

Regulatory Section

Leonard Levin
Staff Coordinator

Regulatory Section (ODG)

Barbara Boockholdt
Section Chief
(202) 307- 7669

James Arnold
Unit Chief, Regulatory Unit/ODGR
(202) 353 - 1414

Daniel Gillen
Unit Chief, Import/Export/ODGI
(202) 307 - 7969

ODGR

Responsibilities & Items of Interest or Concern

Regulatory Unit (ODGR)

- **Primary Responsibilities:**
 - **Scheduled Investigations**
 - **Security**
 - **Drug Theft and Loss**
 - **303 Investigations**
 - **Employment Waivers**
 - **DATA-Waived Physicians**

Regulatory Unit (ODGR)

- **Additional Responsibilities:**
 - **Controlled Substance Ordering System (CSOS)**
 - **Distributor Initiative**
 - **Quota Reviews (ODE)**

Scheduled Investigations

- 21 USC § 823
 - Maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;
 - Compliance with applicable State and local laws;
 - Prior conviction record of applicant under Federal or State laws relating to manufacture, distribution, or dispensing of such substances;
 - Past experience in the [manufacture/distribution] of controlled substances; and
 - Such other factors as may be relevant to and consistent with the public health and safety.

Scheduled Investigations

- Due Diligence policies & procedures:
 - Trends, changes, and justification of controlled substance sales
 - Fulfilling the legitimate medical necessity
- ARCOS reporting
 - Timely & Accurate
- Record keeping requirements
 - Customer registrations are accurate
 - Schedules and drug codes are accurate

Suspicious Orders

- SC Kyle Wright (202) 307-5492
- 21 CFR § 1304.74(b):
 - The registrant shall design and operate a system to disclose 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, and orders of unusual frequency.

Suspicious Orders

- A Suspicious Order CANNOT be filled.
- DEA will no longer accept Excessive Purchase Reports.
 - Excessive Purchases allowed controlled substances into the closed system of distribution to be potentially diverted.
 - Suspicious Orders should not be identified on benchmarks only.
 - Know your customers and their needs.

Suspicious Orders

- The responsibility for making the decision to ship rests with the supplier.
- Controlled substances distributors must define their own parameters for a suspicious order.
- Suspicious order monitoring programs must evolve with the demands of fighting the constantly changing illicit drug market.
- Registrants who routinely report suspicious orders yet fill these orders, with reason to believe they are destined for the illicit market, are failing to maintain effective controls against diversion.

Security

- SC Leonard Levin (202) 307-7894
- Security has two aspects:
 - Physical Security - 21 CFR 1301.71
 - To provide guidance to both the field offices and industry relative to security requirements.
 - Industry will work through their respective field offices.
 - Prevention of diversion, theft, and pilferage is the ultimate goal.

Security

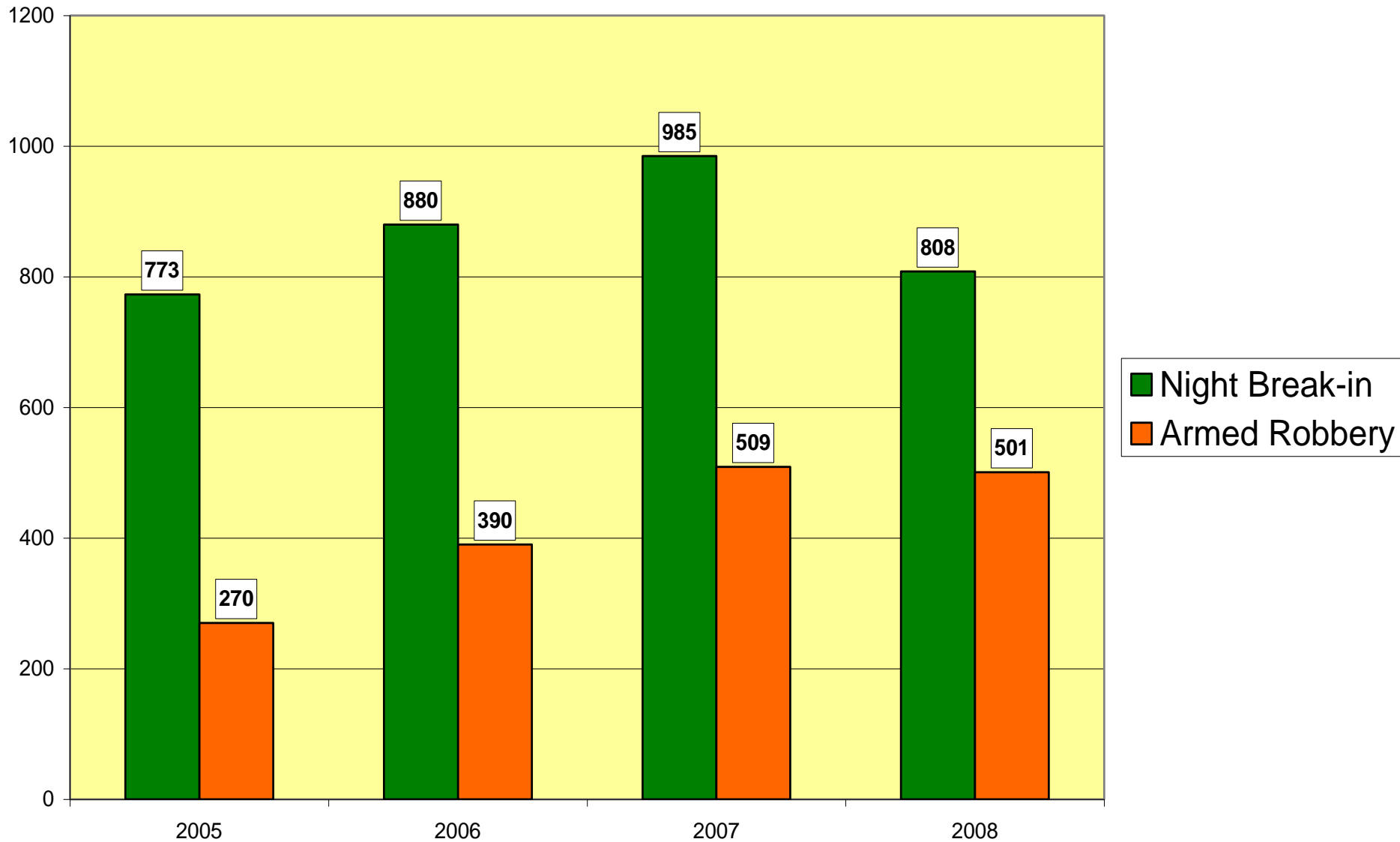
- Personnel Security - 21 CFR 1301.90 - 93
 - Employee screenings
 - A serious, realistic, and thorough screening process helps prevent potential to diversion
 - Employee training and reporting
 - Employees who are security conscious and knowledgeable are a vital defense against diversion
 - Illicit activities by employees
 - Overlapping of physical and personnel security programs should be able to identify most illicit activities

Drug Theft and Losses

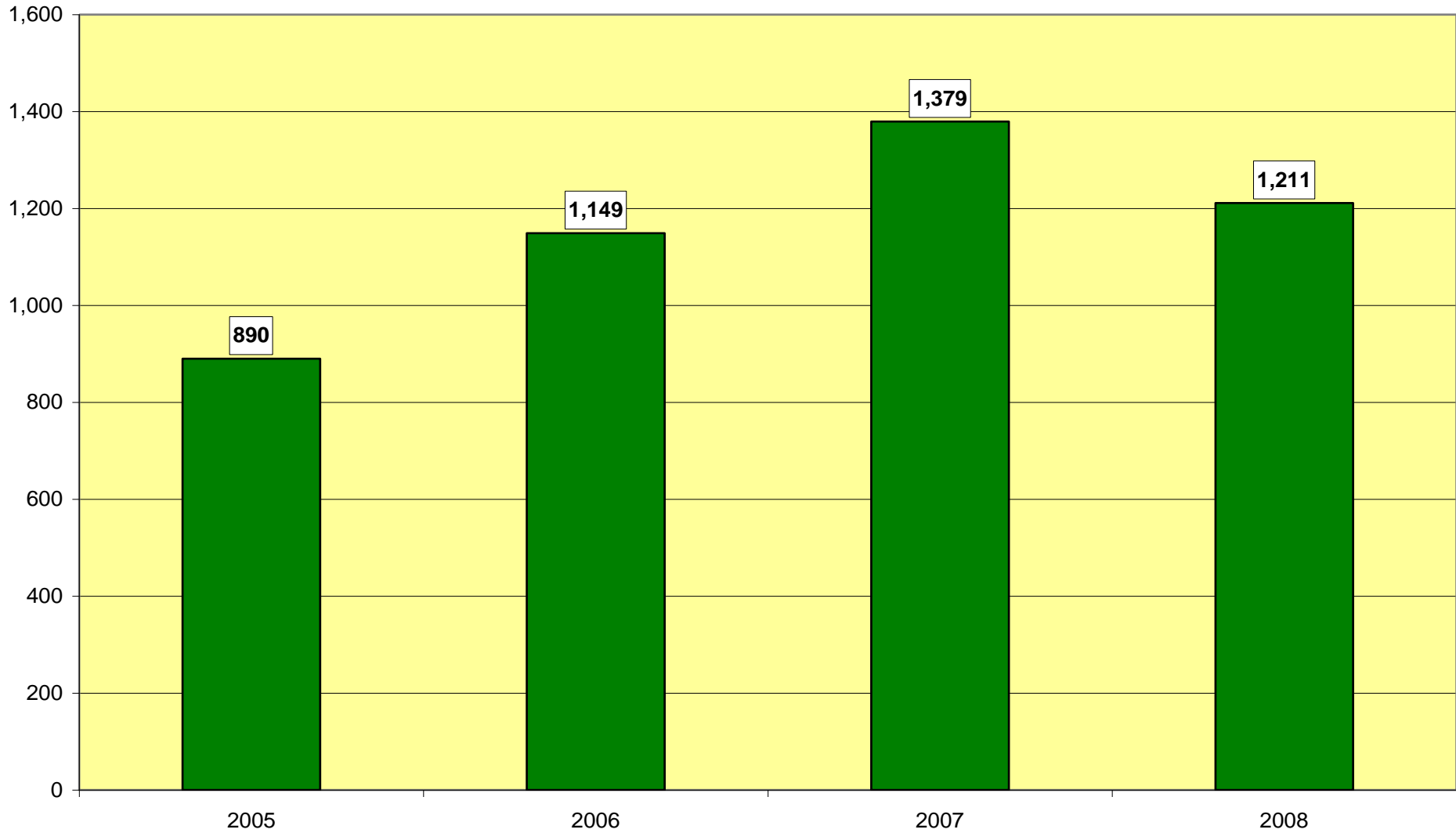
- SC Benjamin Vinson (202) 307-7065
- 21 CFR 1301.76 – Controlled Substances
- 21 CFR 1309.73 – Listed Chemicals

- Objectives & Goals:
 - Deterrence
 - Minimization of product and financial losses
 - Increase the probability of apprehending the suspect
 - Report DEA-106 electronically (if possible) on DEA website once a loss is determined

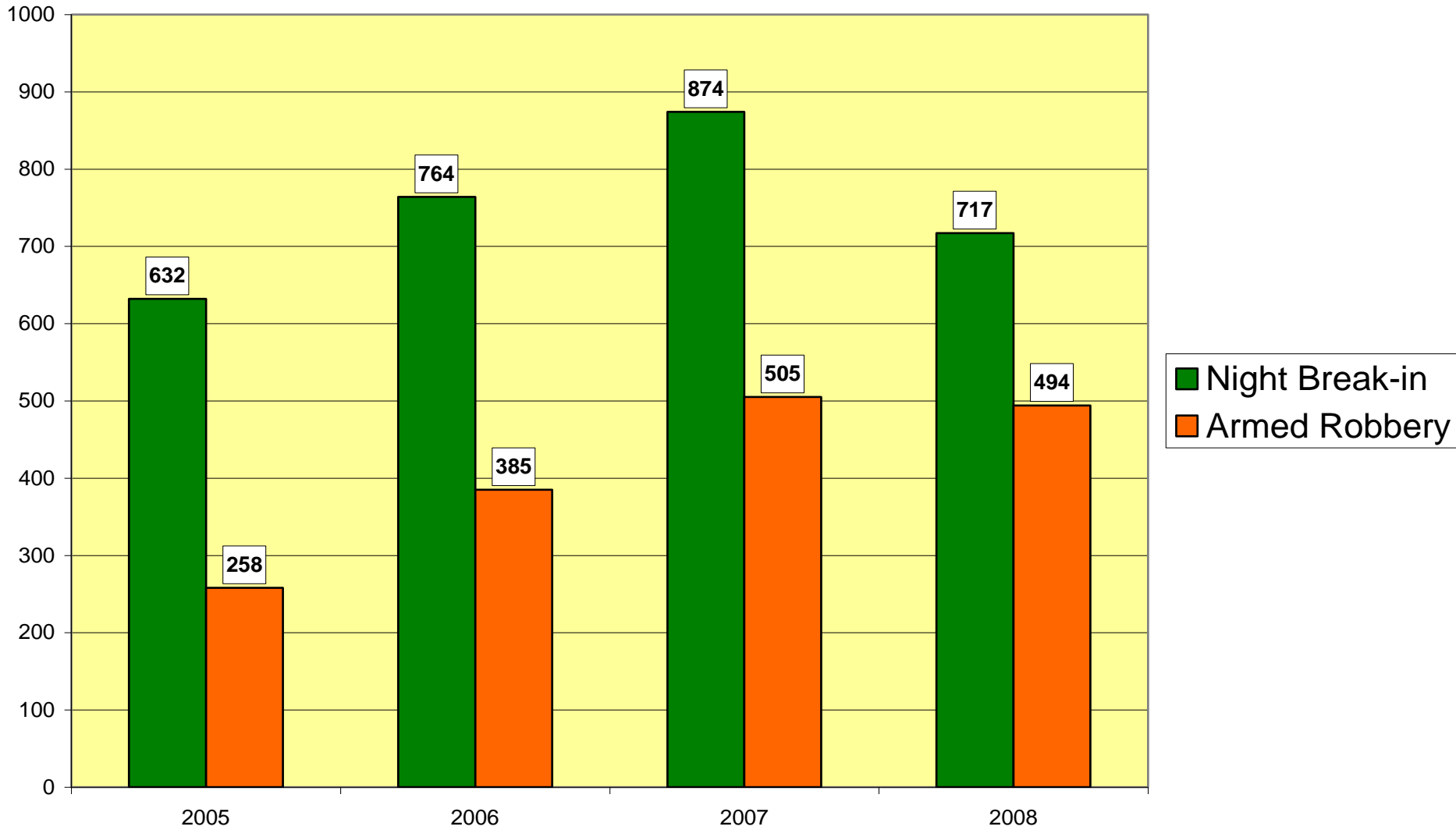
All Business Activities



Pharmacies (All DTL)



Pharmacies DTL Reporting



303 Investigations

- SC John Cavendish (202) 353-7093
- On October 27, 1970, Section 303 was passed into law by Congress.
- 303 was the number used by Congress to track the legislation.
- Once passed by Congress, Section 303 was placed into 21 USC § 823.

303 Investigations

- 21 USC 823(a)

Legislates the Registration of CI & CII Bulk Manufacturers and Includes the Six “Public Interest” Factors Which Must Be Examined and Considered Prior to Granting the Registration.

- 21 USC 958

Legislates the Registration and/or Denial of CI & CII Importers.

303 Investigations

- 21 USC 824

Legislates the conditions under which a registration to manufacture, distribute, or dispense a controlled substance may be denied, suspended, or revoked.

303 Investigations

- 21 CFR § 1301.33 (Manufacturers)
- 21 CFR § 1301.34 (Importers)
- Establishes the regulations which govern the approval and renewal processes for CI & CII bulk manufacturer and importer applications.

303 Investigations

The Section 303 Process is initiated upon receipt by DEA Headquarters of a:

- New Application for Registration
- Renewal Application
- Request to Modify a Registration

(A request to add a new drug code is a new “application”)

303 Investigations

- The review process is required to insure compliance with the requirements of 21 CFR § 1301.33 and § 1301.34.
- These Applications Must, By Law, Be Published in the Federal Register.
- DEA Headquarters approves these applications.

EMPLOYMENT WAIVERS

- SC Michael Arpaio (202) 307-4824
- 21 CFR 1301.76(a)
- “The registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause.”

EMPLOYMENT WAIVERS

- The Regulation Applies To Those “Employees” Who:
 - Have been Convicted of a Felony Offense Relating to Controlled Substances
 - Have had an Application for Registration Denied
 - Have had a DEA Registration Revoked or Surrendered for Cause

EMPLOYMENT WAIVERS

- All Requests for Waivers Should be Addressed to DEA HQS as follows:

Administrator

Drug Enforcement Administration

8701 Morrissette Drive

Springfield, Virginia 22152

Attention: Office of Diversion Control

EMPLOYMENT WAIVERS

- All requests for a waiver **must** come from the Registrant. It cannot be generated by the Employee or Potential Employee of the Registrant.
 - “Appellate Courts will affirm any findings of fact made by the Deputy Administrator if such facts are supported by substantial evidence.”
 - “DEA must examine each case on its merits and make a reasoned determination concerning whether a waiver should be granted.”

DATA Waived Practitioners

- SC Benjamin Vinson (202) 307-7065
- 21 CFR 1301.28
 - Drug Abuse Treatment Act (DATA)
 - Established a system for DEA registered physicians to treat patients for opioid addiction in their office
 - Approved controlled substances can either be administered in the office or prescribed to the patient

DATA Waived Practitioners

- A DEA approved DATA Waived Practitioner has a unique identifier assigned:
 - Dr. Vinson DEA registration is AV1234567
DATA Waived number is **X**V1234567
 - Only Subutex and Suboxone 2 mg and 8 mg are the only controlled substances approved for treatment under the DATA

DATA Waived Practitioners

- Suboxone and Subutex may be prescribed, dispensed, or administered for other than opioid addiction, in which case the unique identifier is not required.
- In all cases where the physician is ordering or prescribing for opioid addiction treatment, the unique identifier **MUST** be utilized.

Controlled Substance Ordering System (CSOS)

- SC Kyle Wright (202) 307-5492
- 21 CFR 1305.21-29; 1311.01-60
- Current Issues & Misconceptions:
 - From start to finish CSOS is electronic.
NO PAPER.
 - CSOS reporting does not relieve the registrant's obligation to report to ARCOS if they are so required.

Controlled Substance Ordering System (CSOS)

- 1305.21 Requirements for electronic orders. (a) To be valid, the purchaser must sign an electronic order for a Schedule I or II controlled substance with a digital signature issued to the purchaser, or the purchaser's agent, by DEA as provided in part 1311 of this chapter.
- 1305.22 Procedure for filling electronic orders. (g) When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived.
- 1305.25 Unaccepted and defective electronic orders. (c) When a purchaser receives an unaccepted electronic order from the supplier, the purchaser must electronically link the statement of nonacceptance to the original order. The original order and the statement must be retained in accordance with §1305.27.

Controlled Substance Ordering System (CSOS)

- 1305.27 Preservation of electronic orders. (a) A purchaser must, for each order filled, retain the original signed order and all linked records for that order for two years. The purchaser must also retain all copies of each unaccepted or defective order and each linked statement.
- 1311.55 Requirements for systems used to process digitally signed orders. (b) A system used to digitally sign Schedule I or II orders must meet the following requirements: (9) The system must archive the digitally signed orders and any other records required in part 1305 of this chapter, including any linked data.
- 1311.60 Recordkeeping. (a) A supplier and purchaser must maintain records of CSOS electronic orders and any linked records for two years. Records may be maintained electronically. Records regarding controlled substances that are maintained electronically must be readily retrievable from all other records.

Controlled Substance Ordering System (CSOS)

- 1305.29: A supplier must, for each electronic order filled, forward either a copy of the electronic order or an electronic report of the order in a format that DEA specifies to DEA within two business days.
- This does not relieve the registrant from also reporting to ARCOS. These are separate reports and reporting requirements.

Controlled Substance Ordering System (CSOS)

- 1311.60(b) Electronic records must be easily readable or easily rendered into a format that a person can read. They must be made available to the Administration upon request.
 - Records means any report requested by DEA (e.g., a listing of all rejected orders)
 - Reports of all processed CSOS orders
 - Individual orders filled

Controlled Substance Ordering System (CSOS)

- What is meant by a “LINKED” record?
- Any activity or action that is part of the original order, must be “LINKED” to the original order.
- The original order has “STAPLED” to it:
 - Acceptance of the order,
 - The order will be partially filled,
 - The order is endorsed with date and count of quantities received.

DISTRIBUTOR BRIEFING

- Distributors and Manufacturers are given an in-depth briefing of their due diligence and regulatory requirements using their own ARCOS data.
- Meeting is One on One.
- Registrant is apprised of DEA's expectations.
- Field offices are encouraged to attend.

Importers/Exporters 362

Manufacturers 441

Distributors 785

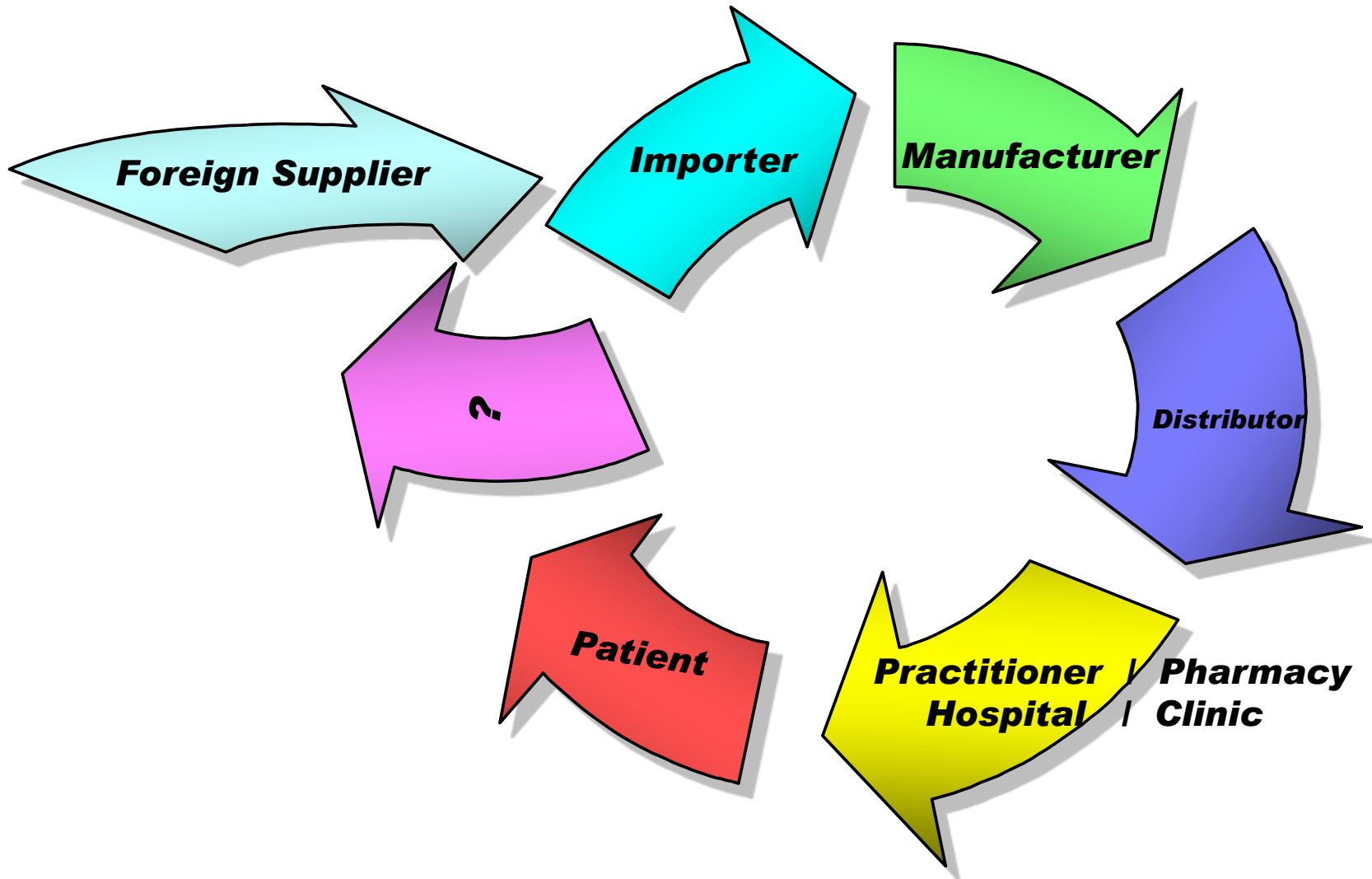
65,049 Pharmacies / 1,026,047 Practitioners / 15,822 Hospitals

Research/Analytical Use 6,818

Narcotic Treatment Programs 1,219

Prescriptions 306,847,094 as of 10/7/2009

The Controlled Substances Act's Closed System of Distribution



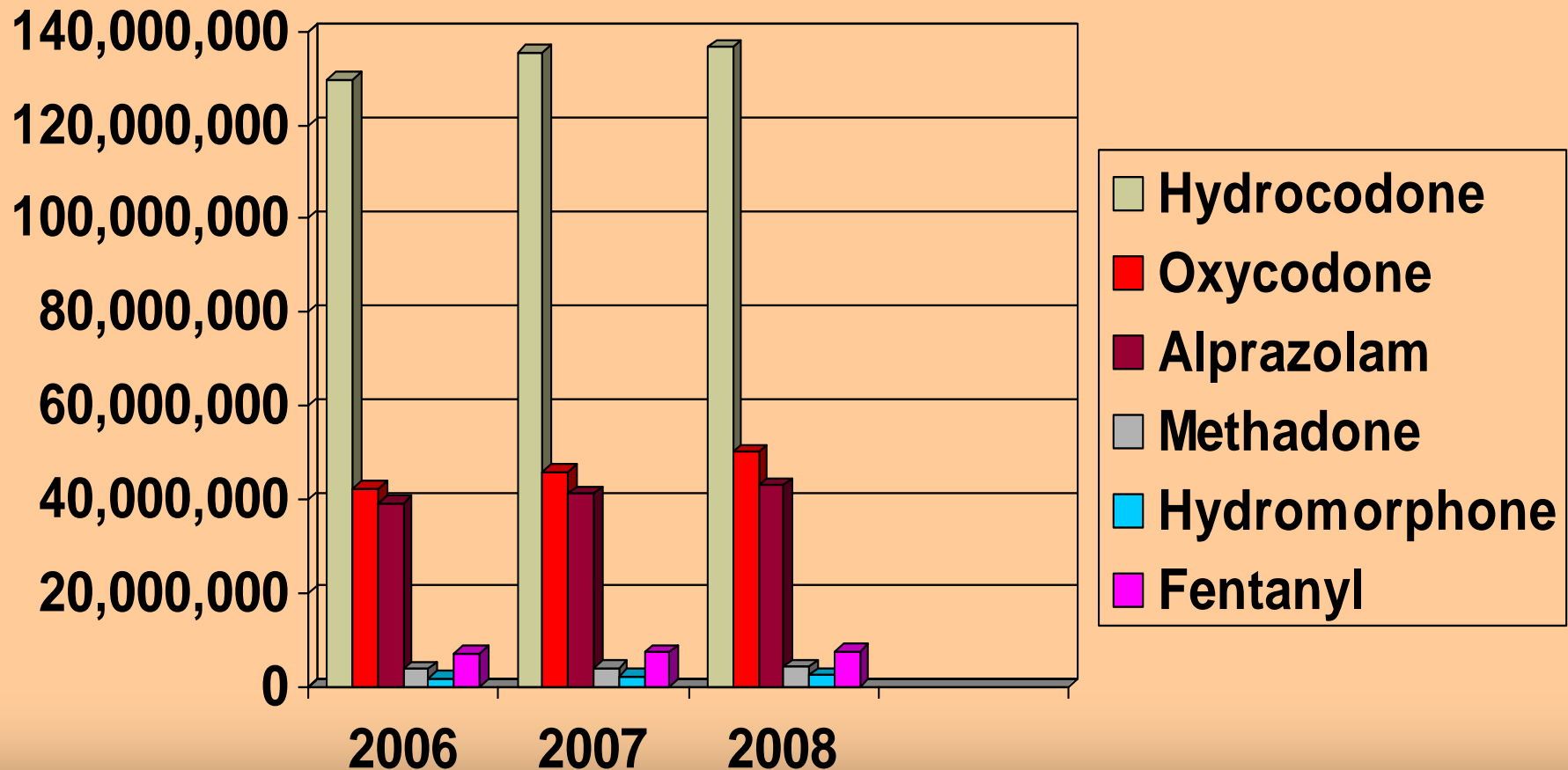
CLOSED SYSTEM OF DISTRIBUTION

- The Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended in 1990 and 1994 created a system for the legitimate manufacturing, distribution, and prescribing/dispensing of controlled substances.
- Each registrant within this “closed system of distribution” has defined privileges and responsibilities in which they must operate.

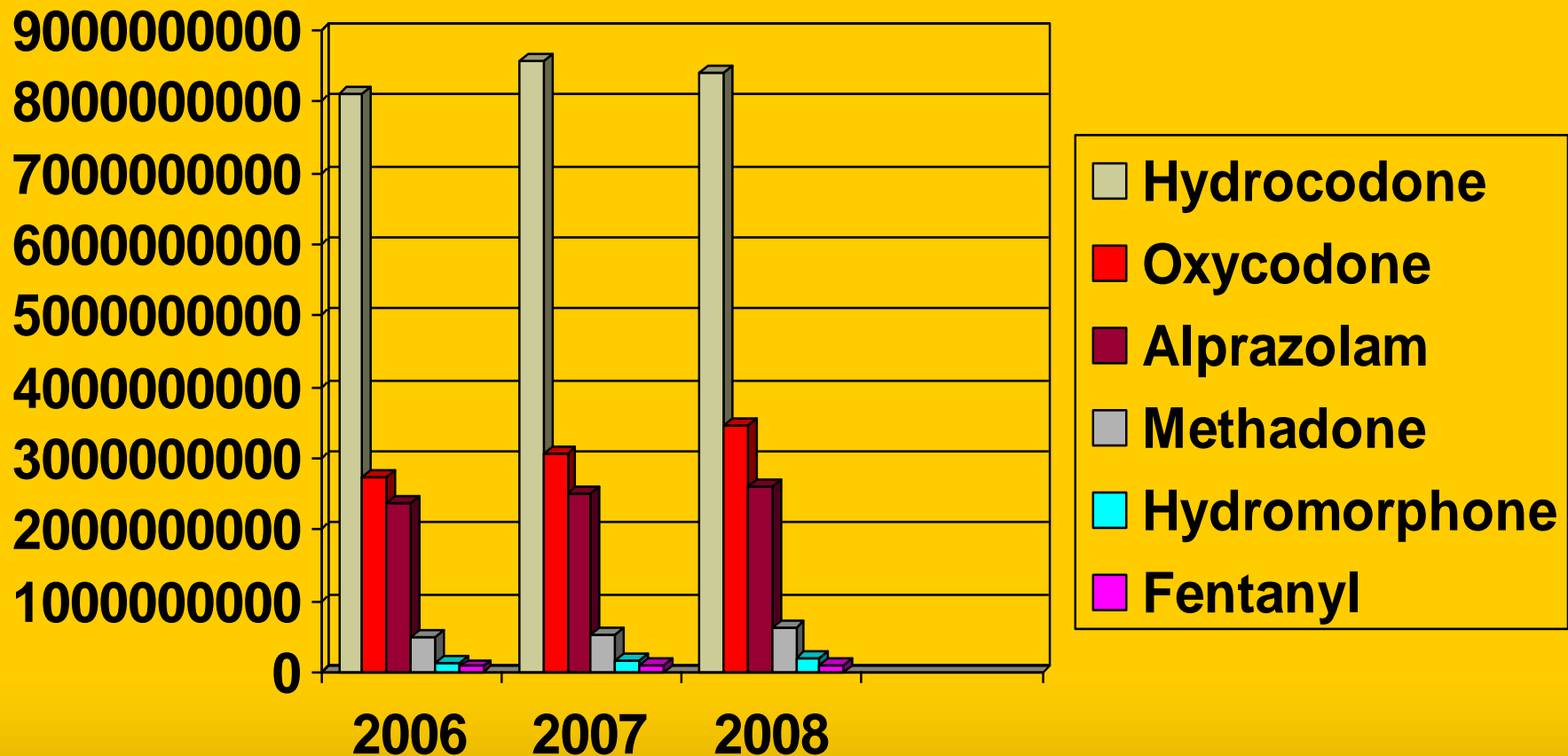
CLOSED SYSTEM OF DISTRIBUTION

- When registrants fail to comply with their responsibilities, those violations represent a danger to the public and jeopardize the “closed system of distribution.”
- DEA is responsible for the oversight and integrity of the system and to protect the public.

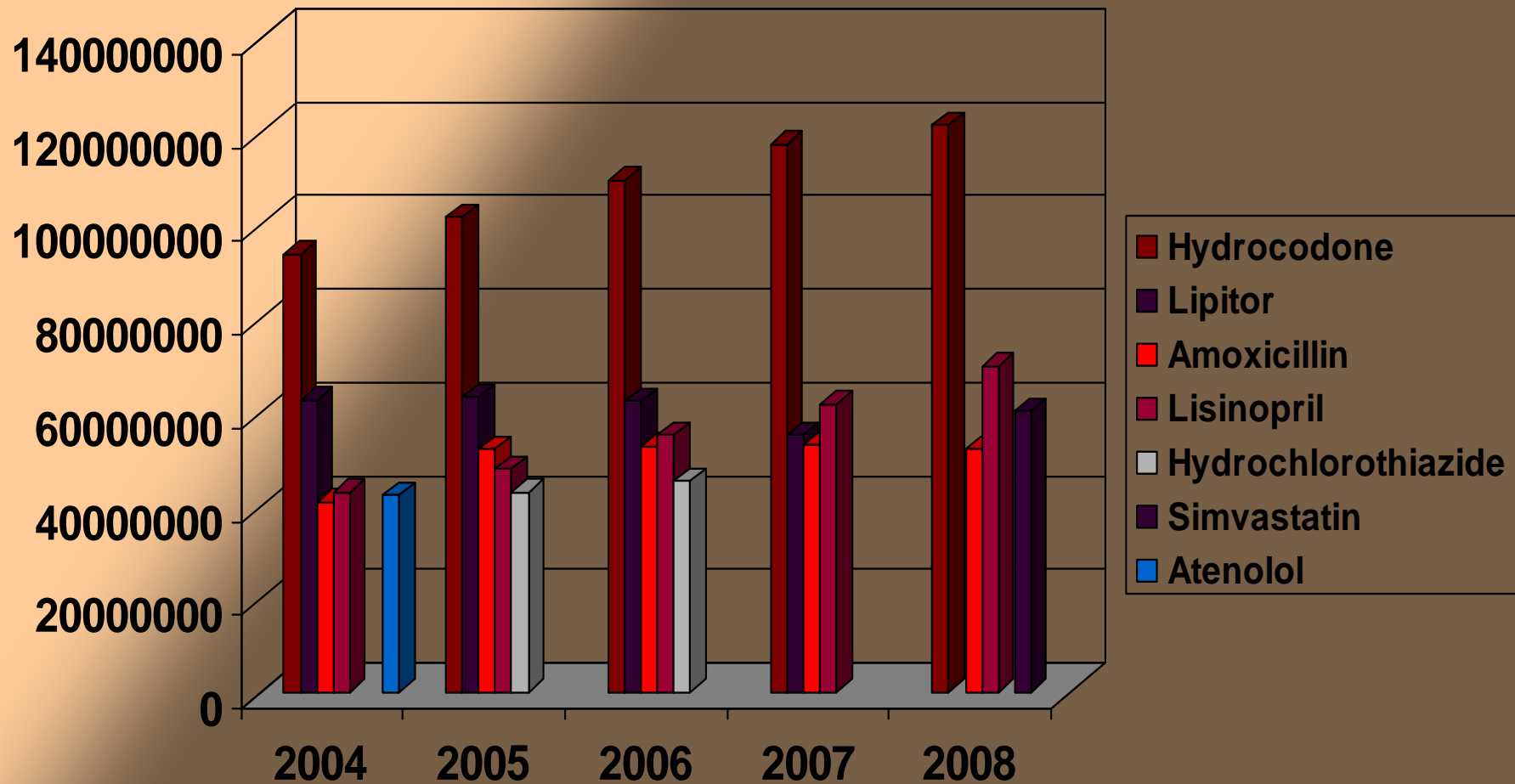
Total Prescriptions Dispensed



Quantity of Controlled Substances in the Supply Chain



Top Five Prescription Drugs Sold in the U.S. (2004-2008)



QUOTA REVIEWS

- SC Jean Willis (202) 307-7964
- ODGR, in conjunction with ODE, reviews the justification for increase in quotas.
- ODGR reviews the customers of the requestor.
- ODGR also compares the registrant's request against ordering history and trends.

QUOTA REVIEWS

- Should DEA determine a lack of justification for an increase or if there are issues with the registrant's customers, the quota request will be reduced accordingly.
- Registrant will be provided an opportunity to justify the quota request by utilizing sound due diligence procedures.

Conclusion

- Diversion Web Site:
 - <http://www.DEAdiversion.usdoj.gov>
- E-Mail:
 - ODG@usdoj.gov



U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

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DIVERSION PROGRAMS

APPLICATIONS & ON-LINE FORMS

ARCOS

CHEMICALS

CONTROLLED SUBSTANCE

SCHEDULES

CSOS

IMPORT AND EXPORT

NFLIS

QUOTAS

REGISTRATION SUPPORT

REPORTS REQUIRED BY 21 CFR

RESOURCES

CAREER OPPORTUNITIES

DEA MAILING ADDRESSES

DRUGS/CHEMICALS OF CONCERN

e-COMMERCE INITIATIVES

FEDERAL REGISTER NOTICES

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OFFICES & DIRECTORIES

PROGRAM DESCRIPTION

PUBLICATIONS

QUESTIONS & ANSWERS

REGULATIONS & CODIFIED CSA

SIGNIFICANT GUIDANCE

DOCUMENTS

LINKS

WELCOME TO THE DIVERSION CONTROL PROGRAM

Registration Number
Toll Free: 1-800-882-9539

REGISTRATION SUPPORT



Save time by applying for and/or renewing your DEA Registration on-line. Data will be entered through a **secure connection** to the **ODWIF** on-line web application system. Minimum requirements: Credit Card and a web browser that supports **128-bit encryption**.

NEW REGISTRATION FEE EFFECTIVE NOVEMBER 1, 2006

[New DEA Number Assignment for Type A \(Practitioner\) Registrants](#)

RENEWAL
Apply
On-Line
**REGISTRATION
APPLICATIONS**

Renewal
Applications

NEW
APPLICATIONS
FOR
REGISTRATION

New Registration
Applications

**DEA
FORM 106
ONLINE**
REPORT
THEFT OR
LOSS OF
CONTROLLED
SUBSTANCES

Comments / Questions?

