



Supply Chain Conference 2024

International Treaty Compliance
UN Reporting and Quota Section
Diversion Control Division





The contents of this document do not have the force and effect of law and are not meant to bind the public or DEA in any way.

This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

I have no financial relationship to disclose.



“The presentation is for educational purposes.

Materials, images, or sounds authored or created by parties other than DEA may be subject to copyright and are used herein in accordance with the fair use provision of Title 17 United States Code Section 107. DEA’s use of these materials does not authorize persons outside of DEA further distribute or use copyrighted materials.”



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

The United States is a party to all three treaties

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



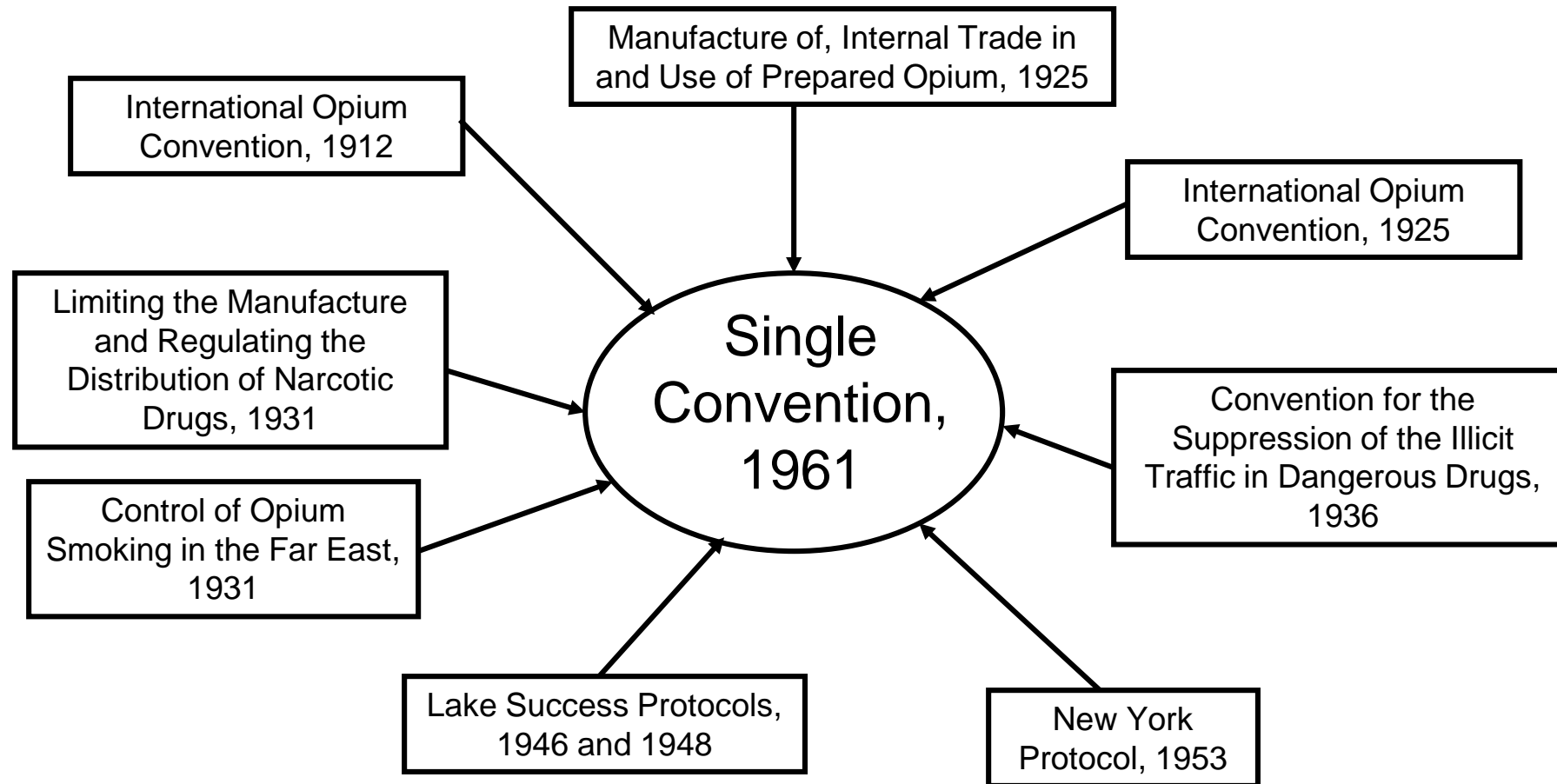


The Single Convention

- Adopted March 30, 1961
- Entered into force 1964
- Replaced previous treaties on opiates, cannabis, and cocaine
- 183 countries are Parties
- Specifically mentioned in preamble and other parts of the CSA
 - CSA outlines U.S. 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

- **141** 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
- Drug controls **extend 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
- Majority of substances listed internationally as Schedule I are controlled domestically in Schedule II of the CSA
- Substances listed include:
 - Alfentanil
 - Cannabis
 - Concentrate of Poppy Straw (now includes noscapine varietal)
 - Meperidine (listed as Pethidine)
 - Oxymorphone





'61 Convention: Four Schedules

- Schedule II: drugs with somewhat lower abuse liability
- Only 10 substances currently listed, including:
 - Codeine
 - Dextropropoxyphene
 - Dihydrocodeine





'61 Convention: Four Schedules

- Schedule III: exempt preparations of drugs in Schedules I or II in **8 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 and a concentration of not more than 2.5 percent in undivided preparations.





'61 Convention: Four Schedules

- 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
- Covers substance listed and the salts
- Currently 18 substances listed including:
 - Carfentanil
 - Etorphine
 - Heroin



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





The Psychotropic Convention

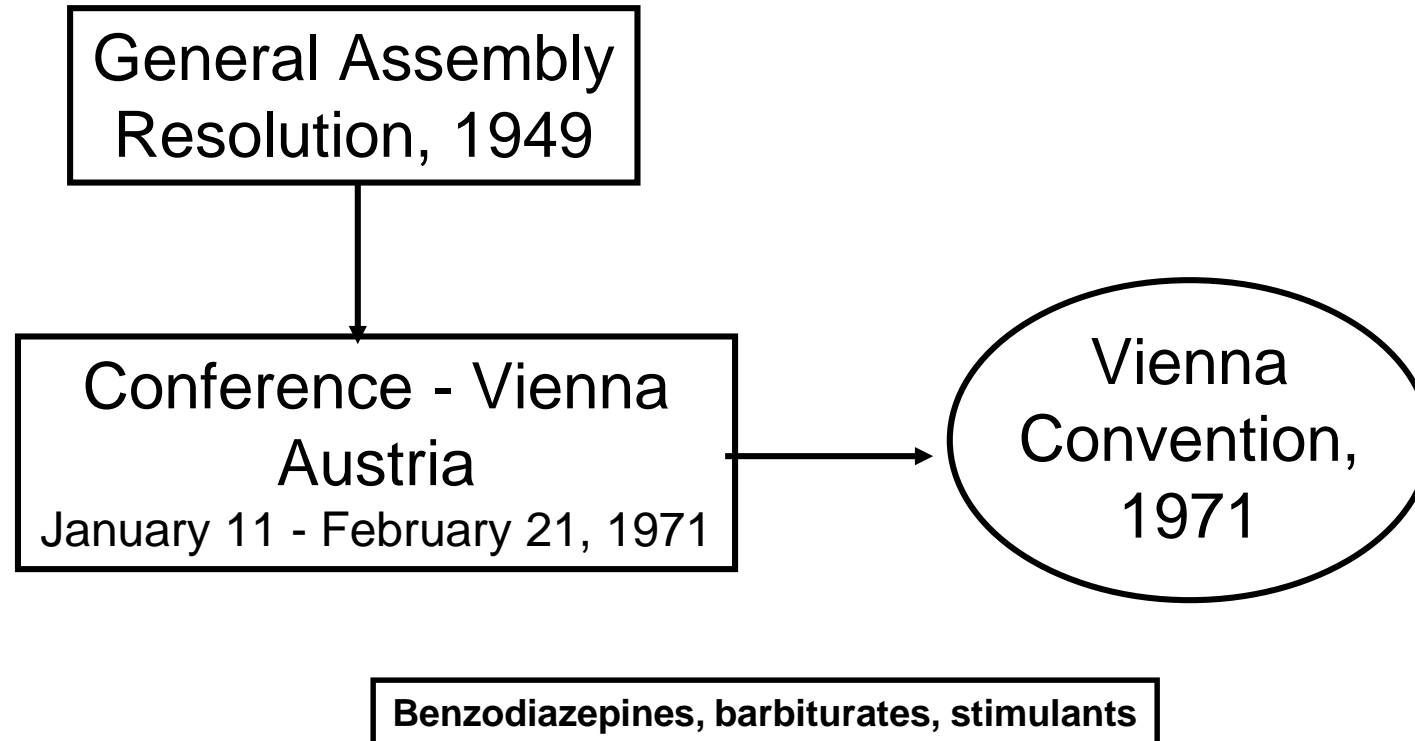
- Convention on Psychotropic Substances 1971
- Adopted in 1971 (Vienna, Austria)
- Entered into force, August 16, 1976
- Presently 179 parties
- Ratified by US in 1980
- Referred to as the “71 Convention”

List of Controlled Substances:

“Green List”



'71 Convention - Historical Perspective





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
- Currently 38 substances listed including:
 - MDMA, LSD, Psilocybin
 - 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
- Currently 60 substances listed including:
 - amphetamine, methylphenidate
 - *delta*-9-tetrahydrocannabinol
 - dexamphetamine, 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
- Current list only contains 9 substances including:
 - Buprenorphine
 - Pentobarbital





'71 Convention: Schedules

- 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
- Currently 77 substances listed including:
 - Alprazolam
 - Midazolam
 - 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”





1988 Convention



- General requirements can be summarized as:
 - “Parties shall take the measures they deem appropriate to prevent diversion of substances in Table I and Table II used for the purpose of illicit manufacture of narcotic drugs or psychotropic substances, and shall co-operate with one another to this end.” (article 12)
- Table I currently lists ~21 chemicals including:
 - Ephedrine, lysergic acid, pseudoephedrine
- Table II currently lists 8 chemicals including:
 - Acetone, Piperidine, Toluene





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

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
- 53 voting members, who meet annually





International Narcotics Control Board



Works on behalf of the CND to promote and monitor compliance with treaty provisions by:

- Endeavoring to ensure that adequate supplies of drugs are available for legitimate purposes
- Assisting governments in preventing diversion of chemicals and drugs into illicit traffic
- Identifying weaknesses in international / national control of drugs and providing assistance
- Administering system for estimates of narcotic drugs and assessments for psychotropic substances
- Monitoring and analyzing the Parties statistical data





World Health Organization



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





UN Office on Drugs and Crime



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

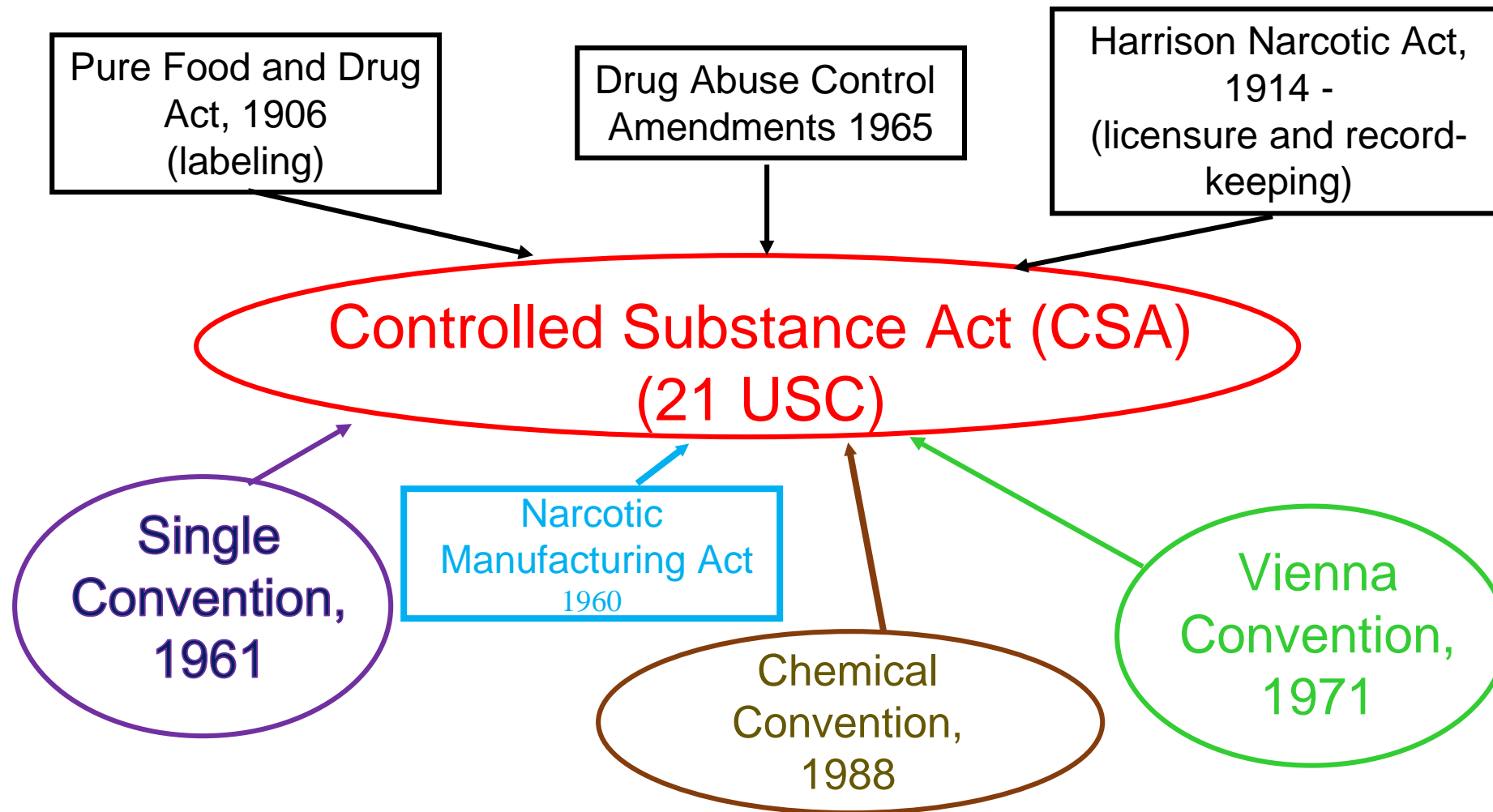




The Controlled Substances Act

- Enacted in 1970
- Substances Covered:
 - All substances on the “yellow” and “green” lists
 - Anabolic Steroids
 - “...**derivatives**, its salts, isomers, and salts of isomers.”







The Controlled Substances Act

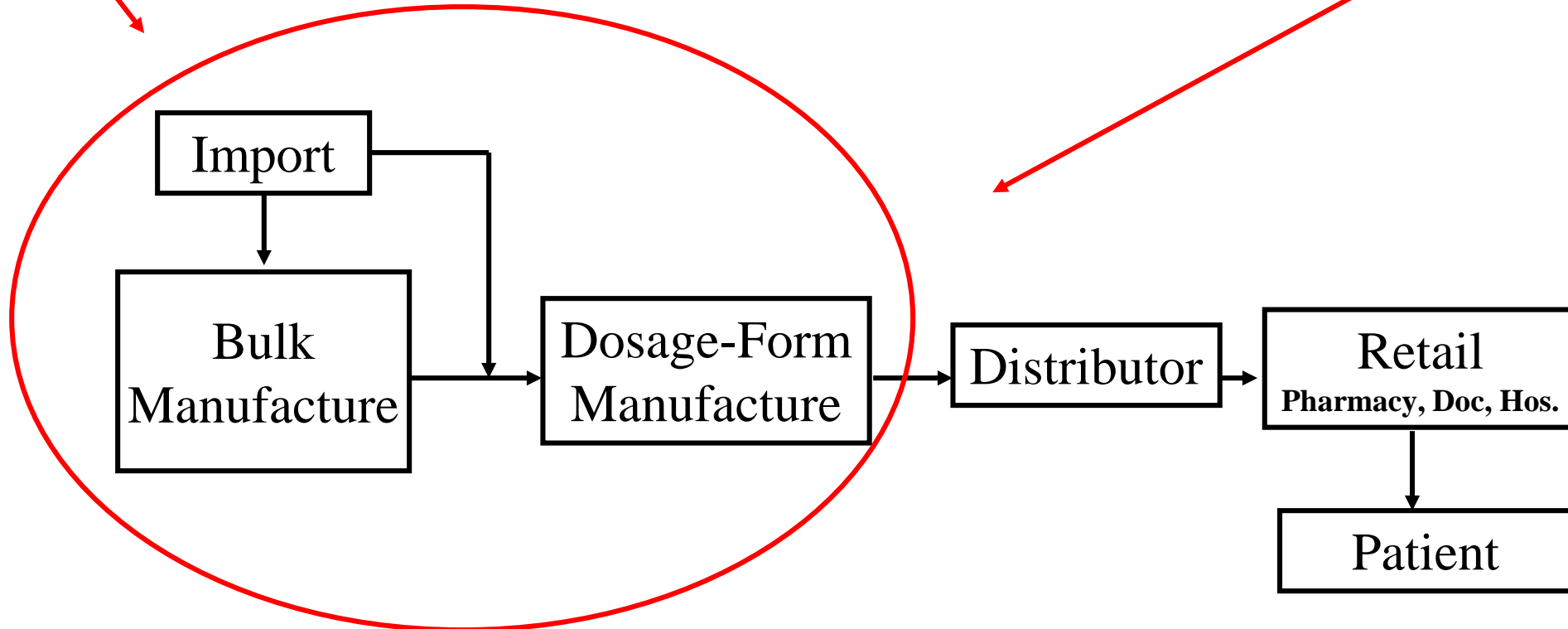
- Five Schedules, placement based upon (21 USC 812(b)):
 - Potential for abuse
 - Currently accepted medical use
 - Psychological or physical dependence
- Schedule I is most restrictive
 - *e.g.* LSD, heroin, MDMA
- Schedule V is least restrictive
 - *e.g.* some codeine preps



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





Summary

- International drug control system based on three treaties
- As a world leader in drug control efforts, the U.S. 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





Questions?

United Nations Reporting and Quota Section (DRQ)

DEAQuotas@DEA.GOV

571-362-3248