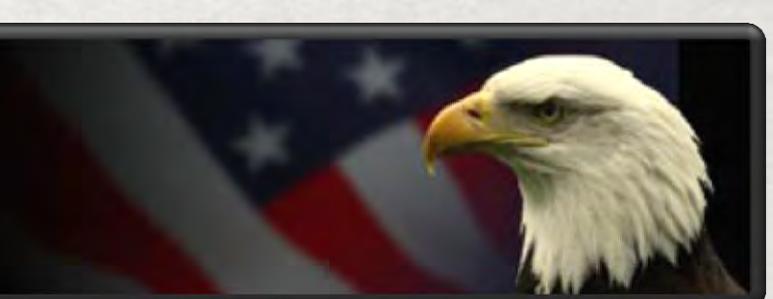




The United States Department of Justice

**Drug Enforcement Administration**



## *The Diversion Control Program*

Chemical Industry Conference

May 5, 2016

Drug Enforcement Administration

Sheraton Mesa Hotel

Mesa, Arizona

May 5, 2016

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Office of Diversion Control



# Goals

- Outline the extent of the crisis
- Describe the Office of Diversion Control's Closed System of Distribution
- Show how Chemical registrants are part of this Closed System of Distribution
- Address some common questions



# National Epidemic

In 2013, approximately 46,471 unintentional drug overdose deaths occurred in the United States. This is 127 a day. It has increased for 14<sup>th</sup> consecutive years.



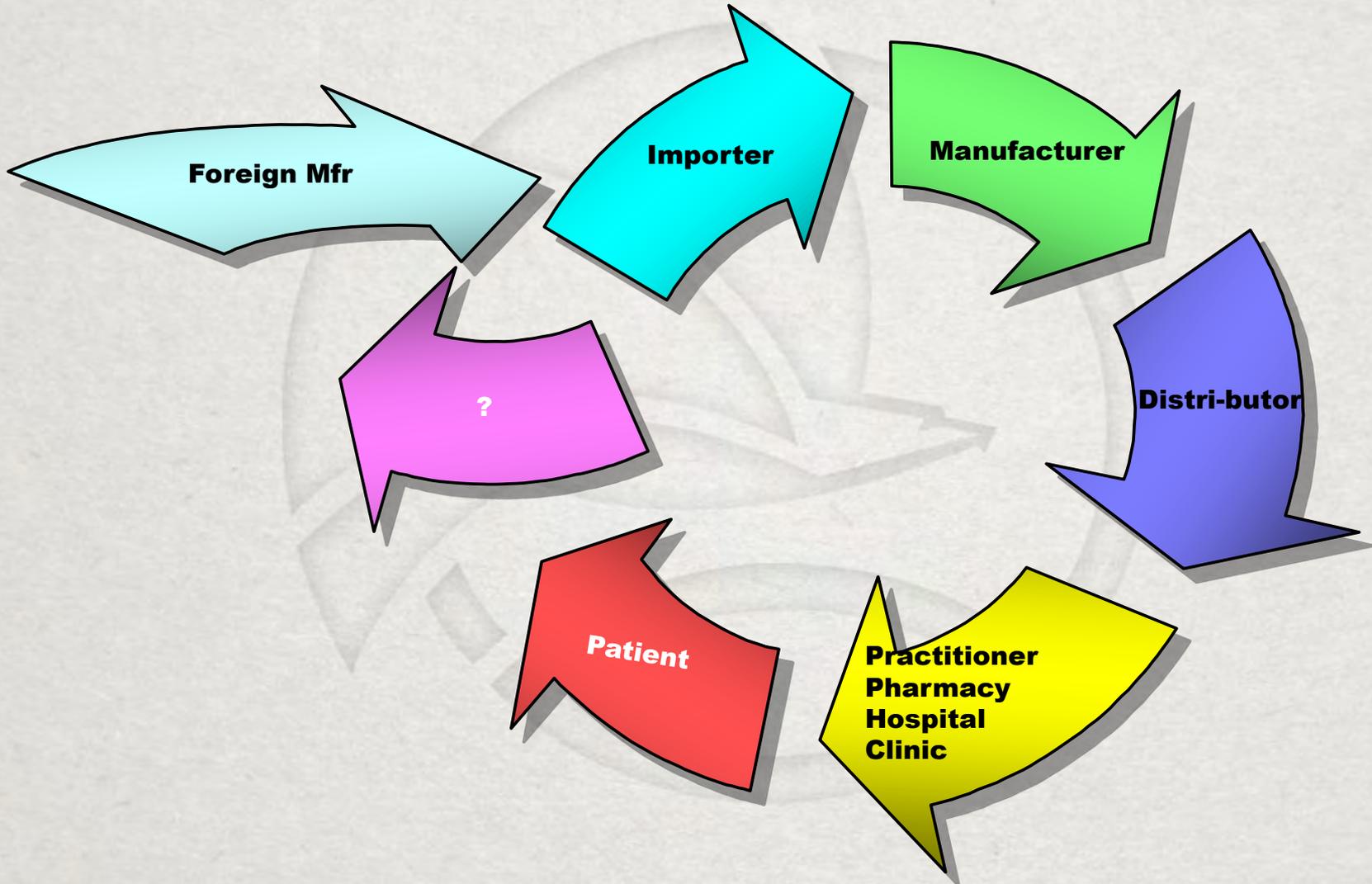
## Controlled Substances Act

The Comprehensive Drug Abuse Prevention and Control Act (1970) is more commonly known as the *Controlled Substances Act of 1970* (CSA).

- Established a single *control system* - narcotic and psychotropic drugs
- Created *five controlled substance schedules* based on drug properties
- Established a “*closed system*” to track and account for controlled substances (import/manufacture - distribution to end-user).
- ***Office of Diversion Control*** monitors all aspects of the legitimate import, export, manufacture, distribution, and dispensing of controlled substances and eventually listed chemicals.



# Closed System of Distribution





## **WHO SHOULD REGISTER?**

**As stated in 21 USC –**

**822(a)(1): “Every person who manufactures or distributes any controlled substance or List 1 chemical .... shall obtain annually a registration ....”**

**“822(b): “Persons registered . . . to manufacture, distribute, or dispense controlled substances or List 1 chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals . . . to the extent authorized by their registration . . . .”**



# Chemical Laws Enforced By DEA





# Code of Federal Regulations

**REGISTRATION** – Persons required to register

## **21 C.F.R. Section 1309.21(a)**

- (1) Every person who manufactures or imports or proposes to manufacture or import a List I chemical or a drug product containing ephedrine, pseudoephedrine, or phenylpropanolamine.
- (2) Every person who distributes or exports or proposes to distribute or export any List I chemical, other than those List I chemicals contained in a product exempted under paragraph (1)(iv) of the definition of regulated transaction in Section 1300.02 of this chapter.



# CHEMICAL REGISTRATIONS

- A. IMPORTER** A chemical importer is a regulated person who, as the principal party in interest in the import transaction, has the power and responsibility for determining and controlling the bringing in or introduction of the listed chemical into the U.S.
- B. EXPORTER** A chemical exporter is a regulated person who, as the principal party in interest in the export transaction, has the power and responsibility for determining and controlling the sending of the listed chemical out the U.S.
- C. DISTRIBUTOR** A chemical distributor is a person who delivers a listed chemical. (“Deliver” includes the actual, attempted or constructive transfer of a listed chemical, whether or not there exists an agency.)
- D. MANUFACTURER** (for Distribution). The term manufacturer means a person who produces, prepares, or compounds a List 1 chemical for delivery to another person.



# **REGISTRATION APPLICATIONS**

## **List 1 Chemicals**

### **Applications:**

- A new Chemical Handler applicant must use the DEA Form 510
- A Chemical Handler that is renewing their DEA registration uses the DEA Form 510A
- Both the DEA 510 and 510A can be completed on line at [WWW.DEAdiversion.usdoj.gov](http://WWW.DEAdiversion.usdoj.gov)



## The Registrants

**Registrant** is a term used to describe an individual or business entity that holds a DEA registration number authorizing the handling of controlled substances and/or List 1 chemical products.

Combined, they are referred to as the ***regulated community***.

Total Controlled Substance Registrants # 1,626,569

Total Chemical Registrants # 984

Manufacturers # 221

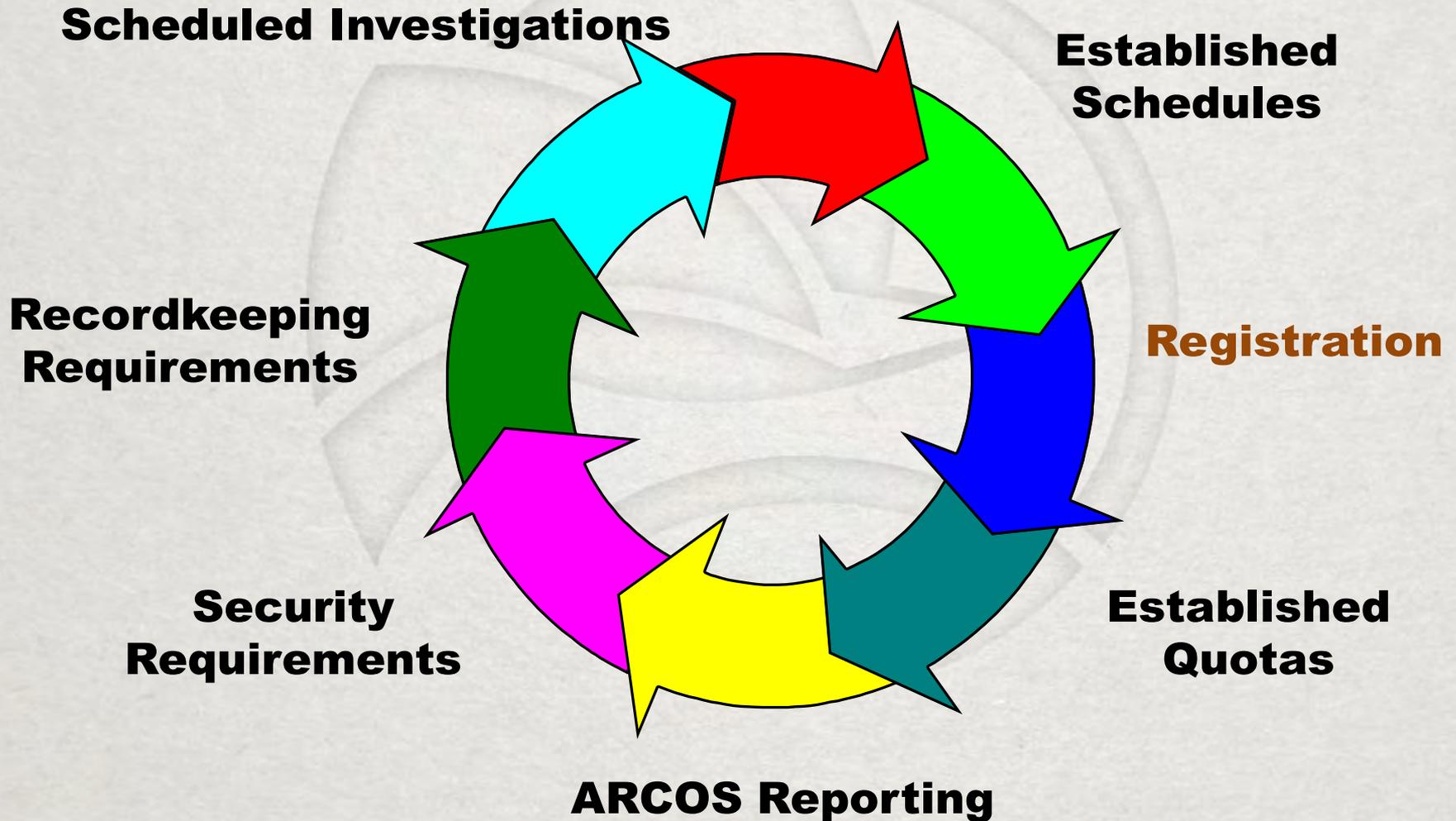
Importers # 201

Distributors # 405

Exporters # 157



# Monitoring the Closed System of Distribution





## Registration Fee Schedule

DEA is authorized by 21 U.S.C. 821 to collect “reasonable fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances and to the registration and control of regulated persons and of regulated transactions.”

| <b><u>REGISTRANT<br/>TYPE</u></b> | <b><u>REGISTRATION<br/>PERIOD</u></b> | <b><u>FEE AS OF<br/>April 16, 2012</u></b> |
|-----------------------------------|---------------------------------------|--|
| Retail Registrants                | 3 Years                               | \$ 731                                     |
| Manufacturer CS/Chemical          | 1 Year                                | \$ 3,047                                   |
| Distributor CS/Chemical           | 1 Year                                | \$ 1,523                                   |
| Reverse Distributor               | 1 Year                                | \$ 1,523                                   |
| Researcher                        | 1 Year                                | \$ 244                                     |
| Analytical Lab                    | 1 Year                                | \$ 244                                     |
| Importer CS/Chemical              | 1 Year                                | \$ 1,523                                   |
| Exporter CS/Chemical              | 1 Year                                | \$ 1,523                                   |
| NTP                               | 1 Year                                | \$ 244                                     |



## Exemption from Chemical Registration

**CFR 1309.24(a) through (k)** – Waiver of registration requirement for certain activities:

- **(b)** – The requirement of registration is waived for any person who manufactures or distributes a scheduled listed chemical product or other product containing a List I chemical that is described and included in paragraph (1)(iv) of the definition of regulated transaction in §1300.02 of this chapter, if that person is registered with the Administration to engage in the same activity with a controlled substance.
- **(c)** - The requirement of registration is waived for any person who imports or exports a scheduled listed chemical product or other product containing a List I chemical that is described and included in paragraph (1)(iv) of the definition of regulated transaction in §1300.02 of this chapter, if that person is registered with the Administration to engage in the same activity with a controlled substance.



# Scheduled Listed Chemical Products

21 United States Code 823(h) no registration required to sell at retail but self certification is required.



# Common Questions

- When can I renew?
- What does my DEA registration number mean?
- How can I modify my DEA registration?
- Ownership of the registration?



## CSA2 Renewal, Delinquent, and Purge Dates

- Renewal is mailed 60 days prior to expiration of current registration. 120 days for bulk manufacturers.
- Renewal applications automatically sent to registrants who have not renewed their registration at least **45 days** prior to expiration.
- If renewal application not submitted by expiration, registration status changed from **Active** to **Expired**.
- Delinquency notices sent to registrants **10 days** after expiration.
- If renewal application not received within **30 days** of expiration, the expired DEA number will be purged from the CSA2 database.
- Purged records = **unrecoverable**.



## Specifics of DEA Registration Numbers (Chemical Registrations)

- DEA chemical registration numbers have nine characters.
- First six characters = numbers
- Seventh character = first letter in registrant's name
- Eighth character = random letter
- Ninth character = letter that identifies business activity of registrant.

W.....Manufacturer (for distribution)

Y.....Distributor

X.....Importer

Z.....Exporter



## **Modification in Registration**

(21 C.F.R. Section 1309.61)

Any registrant may apply to modify his or her registration to authorize the handling of additional List I chemicals or to change his or her name or address, by submitting a letter of request to the Registration Section, Drug Enforcement Administration.

**Letter must include:** the registrant's name, address, and registration number as printed on the certificate of registration, and the List I chemicals to be added to his registration or the new name or address.

**Letter shall be signed in accordance with Section 1309.32(g).**

Mailing addresses can be found in Section 1321.01.



## **Termination of registration** (21 C.F.R. Section 1309.62)

A registration and any modifications of such shall ***terminate*** without any action by the Administration, if and when a registrant:

- Dies
- Ceases legal existence
- Discontinues business or professional practice
- Surrenders a registration – via signed written document or executed DEA Form 104 or for Chemical Registrants the DEA Form 104c



## **Transfer of registration**

(21 C.F.R. Section 1309.63)

No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the Administrator may specifically designate and then only pursuant to his written consent.



# Misconceptions

- (1) Because I have a DEA registration to handle controlled substances I do not need to hold a DEA registration to handle chemicals.
- (1) Because I hold a DEA registration to handle List 1 chemicals my customers must also hold a DEA registration to purchase List 1 chemicals.



## **Assistance with Registration Matters**

A Registration Program Specialist (RPS) is assigned to almost every Division. The RPS serves as liaisons between field personnel and Headquarters.

DEA Headquarters  
Office of Diversion Control  
Registration and Program Support Section (ODR)

Registration Call Center  
1-800-882-9539