“International Drug Control Treaties”

UN Reporting and Quota Section (ODQ)

Office of Diversion Control

Objective

- To discuss the general requirements of the international drug control treaties.

Three International Conventions

- Single Convention on Narcotic Drugs, 1961
- Convention on Psychotropic Substances, 1971
- Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988

US is a party to all three treaties

Goal: limit the use of narcotic drugs and psychotropic substances and their precursors to legitimate medical and scientific purposes.

Definitions:

- Treaty:

  n. a formal agreement between two or more nations in reference to peace, alliance, commerce, etc.

- Party: **United States of America (1 of 183; 9 remain)**

  n. a person who or group that participates in some action, affair, plan, etc: participant

- Competent authority: **DEA**

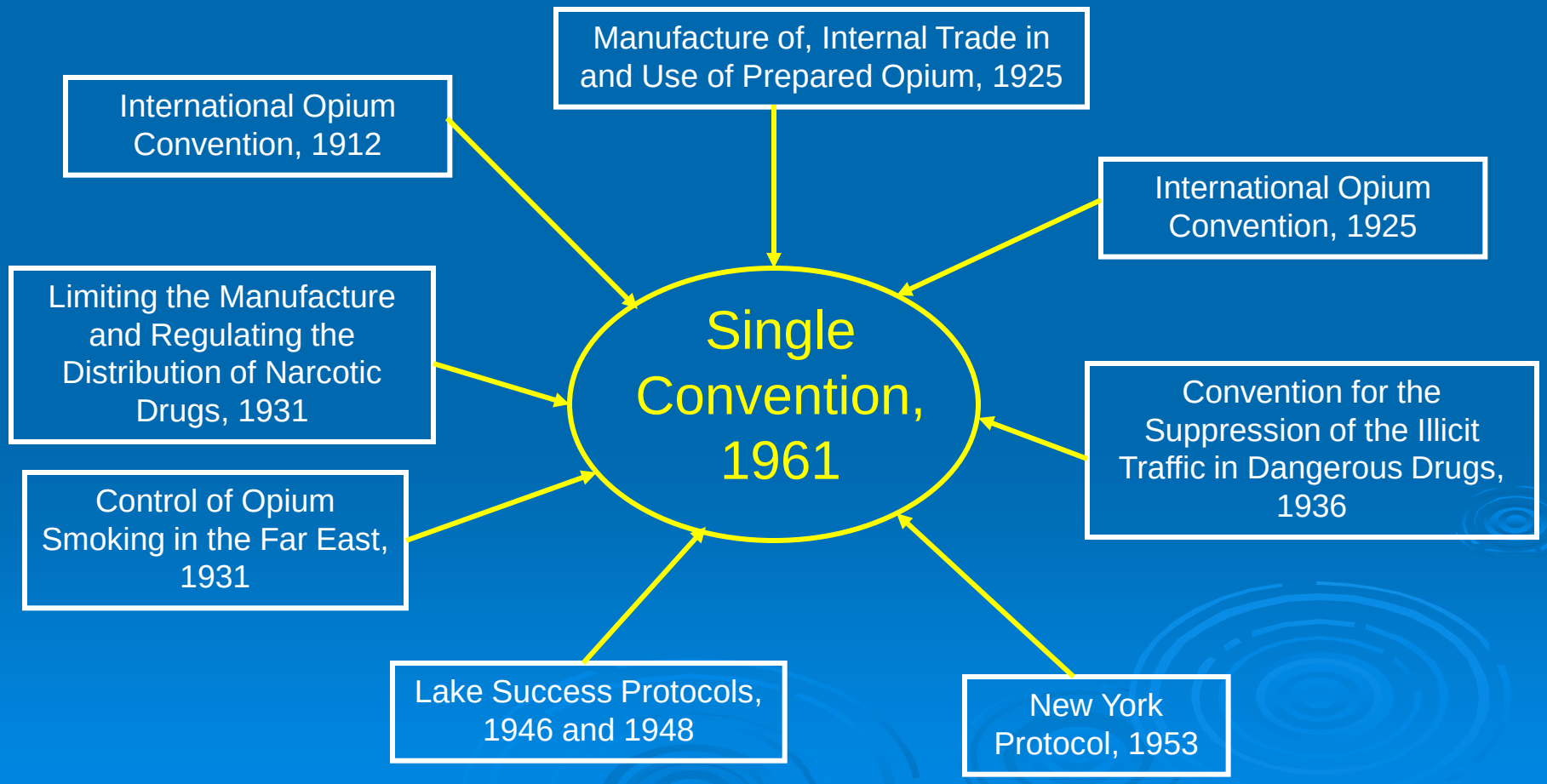
  n. authorities entrusted with functions in the field of the campaign against the illicit traffic

The Single Convention

- Adopted March 30, 1961
- Entered into force, 1964
- Replaced previous treaties on opiates, cannabis, and cocaine
- 185 countries are Parties
- Specifically mentioned in preamble and other parts of the CSA
  - CSA puts U.S. in compliance with the Single Convention
- Also referred to as the "61 Convention"

List of Controlled Substances: "Yellow List"

Single Convention - Historical Perspective: Agreements, Conventions, and Protocols



The Single Convention

Substances Covered

- 119 specific Narcotic drugs controlled
  - Includes opium and its derivatives
    ex. morphine, codeine, heroin
  - Includes synthetic opiates
    ex. meperidine, fentanyl
  - Includes cannabis and coca
    ex. cocaine/ecgonine
- Legal, not pharmacological definition of narcotic
- Controls extended to isomers, esters/ethers, salts thereof, whenever existence is possible

‘61 Convention: Four Schedules

Schedule I: drugs liable to significant abuse and to produce ill effects, but have potential therapeutic uses

(e.g., Cocaine, Heroin, Cannabis, Morphine, Fentanyls)

Majority of substances under control as Schedule II under the CSA

Schedule II: drugs with somewhat lower abuse liability

(e.g., Codeine, Dextropropoxyphene)

Only 10 substances

‘61 Convention: Schedules

Schedule III: exempt preparations of drugs in Schedules I or II - specifically listed formulations

- e.g., Codeine preparations when compounded with one or more ingredients and containing not more than 100 mg of the drug per dosage unit……

Schedule IV: drugs in Schedule I which are particularly liable to abuse and to produce ill effects. Such liability is not offset by substantial therapeutic advantages

- Cannabis, Etorphine, Heroin, Fentanyl analogues - only salts covered

Single Convention -Types of Control

TREATY-BASED OBLIGATION:	Article
Limit to medical and scientific purposes	2, 4
Authorization of imports and exports	31
Record-keeping	34b
Medical prescriptions required	2, 30
Prevent Accumulation of Stocks	29
Licensure of manufacturers and distributors	30
Quotas	29
Possession of drugs under legal authority	33
Security and Inspection	35 - 38

DEA OBLIGATIONS AS COMPETENT AUTHORITY:	
Import/Export Statistics (Form A)	20
Narcotic Estimates (Form B)	19
Narcotic Annual Statistics (Form C)	20

Controls under 1961 Convention

Special Provisions:

- Schedule IV - parties may prohibit / limit manufacture or import
- Opium / Cannabis / Coca cultivation
  - special estimates, reports and controls
  - government agency in control of entire operation from cultivation to distribution
  - limitation on manufacture and import
- Poppy cultivation for seed
- Cannabis for industrial purposes
- Coca leaves for flavoring
- Extracts, CIII preparations exempt from some controls

The Psychotropic Convention

- Convention on Psychotropic Substances 1971
- Adopted in 1971 (Vienna, Austria)
- Entered into force, August 16, 1976
- Presently 183 parties
- Ratified by US in 1980
- Referred to as the “71 Convention”

List of Controlled Substances:
“Green List”

‘71 Convention - Historical Perspective

General Assembly Resolution, 1949

Conference - Vienna Austria

January 11 - February 21, 1971

Vienna Convention, 1971

Benzodiazepines, barbiturates, stimulants

The Psychotropic Convention

- Four Schedules
- Placement is based upon the relative therapeutic value and risk of abuse of each substance
- Schedule I is the most restrictive (e.g., LSD)
- Schedule IV is least restrictive (e.g., diazepam)
- Generally less stringent controls than the Single Convention
- Substantial difference in controls of CI/II vs. CIII/CIV
- Listing of substance is often stereospecific - not extended to esters, ethers, or derivatives

‘71 Convention: Schedules

Schedule I: Substances whose abuse liability constitutes an especially serious risk to the public health and which have very limited, if any, therapeutic usefulness

- MDMA, LSD, 2,5-DMA
- specific isomers and stereochemical variants of tetrahydrocannabinol

‘71 Convention: Schedules

Schedule II: Substances whose abuse liability constitutes a substantial risk to the public health and which have little to moderate therapeutic usefulness

- Amphetamine, Methaqualone
- *delta*-9-tetrahydrocannabinol
- dextroamphetamine, levamphetamine and amphetamine are listed separately

‘71 Convention: Schedules

Schedule III: Substances whose abuse liability constitutes a substantial risk to the public health and which have moderate to great therapeutic usefulness

– Butalbital, Pentobarbital, Buprenorphine

Schedule IV: Substances whose abuse liability constitutes a small but still significant risk to the public health and which have therapeutic usefulness from little to great

– Benzodiazepines, Phentermine, phendimetrazine

‘71 Convention - Types of Control

TREATY-BASED OBLIGATION:	Article
Import/Export Authorizations or Declarations	12
Record-keeping	11
Medical prescriptions required	9
Licensure of manufacturers and distributors	8
Security and Inspection	8,15
Restrict import/export of certain drugs	13

DEA OBLIGATIONS AS COMPETENT AUTHORITY:	
Import/Export Statistics (Form AP)	16
Assessment of Medical Need (Form BP) – req’d. for I and II only	Resolution
Annual Statistics (Form P)	4,16

1988 Convention

- It provides the legal basis for the international control of precursors and essential chemicals used in the illicit manufacture of drugs.
- Each party state must put control mechanisms in place in order to engage in manufacturing activities and distribution of these chemicals.
- Presently 183 parties

List of Controlled Chemicals:

“Red List”

International Organizations

- Commission on Narcotic Drugs (CND)
  - http://www.unodc.org/unodc/en/commissions/CND/index.html
- International Narcotics Control Board (INCB)
  - http://www.incb.org
- World Health Organization (WHO)
  - www.who.org
- United Nations Office on Drugs and Crime (UNODC)
  - http://www.unodc.org

Commission on Narcotic Drugs (CND)

- The central policy-making body of the United Nations in drug related matters.
- Monitors the implementation of the three international drug control conventions and is empowered to consider all matters pertaining to the aim of the conventions.
- Decides, on the basis of recommendations by the World Health Organization (WHO), to place, remove or transfer narcotic drugs and psychotropic substances under international control.
- 55 voting members, who meet annually

International Narcotics Control Board (INCB)

Works on behalf of the CND to:

- Promote compliance with treaty provisions
- Ensure that adequate supplies of drugs are available for legitimate purposes
- Seek to limit diversion into illicit traffic
- Identify weaknesses in international / national control of drugs and provides assistance
- Maintain estimate systems
- Receive / analyze statistical data from Parties

World Health Organization (WHO)

- The directing and coordinating authority for health within the United Nations system.
- The WHO Expert Committee on Drug Dependence plays a central role in the international drug control system.
- Carries out medical and scientific evaluations of the abuse liability of dependence producing drugs falling within the terms of the conventions.

United Nations Office on Drugs and Crime (UNODC)

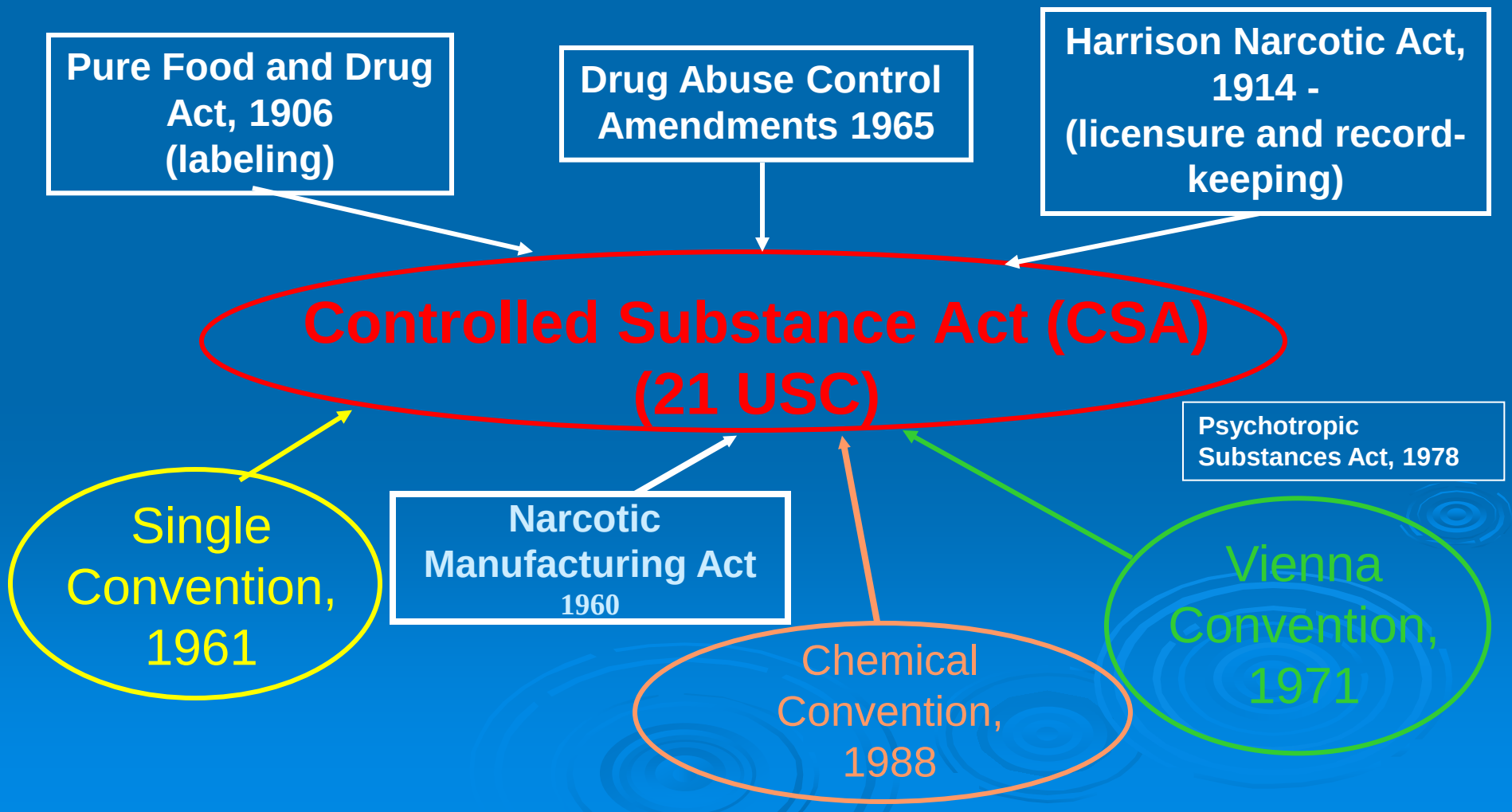
- Mandated to assist Member States in their struggle against illicit drugs, crime, and terrorism.
- Compiles statistics on illicit drug manufacturing and transportation.
- Publishes an annual report to help Member States address the threat posed by drugs, crime and terrorism

The Controlled Substances Act

- Enacted in 1970

- Substances Covered:
  - All substances on the "yellow" and "green" lists
  - Anabolic Steroids
  - "…derivatives, its salts, isomers, and salts of isomers."

CSA - Historical Perspective:



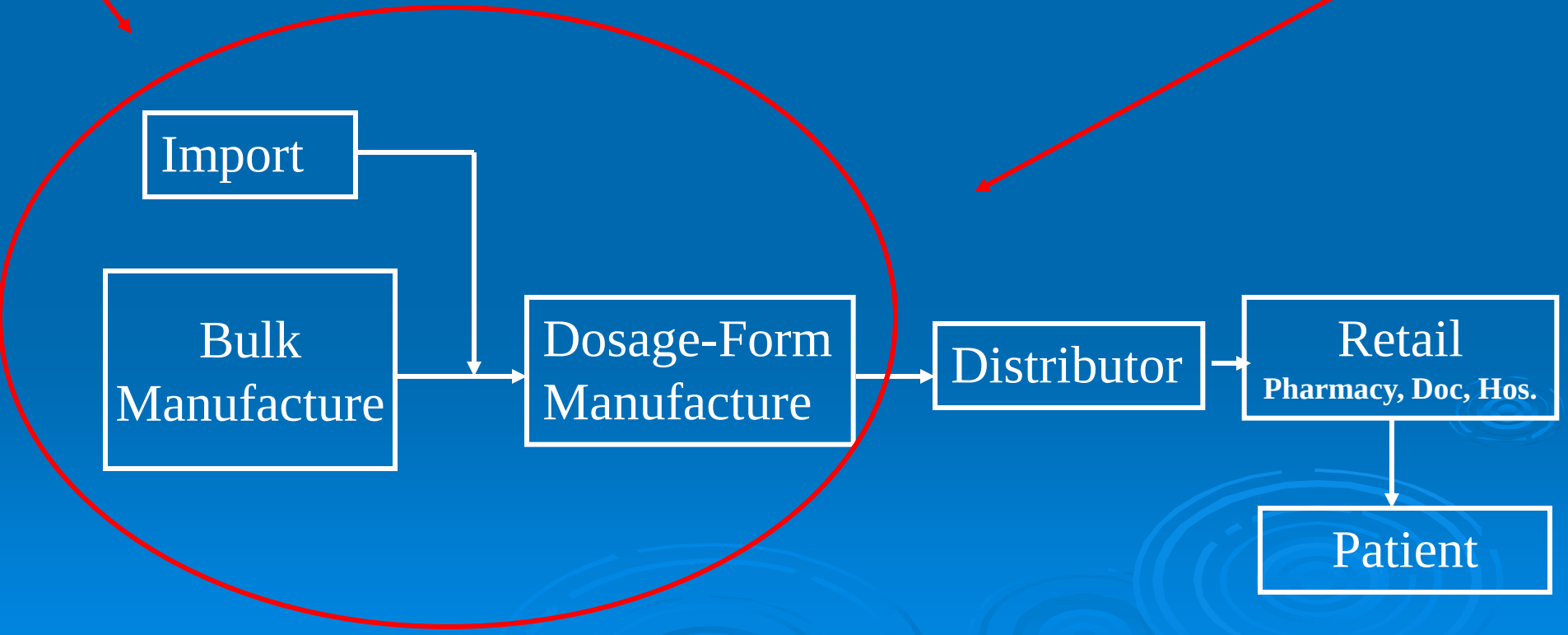
The Controlled Substances Act

- Five Schedules, placement based upon (21 USC 812(b)):
  a. Potential for abuse.
  b. Currently accepted medical use.
  c. Psychological or physical dependence.

- Schedule I is most restrictive (LSD, heroin, MDMA)
- Schedule V is least restrictive (some codeine preps)

The CSA creates a tightly controlled "closed system" of drug distribution.

Preventing diversion at this level of drug distribution is paramount to the success of the Diversion Program



Code of Federal Regulations (CFR)

"Codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government."

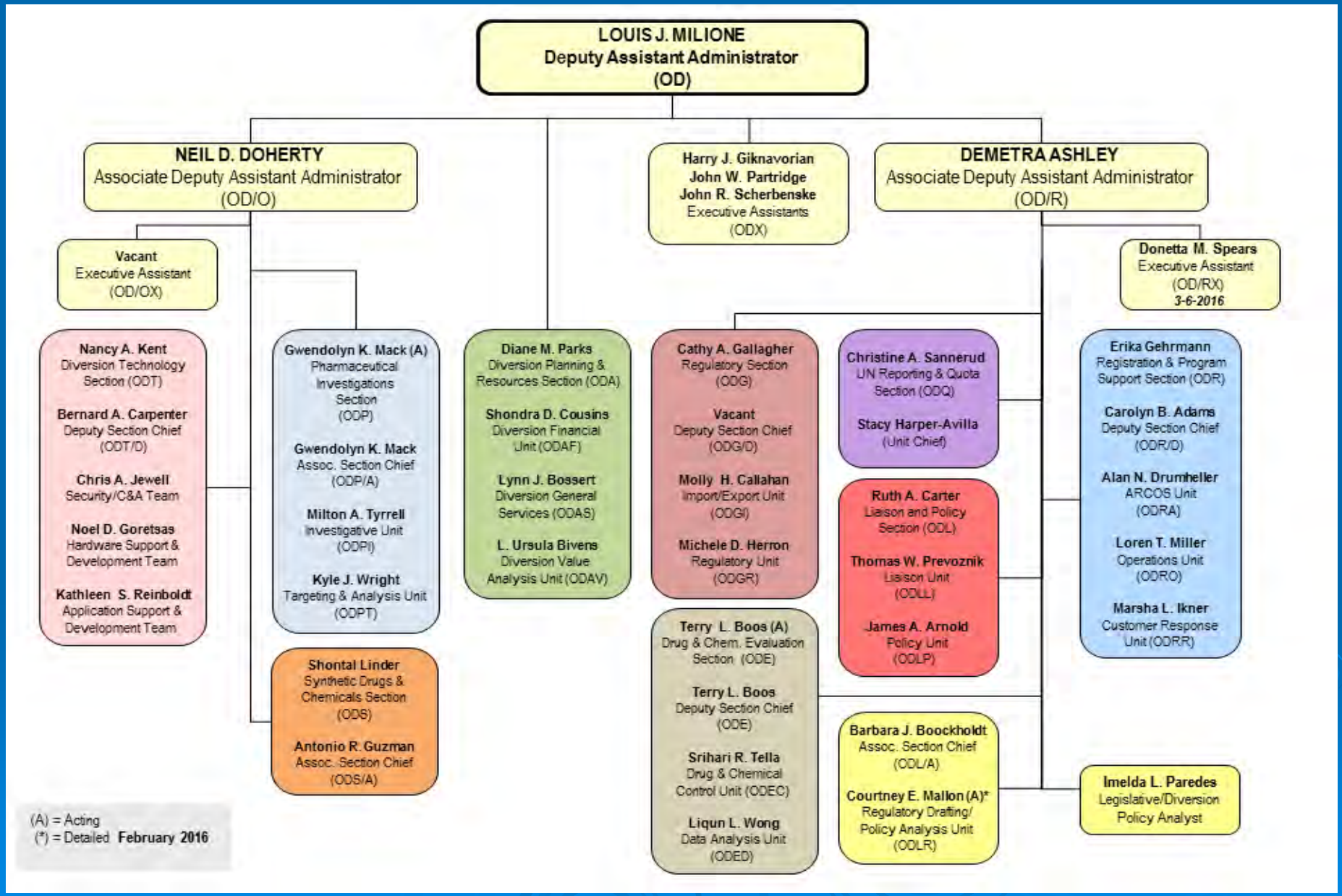
- The CFR is the "how to" guide for both the public and the Federal Government.
- Individual agencies make additions or changes to the code
- Updated once per year (total of 50 titles)
- www.gpoaccess.gov/cfr/index.html

What is the Federal Register (FR)?

- "The Federal Register is the official publication for rules, proposed rules, and notices of Federal agencies and organizations, as well as executive orders and other presidential documents."
- Communicated to the public
- Published daily
  - www.gpoaccess.gov/fr/index.html

Seminar Outline:

Regulatory Function	21 USC §	21 CFR §
Registration	823	1301.33-301.34
Quotas	826	1303
Import / Export	951 - 971	1312 -1313
Reporting / Recordkeeping	827	1304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Summary

- International drug control system based on three treaties
- As a world leader in drug control efforts, the US has consistently supported the requirements and spirit of the treaties.
- Treaties form the basis for the statutory framework of the CSA and much of our drug control policy.
- The CSA (and Congressional changes to the CSA) are implemented through the CFR, as communicated to the public in the FR.