy was shut down Friday after being raided by federal authorities. Box after box, special agents with the Drug Enforcement Administration Office of Diversion Control hauled evidence out of Gulf Coast Medical Pharmacy. It was just another battle in the war against prescription drug abuse. A DEA spokesperson tells us the independent pharmacy, ... was raided and shut down as part of an ongoing federal investigation. What they're looking for is not yet being released. But with Florida at the epicenter of the pill mill crisis, employees at the medical office building aren't surprised, they're relieved. They tell us they often worry about suspicious people roaming the hallways. Some even say they've seen syringes leftover in the bathroom. One woman looking to fill a prescription of Roxicodone, who wished to remain anonymous, told us "It was always really, really busy when I was here, like lines out the door. You can tell right off the bat, it's not right, if you know what I mean."

HEALTH INDUSTRY | Updated March 13, 2012, 6:19 p.m. ET

# Judge Rules Against CVS in Oxycodone Fight

BY DEVLIN BARRETT

WASHINGTON—A federal judge ruled against CVS Caremark Corp. Tuesday in a dispute with the Drug Enforcement Administration over whether two of the company's CVS stores in Florida had failed to closely monitor sales of the highly addictive painkiller oxycodone.

The DEA acted appropriately in moving to suspend the controlled-substances licenses of the stores, ruled Judge Reggie Walton, though he stayed his ruling until Wednesday morning to give CVS time to appeal.

Judge ...

# Actions Taken by DEA

## CVS Pharmacy #219

- Immediate Suspension Order
  - February 4, 2012
  
- Revocation of Registration
  - October 10, 2012
  - Committed acts inconsistent with the public interest.
  - 21 U.S.C. 824 (a)(4)

# Actions Taken by DEA

CVS Pharmacy #0595

- Immediate Suspension Order
  - February 4, 2012
  
- Revocation of Registration
  - October 10, 2012
  - Committed acts inconsistent with the public interest.
  - 21 U.S.C. 824 (a)(4)

# October 12, 2012 Decision

- “The respondents dispensed controlled substances where the prescribers were without authorization to prescribe, and under circumstances where a reasonable pharmacist would have concluded that the prescriptions were not issued for a legitimate medical purpose and in the usual course of a professional practice. The red flags that existed were recognized, or should have been, and the convincing expert evidence of record establishes that the red flags were not resolvable by a reasonable and professional pharmacist.”

# Actions Taken by DEA

## Cardinal Health Distribution Center

- Immediate Suspension Order
  - February 3, 2012
- Memorandum of Agreement
  - May 14, 2012
  - Suspension of CS Privileges for Two Years.
  - Failure to maintain effective controls against diversion
  - Failure to detect and report suspicious orders
  - 21 U.S.C. 823 (b)(e)

# Letters: Suspicious Orders

- **September 27, 2006**
  - **All Distributors**
- **December 27, 2007**
  - **All Manufacturers**
  - **All Distributors**

# Distributor Initiative

- **“Distributor Initiative”**
  - **Meet with Manufacturers and Distributors**
  - **Given an in-depth briefing of their due diligence/regulatory requirements using their own ARCOS data**
  - **Apprised of DEA’s expectations**

# Continuing Efforts

- **Continuing to monitor manufacturing and distributor activities and identify registrants to brief.**
- **Monitor bulk hydrocodone and oxycodone powder distributions**
- **Monitor practitioners ordering directly from distributors**

# Summary

- All applicants and registrants shall provide **effective controls** and procedures to guard against theft and diversion of controlled substances.

# Summary

## All DEA Registrants Must:

- Take and Keep Inventories
- Make and Keep Records
- Make and Keep Reports
- Maintain physical security and implement certain security procedures.

# Summary

- A prescription not issued for a legitimate medical purpose by an individual practitioner not acting in the usual course of his professional practice is not a prescription under Federal Law

# Summary

- A corresponding responsibility rests with the pharmacist (the pharmacy) who fills the prescription .

# Summary

- **A pattern of drugs being distributed to Doctors and Pharmacies who are diverting controlled substances demonstrates the lack of effective controls against diversion by the Doctors, the Pharmacies, and the registrant supplying those substances.**

# Summary

- **Suspicious Orders must be reported to DEA.**
- **Suspicious Orders must not be shipped.**

# Summary

[www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)

- **Current Revocation Actions**
- **Policy Changes**
- **Validation of Registration**
- **Links to web sites with useful information (AMA, Pain Management, Pharmacy, etc.)**
- **Other**

# Contact Information:

James Arnold, Chief  
Regulatory Unit/ODGR  
Drug Enforcement Administration  
8701 Morrisette Drive  
Springfield, Virginia 22317

202-353-1414 (Office)

202-307-8101 (Fax)

[James.A.Arnold@usdoj.gov](mailto:James.A.Arnold@usdoj.gov)