Drug Enforcement Administration

BREAKOUT SESSION

Regulatory Matters

Cathy A. Gallagher
Section Chief, Regulatory Section
Michele Herron
Unit Chief, Regulatory Unit

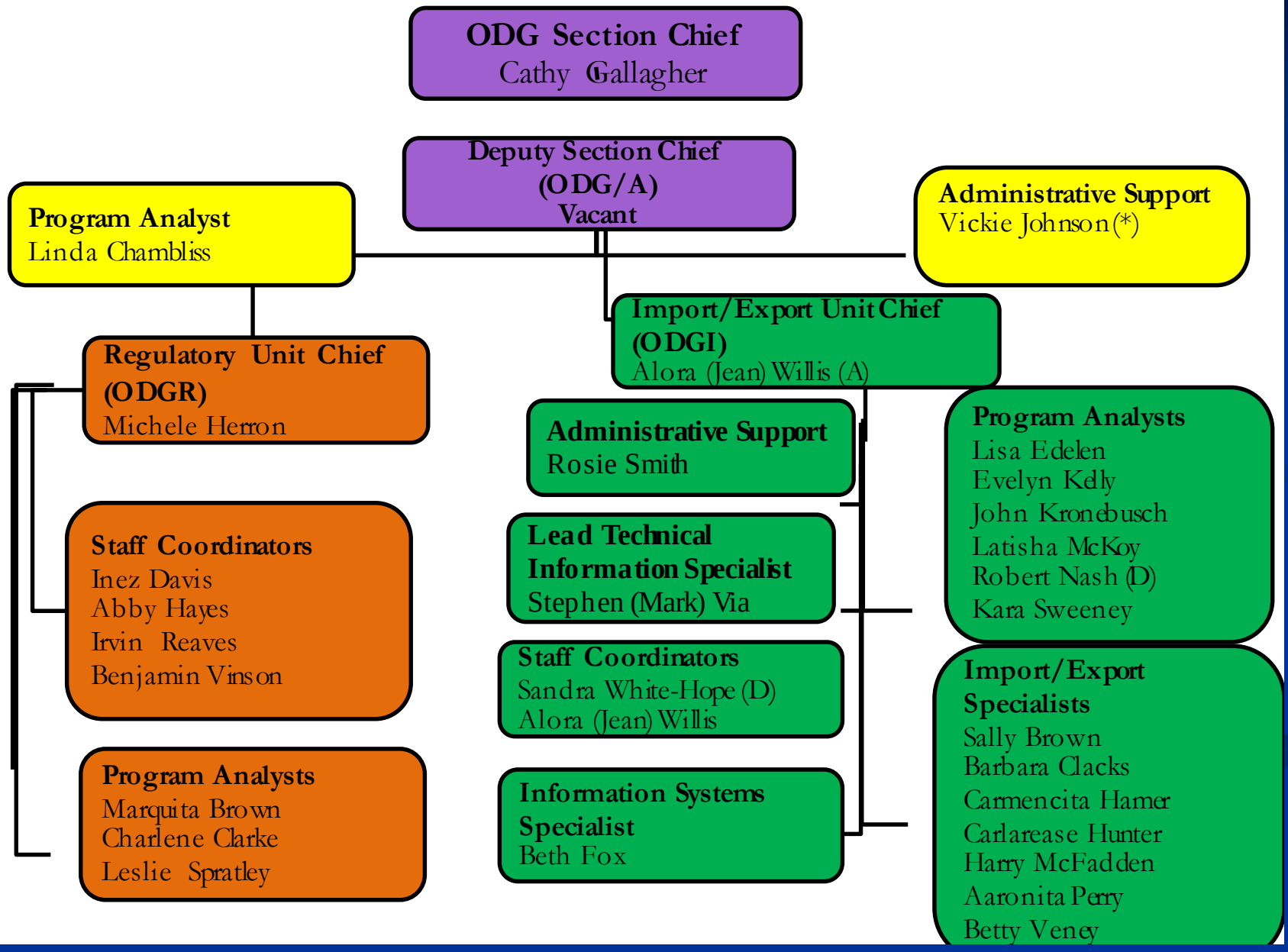
September 24, 2015

Regulatory Section

Cathy Gallagher
Section Chief

Michele Herron
Unit Chief, Regulatory Unit/ODGR

Alora (Jean) Willis
Acting Unit Chief, Import/Export/ODGI
Molly Callahan – Reports November 2015


ODG Section Chief
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Deputy Section Chief (ODG/A)
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Program Analyst
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Administrative Support
Vickie Johnson (*)
Import/Export Unit Chief (ODGI)
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Evelyn Kelly
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Sally Brown
Barbara Clacks
Carmencita Hamer
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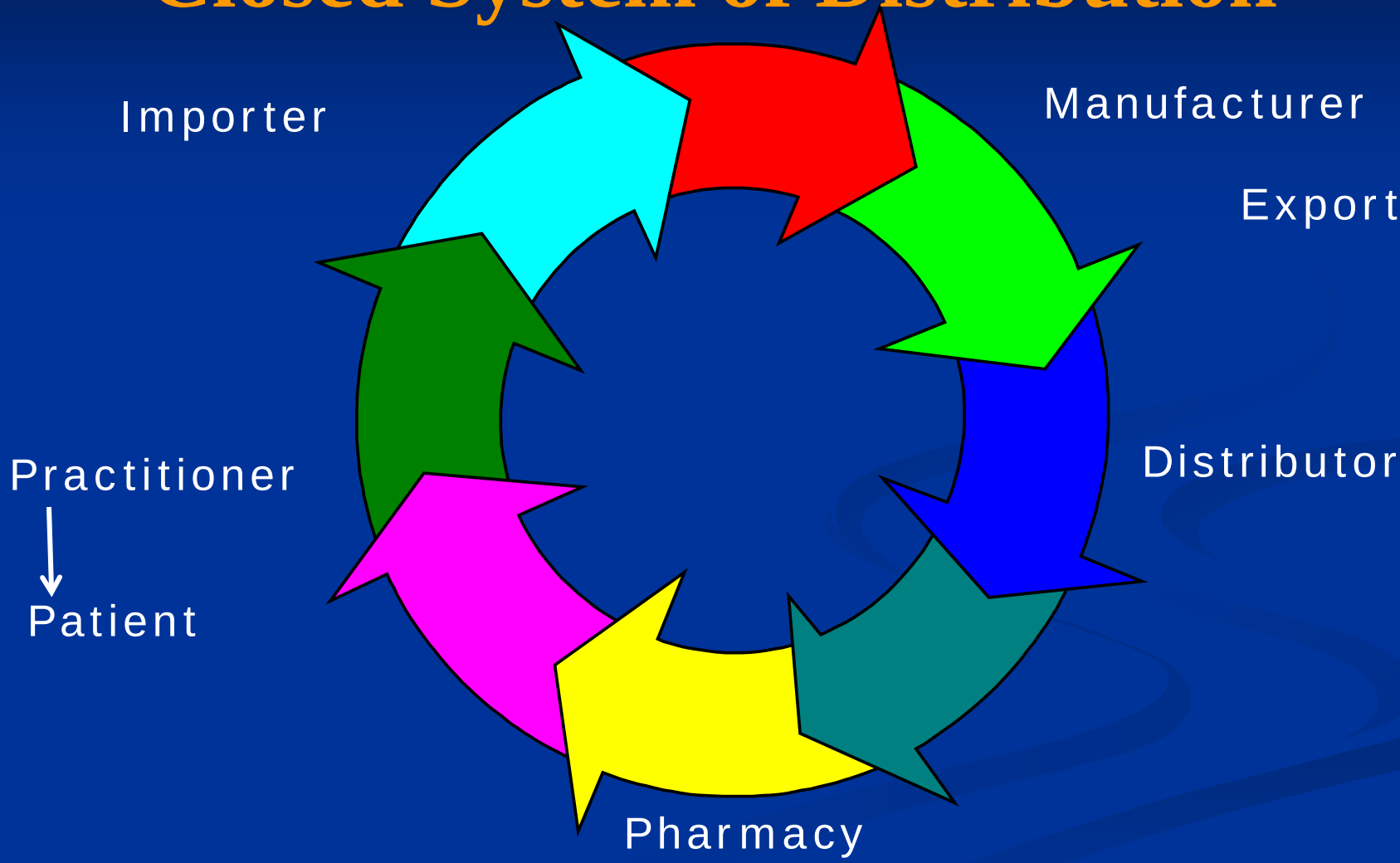
Harry McFadden
Aaronita Perry
Betty Veney
Program Analysts
Marquita Brown
Charlene Clarke
Leslie Spratley
Information Systems Specialist
Beth Fox

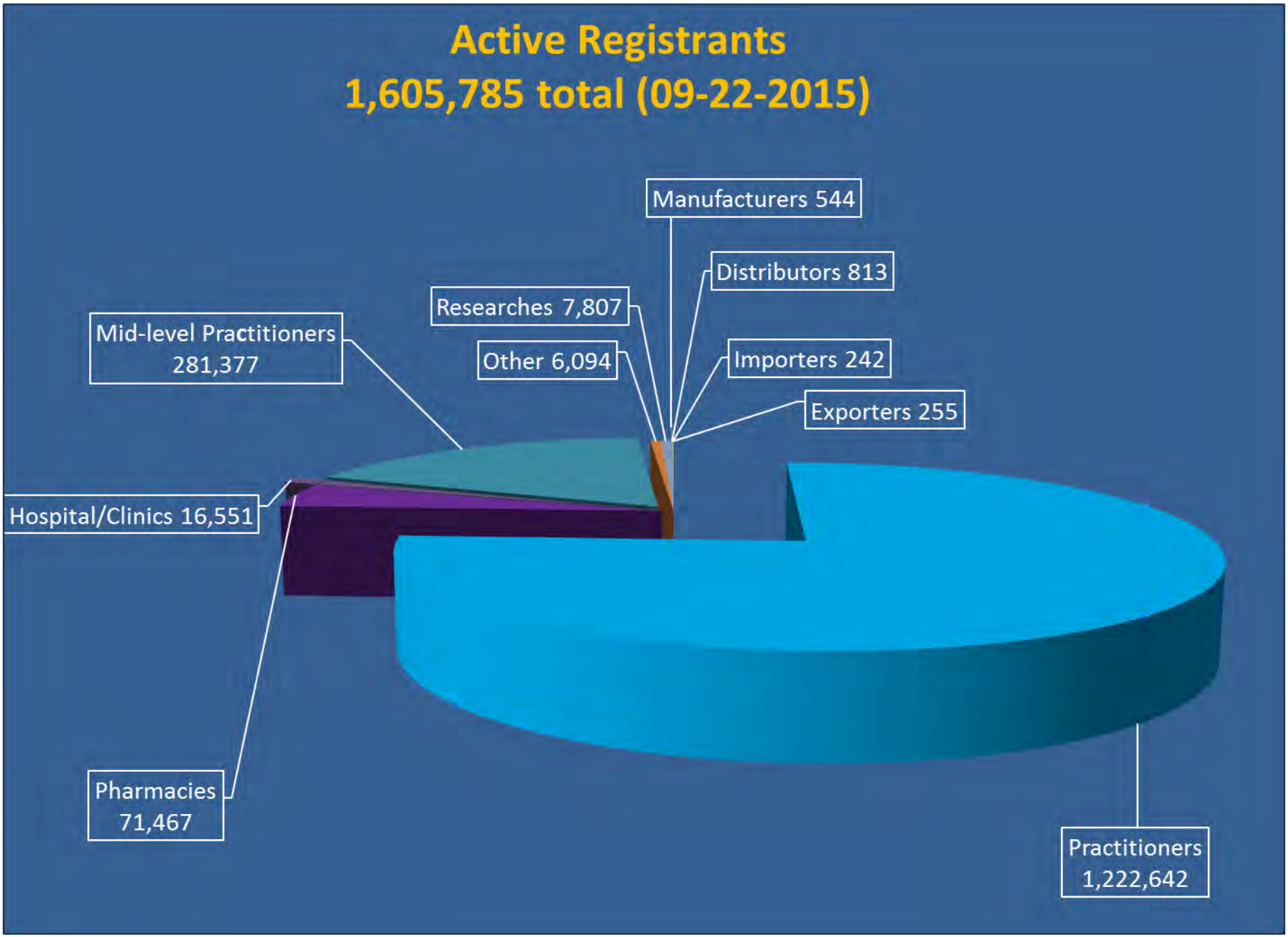
ODGR Primary Responsibilities

- Scheduled Investigations
- National Investigations
- Civil Settlement Agreement
- Distributor Initiative
- Theft/ Loss Reports
- Employment Waivers
- HQS Security Coordination
- Memorandum of Agreement
- Researcher Pre-Registration Investigation
- Quota Reviews
- Registration
  - NOAs and NORs

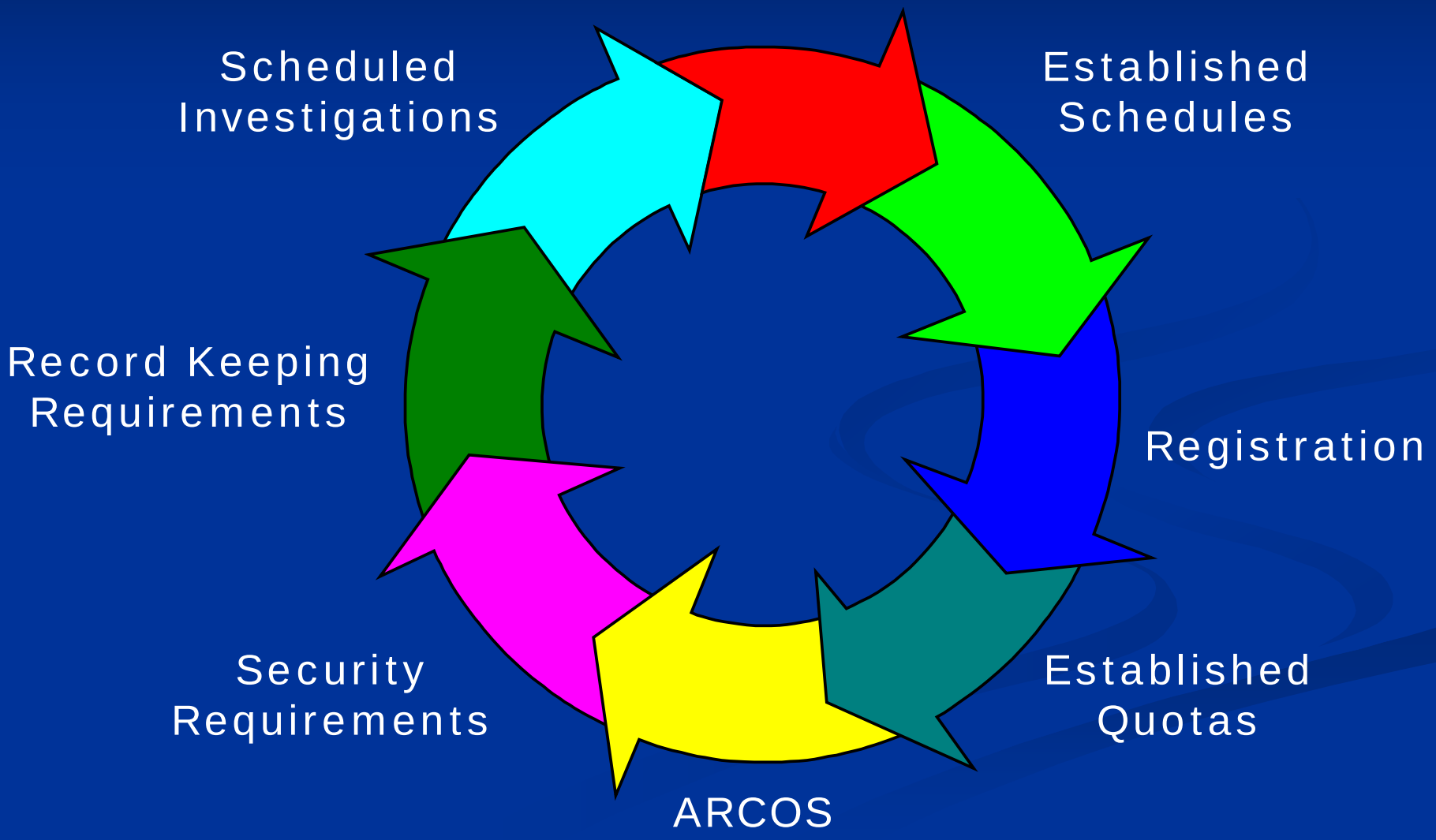
The CSA's Closed System of Distribution



Active Registrants
1,605,785 total (09-22-2015)



Closed System of Distribution



Closed System of Distribution

The DEA is responsible for:

- the oversight of the system
- the integrity of the system
- the protection of the public health and safety

Legal Foundation

- Controlled Substances Act
- Code of Federal Regulations
  - Registrations
  - Recordkeeping
  - Authorization of imports and exports
  - Re-exportation
  - Security

Discussion Points

- Scheduled Investigations
- Reference Samples/Registrations
- Controlled Substances manufactured in U.S.

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

- Authority – Notice of Inspection/Administrative Inspection Warrant
- ARCOS
- Record Keeping Requirements
- Due Diligence Policies & Procedures
- Security
- Accountability
  - On Hand Count
  - Receipts and Distributions

Recordkeeping

- Record Keeping Requirements
  - Must maintained the records required to be kept for 2 years
  - Must keep complete and accurate records of substances manufactured, imported, received, sold, delivered, exported or otherwise disposed by registrant.
  - Separate records for each independent activity
    - Dates
    - Quantity
    - Invoices and DEA Official Order Form 222

Inventories

- Initial and Newly controlled substances
- Biennial Inventory
- Manufacturer – Bulk Form
  - Name of substance
  - Total Quantity of substance to the nearest metric unit weight
- Manufacturer – Finish Form
  - Name of substance
  - Each finished form (e.g. 10 mg)
  - Number of units/volume in each commercial container (e.g. 100 Tab Bottle)

Records

- Manufacturer: Bulk
  - Name of substance
  - Quantity of manufactured bulk form (Date, Qty, Batch #)
  - Quantity received from other registrants (Date, Qty, Name, DEA#)
  - Quantity imported directly by registrant's Importer Registration (Date, Qty, Import Permit/Declaration #)
  - Quantity in finished form (Date, Batch, Qty, Form, Units, Qty in QA, Qty lost and causes, theoretical and actual yields, other info)
  - Quantity used to manufacture other controlled and noncontrolled substances (Date, Qty, Name, Address, and DEA #)
  - Quantity exported directly by registrant's Exporter Registration (Date, Qty, Export Permit/Declaration #)

Records

- Manufacturer: Bulk
  - Quantity distributed or disposed (complimentary samples or destruction)
  - Originals of all written certification of available procurement quotas submitted by other persons

Records

- Manufacturer: Finished Form
  - Name
  - Each finish form (e.g. 10 mg)
  - # of units/volume (e.g. 100-tab btl, 3-ml vial)
  - # of containers
  - # of finished form and/or commercial containers from other persons (Date, Qty, DEA #, Address)
  - # of finished form and/or commercial containers directly imported by registrant (Date, Qty, Import Permit/Declaration #)

Records

- # of units and/or commercial containers manufactured by registrant from units in finished form received from others or imported including:
  - Date and Batch #
  - Operation Performed (repackaging or relabeling)
  - Qty of units in finished form used in manufactured
  - Qty loss during manufacture with causes
  - Other pertinent information
- Qty of commercial containers distributed to other registrants (Date, Qty in each reduction from inventory, Name, Address, DEA#)
- Qty directly exported and permit/declaration ## of finished form and/or commercial containers directly imported by registrant (Date, Qty, Import Permit/Declaration #)

Importer Records

- Import Permit: DEA 35
- Application for Permit: DEA 357
- Declaration: DEA 236
  - Filed 15 Days in advance
- Declaration: DEA 486
    - Filed 15 Days in advance ????

  - 21 C.F.R. §1312.11(a)-(b), 1313

Exporter Records

- Export Permit: DEA 236
- Application for Permit: DEA 161
- Declaration: DEA 486
  - Filed 15 Days in advance

21 C.F.R. § 1312.23 & 1313.12

Registration

- 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
- Federal Register

Registration

- 21 USC § 958

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

- 21 USC § 824

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

Import Issue

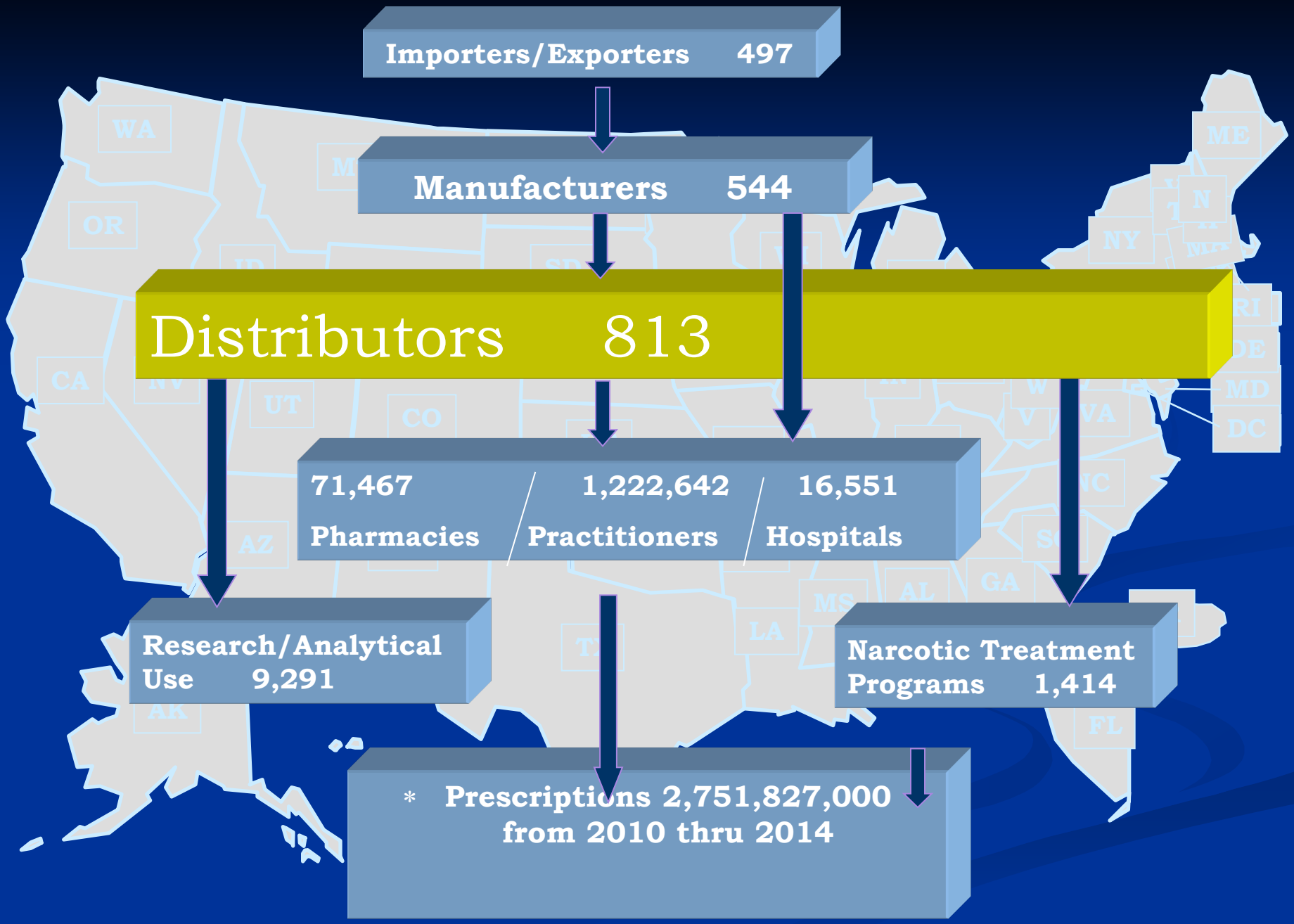
- 21 U.S.C. § 952
- It shall be unlawful to import …
  - Such amounts of any CS … that AG finds to be necessary to provide for medical, scientific, or other legitimate needs of the U.S. –
    - Emergency
    - Lack of competition among domestic manufacturers is inadequate or
    - CS is in limited quantities for scientific, analytical, or research uses.

Import Issue

- Reference Standard – Import Finish Form for Sale
- C.S. manufactured in U.S.

Distributor Initiative

- 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.



IMS Data

Drug Enforcement Administration, Office of Diversion Control

Drug Theft and Losses

- Objectives & Goals:
  - Accountability
  - 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

- 21 CFR § 1301.76 – Controlled Substances
- 21 CFR § 1309.73 – Listed Chemicals

Drug Theft and Losses

- Upon Discovery: 21 C.F.R. §1301.74
  - FR Published – September 12, 2005
  - The registrant shall notify the Field Division Office of the Administration in his area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss.

DEA Form 106

- Paper Copies
  - Need to take a look at them for mistakes
    - Wrong DEA #s
    - Not legible
    - NDC #
    - Recent Copies/New form
- Who has to report?
- Encouraging you to submit online

Q & A

Who You Gonna Call?

Contact Information:

- DEA Website: www.deadiversion.usdoj.gov
  - Field Offices
- Regulatory Unit: 202-307-7194


U.S. Department of Justice
Drug Enforcement Administration
Rx
Office of Diversion Control