# USP <800>
# Impact on Community Pharmacies

Charles Lager RPh, MBA

Thursday, April 8, 2021

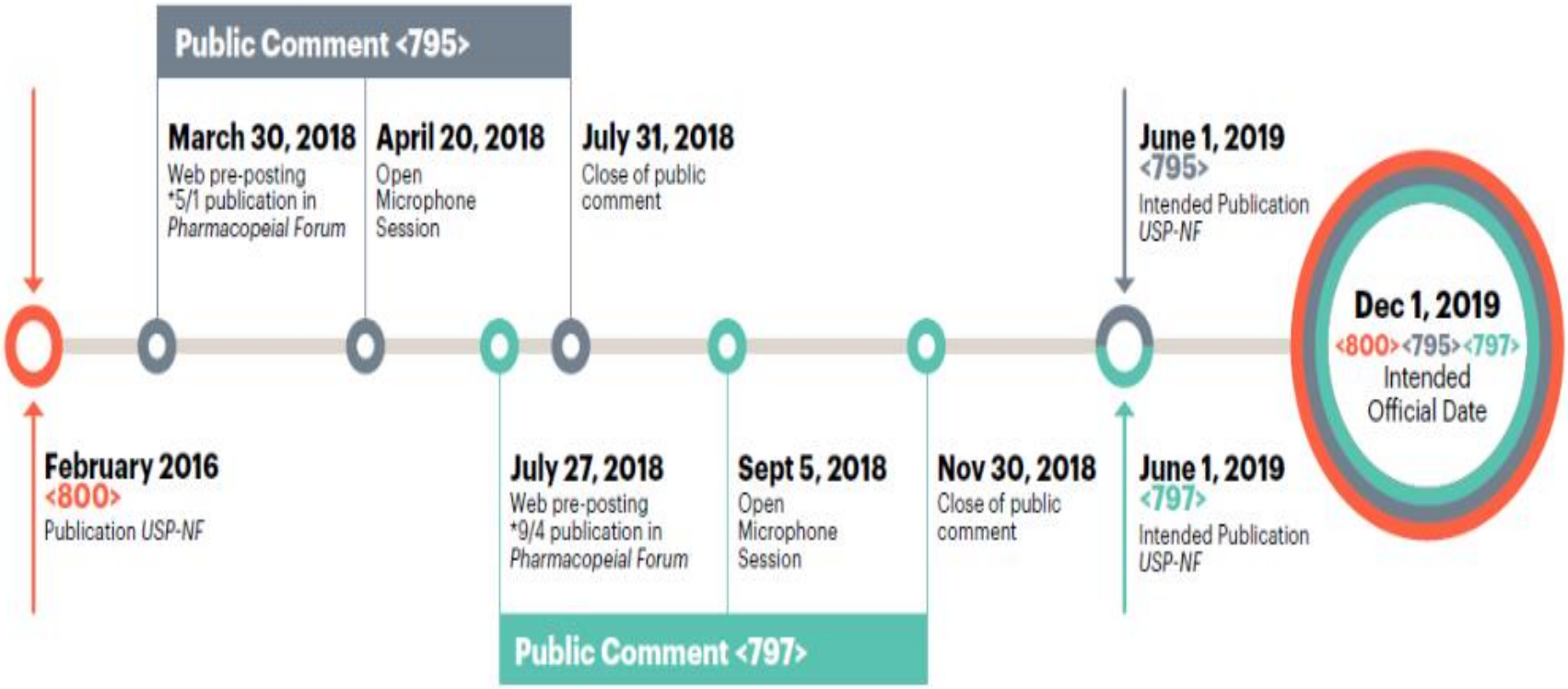
# Agenda

- About USP <800>
  - Potential Risks
  - Types of Exposure
- NIOSH
- Scope of <800>
- <800> Compliance
  - Personnel
  - Facility
- Community Pharmacy Implications
- Questions

# About United States Pharmacopeia (USP)

- USP, a scientific organization that sets standards for identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. USP's standards are enforceable in the U.S. by the Food and Drug Administration.
- Council of Experts
  - Six Separate Councils
  - Compounding falls under Healthcare Quality Standards Collaborative Group
- General Chapters terminology
  - "Shall" or "Must" = required
  - "Should" = recommendation

# Revision Timelines



# What is Exposure?

- Protect patients, personnel and the environment from exposure to hazardous drugs
  - Applies to all healthcare settings
  - Applies to all personnel
- More than **8 million workers** are exposed to hazardous drugs every year
- More than **12 billion doses** of hazardous drugs are handled by US providers each year

# What are the Potential Risks?

- **To Healthcare Worker**
  - Cancer
  - Infertility
  - Reproductive Outcomes
- **Symptoms**
  - Hair Loss
  - Cardiac Toxicity
  - Hearing Loss
  - Nausea
  - Rashes

# Who is at Risk?

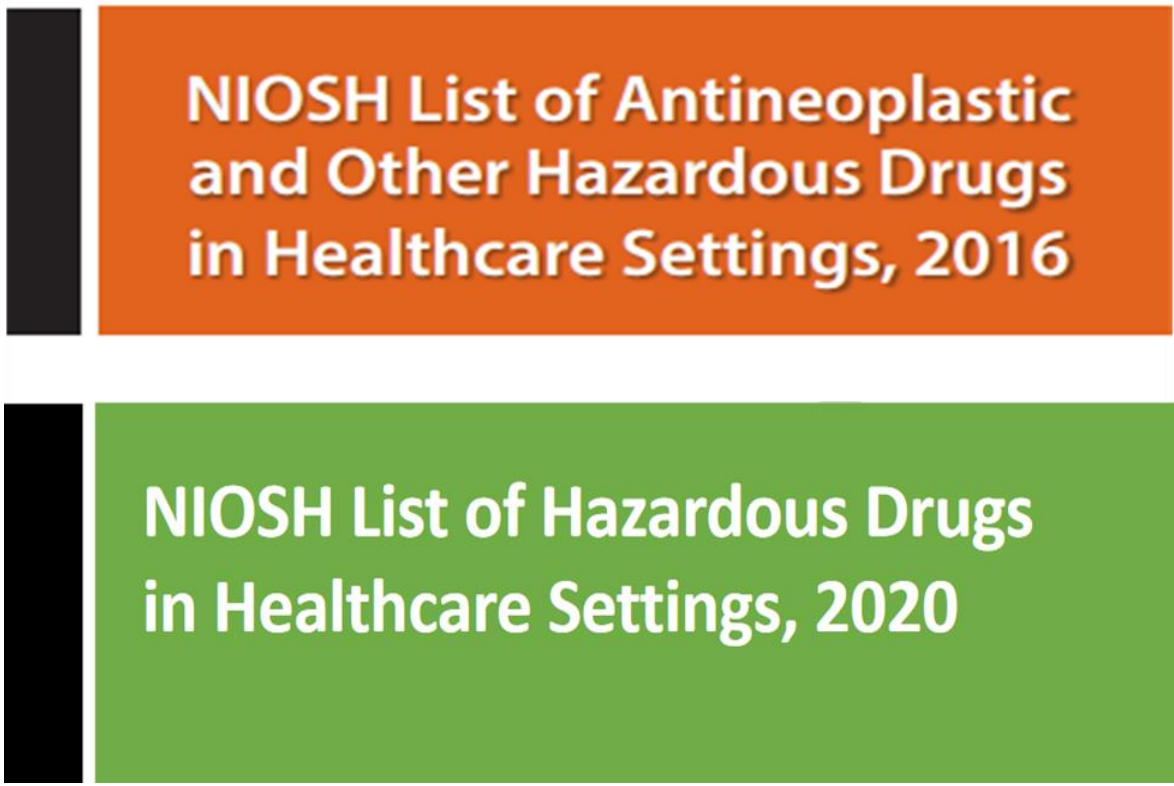
- Pharmacists
- Pharmacy Technicians
- Nurses
- Physicians
- Physician Assistants
- Home Health Aides
- Housekeeping
- Janitorial Services
- Environmental Services
- Veterinarians

# Types of Exposure

- **Vehicle / Route**
  - Dermal absorption
  - Mucosal absorption
  - Inhalation
  - Injection
  - Ingestion
- **How / Where**
  - Receipt
  - Dispensing
  - Compounding & other manipulation
  - Administration
  - Patient Care Activities
  - Spills
  - Transport
  - Waste

**NIOSH** List Tables 2004-2010-2012-2014-2016
Next Published – ?????

- **Examples:**
  - BC Control
  - Hormone
  - Warfarin

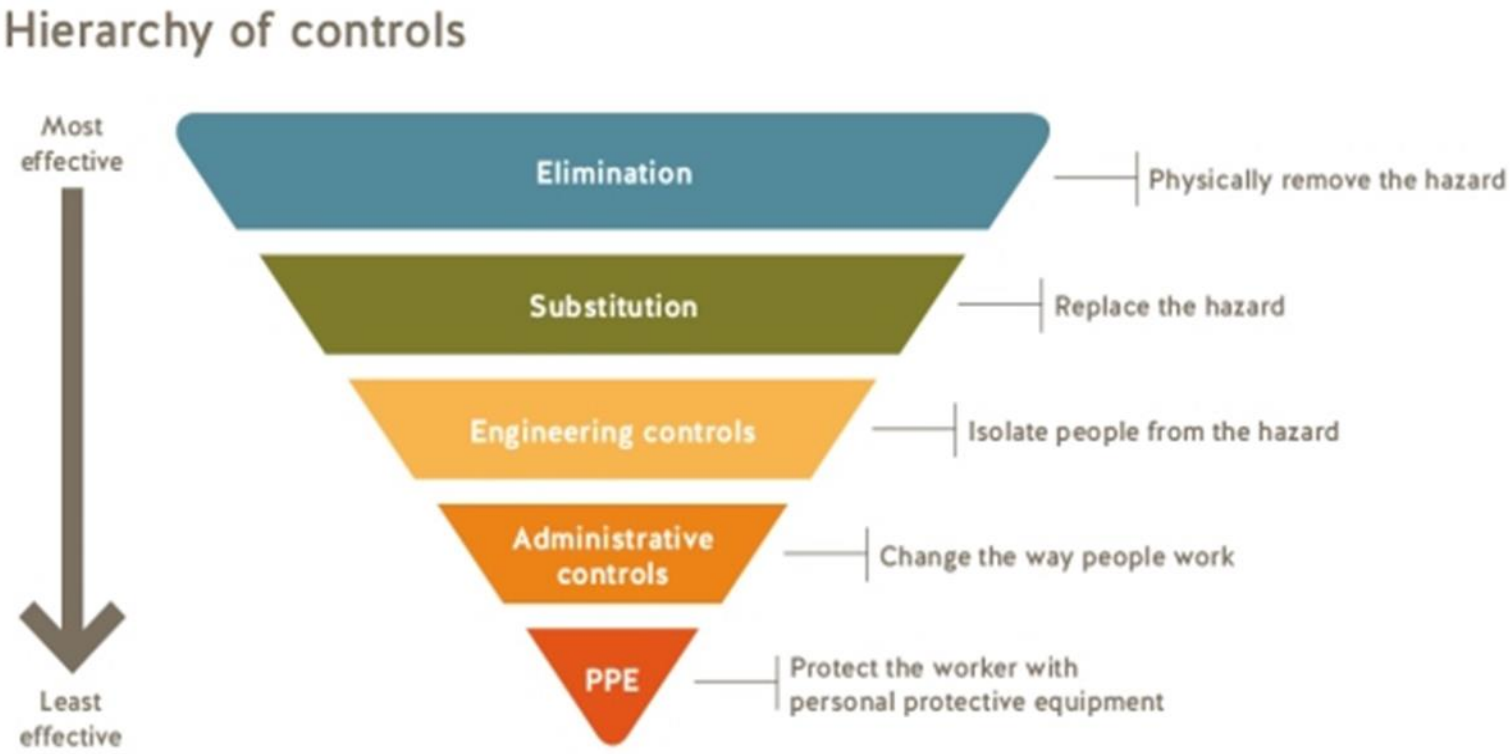


# What is a HD?

Any drug identified by at least one of the following criteria:

| Characteristic | Description |
|---|---|
| Carcinogenic | A substance or agent that can cause cancer |
| Teratogenic or developmental toxicity | A substance or agent capable of producing fetal malformation |
| Reproductive toxicity | Adverse effects on the male and/or female reproductive systems caused by exposure to a toxic substance or agent |
| Organ toxicity at low doses | Toxicity of an organ by a pharmaceutical when it is administered in low doses |
| Genotoxic | A substance or agent causing deleterious action on a cell's genetic material affecting its integrity; the degree to which something causes damage to or mutation of DNA |
| Similar drugs | New drugs whose structure and toxicity are similar to existing drugs determined hazardous by the above criteria |

# Scope of USP <800>
# Approach to Compliance



# Key Steps to Compliance

- Review the NIOSH list
- Divide into two lists
- Follow containment requirements in USP <800>
- Perform an Assessment of Risk (AOR)
- Identify the drugs and dosage forms that are stocked
- Determine your approach
- Two handling options:
  - Treat all dosage forms of all HDs the same
  - Follow containment requirements of USP <800>
- Identify & use alternative containment strategies and/or work practices for specific dosage forms of HDs that are not antineoplastic agents or are not Active Pharmaceutical Ingredients (API)

# Assessment of Risk (AOR)

- Minimum Considerations
  - Type of HD
  - Dosage form
  - Risk of exposure
  - Package
  - Manipulation

# Personnel Requirements

- Compounding personnel (if applicable)
  - Must be qualified and trained
    - Understand fundamental practices and precautions
    - Continually evaluate these procedures
    - Continually evaluate final HD preparations
    - Minimize exposure to personnel
    - Minimize contamination of the environment
- Must have a designated person assigned to oversee
- Personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs
- Demonstration of competency must be documented every 12 months

# Personal Protective Equipment (PPE) SOP's Required

- Receipt
- Storage
- Transport
- Compounding
- Administration
- Cleaning
- Spill Control
- Waste Disposal


Image courtesy of 3M

# Community Pharmacy

## Steps to Compliance

# **Step One**
# Assessment

- Must have P&P's addressing
  - Receipt; Storage; Compound; Dispense; Disposal
  - Assessment of Risk
- If any manipulation is required – If on the NIOSH list
  - Crushing tablets or opening capsules to make a suspension
  - Splitting tablets
  - No option, must treat with all the containment strategies and work practices in <800>

# Step Two
# "Receiving"

- Can you tell from the outside of your packages that a hazardous drug is inside?
- Do you have any anti-neoplastics that must be manipulated other than counted or packaged?
- Need to identify – specific to drug and dosage form – those agents that will be handled differently from <800> and identify strategies in your Assessment of Risk

# Step Three
# "Work Practices"

- Identify HDs by bins or shelf stickers
- Buy in unit-of-use when possible
- Use separate equipment for HD's
  - Designated counting tray and spatula
  - Wear chemo gloves tested to ASTM D6978
  - Decontaminate tray after use
- No HD's to be placed in automated dispensing machines or pill counters

# Step Four
# "Drug Storage"

- Identify as HDs
- Store in yellow, lidded bins
- Clearly note what must be done if manipulation of the dose is required

# Hazardous Drugs vs Hazardous Materials



**NIOSH**

HDs that are hazardous to personnel

**EPA**

Materials that are hazardous to the environment

# Step Five
# "HD Disposal"

- Expired HD's are very costly to your Pharmacy
- What to do:
  - Pull HD's 9 months prior to expiration
    - Unless you are guaranteed to dispense
  - What is hazardous waste?
    - Includes empty vials or dust / residue in containers
    - Empty HD containers must be labeled as hazardous waste
    - Dispose via the EPA's Resource Conservation & Recovery Act (RCRA) rules

# What Evidence Your TCT Surveyor will be evaluating

- Your Compliance to:
  - Policy & Procedures
  - Assessment of Risk – documented annually
  - Personnel Training and documentation
  - Work Practices
  - Receiving and Inventory control of HD's
  - Disposal

# Questions
# Thank You

Charles Lager RPh, MBA

Senior Pharmacy Advisor

clager@thecomplianceteam.org