NIOSH 2020:
What you need to know

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Learning Objectives

1. Discuss changes in the Draft NIOSH 2020 list and potential implications

2. Understanding how to develop internal hazardous drug list

Background

1983 - ASHP guidance on hazardous drugs

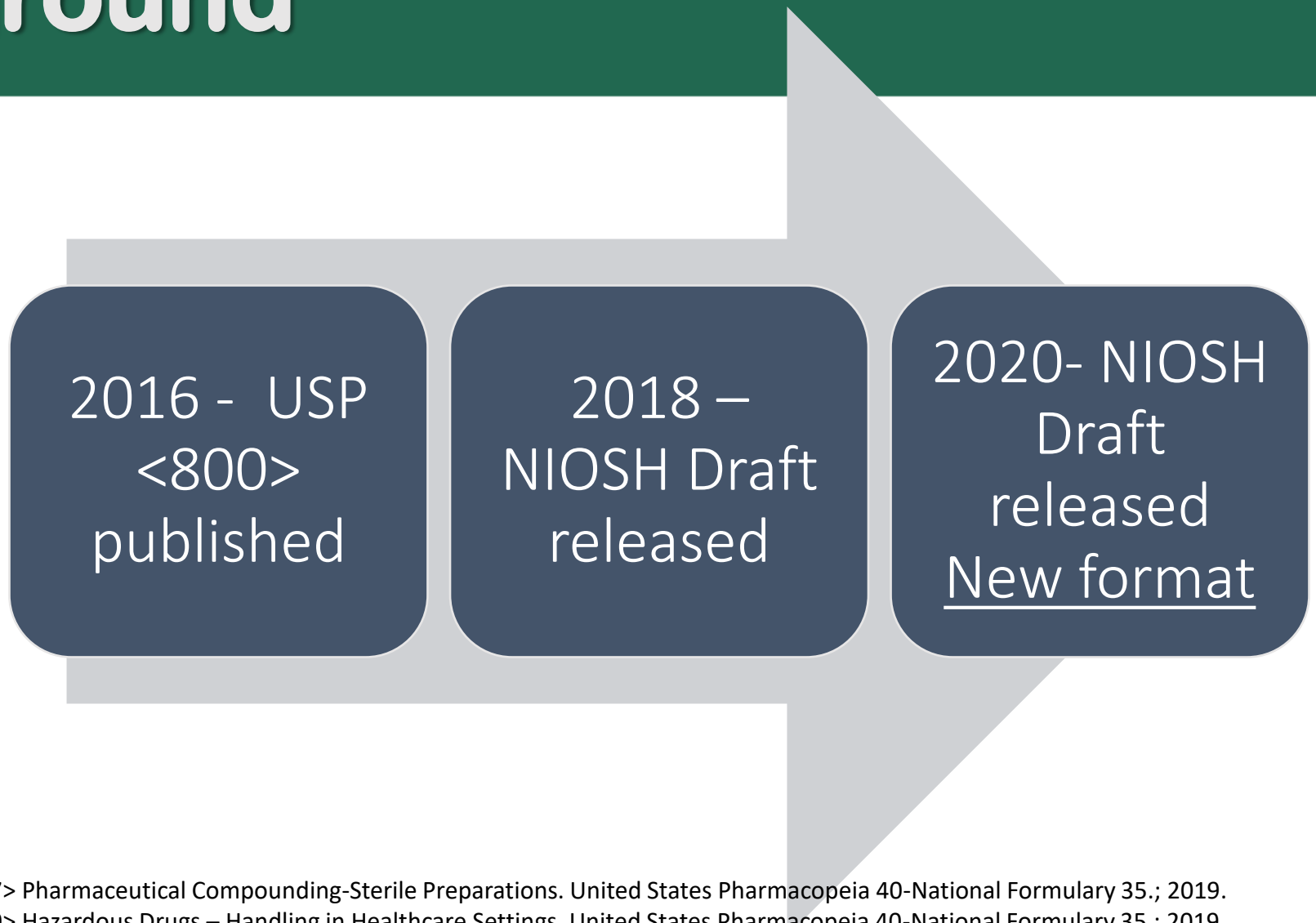
2004 - NIOSH Alert: Preventing Occupational Exposure to Antineoplastics

2006 - ASHP Guidelines harmonize with NIOSH

2008 - USP <797> revised, created HD enforceable standards

1. USP Chapter <797> Pharmaceutical Compounding-Sterile Preparations. United States Pharmacopeia 40-National Formulary 35.; 2019.
2. USP Chapter <800> Hazardous Drugs – Handling in Healthcare Settings. United States Pharmacopeia 40-National Formulary 35.; 2019.
3. Power LA. ASHP Guidelines on Handling Hazardous Drugs . American Journal of Health-System Pharmacy, Volume 75, Issue 24, 15 December 2018.

Background



1. USP Chapter <797> Pharmaceutical Compounding-Sterile Preparations. United States Pharmacopeia 40-National Formulary 35.; 2019.
2. USP Chapter <800> Hazardous Drugs – Handling in Healthcare Settings. United States Pharmacopeia 40-National Formulary 35.; 2019.
3. NIOSH [2020]. NIOSH list of hazardous drugs in healthcare settings 2020. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP, Ovesen JL, Whittaker C. Cincinnati, OH: U.S.
4. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication

Exposure Risk

- Manufacturing
- Distribution
- Receipt
- Storage
- Transport
- Compounding
- Administration
- Waste handling
- Care of treated patients

Routes of Exposure

- Inhalation
- Dermal absorption
  - Skin contact with contaminated surfaces is the primary route
- Accidental injection
- Ingestion

1. United States Department of Labor. Occupational Safety and Health Administration. Dermal Exposure

Exposure Risk

- Multi center study from 1999 showed surface contamination with antineoplastic HDs in both compounding and infusion areas
  - Measurable amounts of chemotherapy (cyclophosphamide, ifosfamide, and fluorouracil) were detected in 75% of the pharmacy wipe samples and 65% of the infusion area wipe samples

1. T H Connor et al. Surface contamination with antineoplastic agents in six cancer treatment centers in Canada and the United States, American Journal of Health System Pharmacy, Volume 56, Issue 14, July 15, 1999: 1427-1432

Exposure Risk

- NIOSH-sponsored study in 2010 looked at HD contamination and other risk points from the 1999 study
  - Found 75% of the pharmacy wipe samples and 43% of the infusion wipe samples.
- Multiple other international studies showing similar results

1. T H Connor, DeBord DG et al. Evaluation of Antineoplastic drug exposure of healthcare workers at three university based US cancer centers. J Occup Environ Med. 2010: 52(10):1019-1027

USP 800 Hazardous Drug List

- In 2016, USP Chapter 800 adopted the NIOSH HD list as the list of antineoplastic and other HDs that an organization should review
  - This list may be modified to include only the drugs that they handle and must be reviewed at least every 12 months
- 2018 NIOSH draft was published but never finalized after comment period

1. USP Chapter <800> Hazardous Drugs – Handling in Healthcare Settings. United States Pharmacopeia 40-National Formulary 35.; 2019.

ASBM Comments to NIOSH 2018

- ASBM comment on NIOSH 2018 Draft
- Recommended exclusion of large MW proteins

SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

16 April 2018

Submitted via e-mail to: hazardousdrugs@cdc.gov

NIOSH Docket Office
Robert A. Taft Laboratories
MS–C34
1090 Tusculum Avenue
Cincinnati, OH 45226–1998

RE: Alliance for Safe Biologic Medicines comments on NIOSH Hazardous Drugs List Additions for 2018; Reference CDC-2018-0004 and Docket Number NIOSH 233-B

The Alliance for Safe Biologic Medicines (ASBM) appreciates the opportunity to comment on the proposed additions to the NIOSH Hazardous Drug List for 2018 as posted to the Federal Register in February of this year.

ASBM is an organization composed of diverse healthcare groups — from patients to physicians, medical innovators, and others who are working together to ensure patient safety is at the forefront of biologic and biosimilar policies.

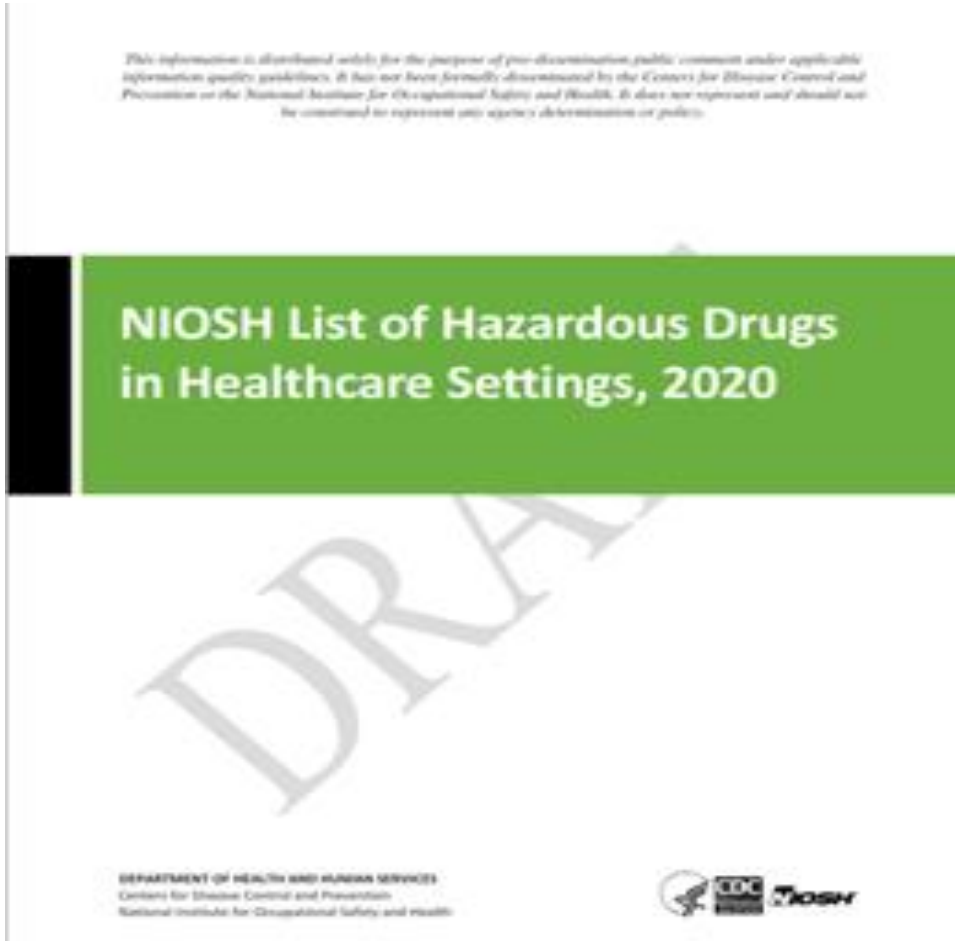
We respectfully suggest that **therapeutic proteins of large molecular weight are categorically excluded from the NIOSH Proposed List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings.** Therefore, we recommend that **blinatumomab, bevacizumab, and trastuzumab, and darbepoetin alfa are removed from the current NIOSH Proposed List.**

As we understand it, the routes of exposure for healthcare workers are mainly inhalation, ingestion, and skin contact. Large molecular weight proteins pose very little risk from exposure via any of these routes. These proteins are too large to be absorbed through skin contact, and if ingested, they would be destroyed by digestion; if inhaled, the pulmonary system would prevent absorption. Consequently, these drugs are all administered by injection. The only potential risk to healthcare workers is of an accidental needle stick, which would not inject a pharmacologically active dose.

1. https://safebiologics.org/wp-content/uploads/2020/08/ASBM_NIOSH_comments-FINAL-2018.pdf

NIOSH 2020 Draft - Revision

- May 2020 –another Draft NIOSH list and Name revision
  - Comment period ended July 30th 2020
- Now called *NIOSH list of hazardous drugs in healthcare settings*



1. NIOSH [2020]. NIOSH list of hazardous drugs in healthcare settings 2020. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP, Ovesen JL, Whittaker C. Cincinnati, OH: U.S.
2. https://www.federalregister.gov/documents/2020/05/01/2020-09332/hazardous-drugs-draft-niosh-list-of-hazardous-drugs-in-healthcare-settings-2020-procedures-and-risk

NIOSH 2020 Draft - Revision

- Grouped into two tables
- Table 1
  - Contain MSHI in the package insert and/or
  - Meet the NIOSH definition of a hazardous drug and
  - Classified by the NTP as “known to be a human carcinogen,” and/or classified by the IARC as “carcinogenic” or “probably carcinogenic.”

1. NIOSH [2020]. NIOSH list of hazardous drugs in healthcare settings 2020. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O’Callaghan JP, Ovesen JL, Whittaker C. Cincinnati, OH: U.S.
2. https://www.federalregister.gov/documents/2020/05/01/2020-09332/hazardous-drugs-draft-niosh-list-of-hazardous-drugs-in-healthcare-settings-2020-procedures-and-risk

NIOSH 2020 Draft - Revision

- Table 2
  - “Drugs that meet the NIOSH definition of a hazardous drug but are not drugs that have MSHI or are classified by the NTP as “known to be a human carcinogen,” or classified by the IARC as “carcinogenic” or “probably carcinogenic.” (some also may have adverse development and/or reproductive effects)

1. NIOSH [2020]. NIOSH list of hazardous drugs in healthcare settings 2020. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O’Callaghan JP, Ovesen JL, Whittaker C. Cincinnati, OH: U.S.
2. https://www.federalregister.gov/documents/2020/05/01/2020-09332/hazardous-drugs-draft-niosh-list-of-hazardous-drugs-in-healthcare-settings-2020-procedures-and-risk

Risk of Occupational Exposure

- The draft *Managing Hazardous Drug Exposures: Information for Healthcare Settings*
  - Intended to assist employers in establishing their own hazardous drugs management procedures specific to their workplace

1. https://www.federalregister.gov/documents/2020/05/01/2020-09332/hazardous-drugs-draft-niosh-list-of-hazardous-drugs-in-healthcare-settings-2020-procedures-and-risk

Risk of Occupational Exposure

- *NIOSH response:*
  - "Risks associated with how and how often a hazardous drug is used in a particular setting, and evaluation of exposure factors for all occupational exposures is beyond the scope of the *List.*"

1. https://www.federalregister.gov/documents/2020/05/01/2020-09332/hazardous-drugs-draft-niosh-list-of-hazardous-drugs-in-healthcare-settings-2020-procedures-and-risk

Viewpoints

ASBM Comments

- ASBM supported the NIOSH revision
- Change would allow for
  - Better medication access
  - Healthcare cost reduction

SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

30 July 2020

Submitted electronically via www.regulations.gov

NIOSH Docket Office
Robert A. Taft Laboratories, MS-C34,
1090 Tusculum Avenue,
Cincinnati, OH 45226-1998

RE: Alliance for Safe Biologic Medicines comments on *NIOSH List of Hazardous Drugs in Healthcare Settings, 2020* ; Reference CDC-2020-0046 and NIOSH-233-C

The Alliance for Safe Biologic Medicines (ASBM) appreciates the opportunity to comment on the proposed additions to the NIOSH Hazardous Drug List for 2020 as posted to the Federal Register in February of this year.

care providers, imposing requirements for safe receipt, storage, preparation, and administration. These burdens would have increased health care costs unnecessarily and negatively affected access to these new, breakthrough therapies; such as by limiting which sites these critical medications are available and can be administered, such as infusion clinics and a physician's office setting.

ASBM recognizes that balancing health care worker safety against health care cost impact and patient access is a complicated consideration in policy development, and we trust that NIOSH will continue to make good decisions as it attempts to strike the proper balance during its deliberations.

1. https://safebiologics.org/wp-content/uploads/2020/08/ASBM_NIOSH_comments-2020-FINAL.pdf

ASHP Comments

- Supports the elimination of the AHFS therapeutic classification as a method of categorizing
  - "AHFS classification indicates the drug is used to treat cancers, regardless of mechanism of action or toxicity."
- Supports categorization into tables based on IARC and NTP classification

1. https://www.ashp.org/advocacy-and-issues/key-issues/medication-safety/niosh-list-of-hazardous-drugs-in-healthcare-settings-2020?loginreturnUrl=SSOCheckOnly

ASHP Comments

- Concern over the **Definition of Hazardous Drugs**
  - List limited to drugs approved by FDA's Center for Drug Evaluation and Research (CDER)
- Concern over criteria: "unless the drug also **exhibits a molecular property that may limit the potential for adverse health effects** in healthcare workers from exposure to the drug."
  - Most MABS excluded from list due to this reason

1. https://www.ashp.org/advocacy-and-issues/key-issues/medication-safety/niosh-list-of-hazardous-drugs-in-healthcare-settings-2020?loginreturnUrl=SSOCheckOnly

ASHP Comments

- Concern over the use of manufacturer's special handling information (MSHI) as a criteria for categorization.
  - No requirement to include MSHI information in prescription drug labeling.
  - **Disincentive for manufacturers** to MSHI in product labeling for hazardous drugs in the future.

1. https://www.ashp.org/advocacy-and-issues/key-issues/medication-safety/niosh-list-of-hazardous-drugs-in-healthcare-settings-2020?loginreturnUrl=SSOCheckOnly

ASHP Comments

- ASHP proposed consideration of a drug's mechanism of action.
  - "If a new drug is not classified by IARC nor the NTP and does not include MSHI but the mechanism of action is the same or very similar to a drug already in Table 1, the new drug should be included in Table 1 until evidence exists to demonstrate it is not carcinogenic. "

1. https://www.ashp.org/advocacy-and-issues/key-issues/medication-safety/niosh-list-of-hazardous-drugs-in-healthcare-settings-2020?loginreturnUrl=SSOCheckOnly

Implications of NIOSH revision

Action	Current
Medication Access	Ability to provide MAB's in non-oncology infusion centers, doctors offices etc
Cost savings	No need for CSTD's (Ex. $13-$23 or more per dose) No need for BSC and Negative pressure cleanrooms Pharmaceutical waste Empty vials/bags would not need to be disposed of as Trace hazardous waste
Hazardous exposure risk	Additional routes of exposure (inhalation, accidental injection) and unknowns

Assessment of Risk

- Determination of risk
- Requires review of:
  - Available dosage forms
  - Packaging
  - Manipulation requirements
  - Risk of Exposure
  - PPE
  - Containment strategies

HOPA
Hematology/Oncology Pharmacy Association

Approved/Effective Date:	
Approved by:	
Annual Review by:	
Date Reviewed:	

ASSESSMENT OF RISK FORM

TO BE COMPLETED FOR ANY DRUG BEING CONSIDERED FOR CONTAINMENT STRATEGIES THAT DIFFER FROM FULL NIOSH RECOMMENDATIONS, AS DEFINED IN USP GENERAL CHAPTER <800> HAZARDOUS DRUGS-HANDLING IN HEALTHCARE SETTINGS.

Drug Name		
Dosage Form	☐ Tablet / Capsule ☐ Oral Liquid (commercial) ☐ Compounded liquid	☐ Pre-filled syringe ☐ Solution/powder for injection ☐ Other:
NIOSH Category:	☐ Table 1: Antineoplastic Drugs that only require packaging or counting ☐ Table 2: Non-antineoplastic Drugs ☐ Table 3: Reproductive Toxin Drugs	
Description of Packaging	☐ Final dosage form, ready for dispensing directly to patient (*i.e., unit dose, unit-of-use*) ☐ Bottle of [tablet/capsule/liquid] to be repackaged ☐ Other:	
Description of Required Manipulation	☐ None (product available in ready-to-dispense package) ☐ Repackaging only (e.g. counting; transfer container) ☐ Other:	
Risk of Exposure	☐ Skin contact ☐ Ingestion ☐ Inhalation ☐ Injection ☐ Other (specify):	
Alternative Containment Strategies and/or Work Practice	[Engineering Control *(i.e., BSC, containment isolators, CSTDs, temporary designated prep. area)*]	
	[Administrative Control *(i.e., educational materials, acknowledgement form, training)*]	
	[PPE Strategies *(i.e., gloves, gowns, booties, head cover, face shield, eye protection, respirators)*]	
Recommendation	☐ Follow all containment requirements (as per USP<800>) ☐ Follow alternative containment strategies documented above	

AoR = assessment of risk; API = active pharmaceutical ingredient; CSTD = closed system drug-transfer device; HD = hazardous drug; MSHG = Manufacturer Suggested Safe Handling Guideline; NIOSH = National Institute for Occupational Safety and Health; PPE = personal protective equipment; USP = U.S. Pharmacopeia

1. https://www.hoparx.org/images/hopa/resource-library/professional-tools/USP800_Assessment_of_Risk_Form.pdf

Miami Cancer Institute
BAPTIST HEALTH SOUTH FLORIDA

Drug Name	Divalproex
Dosage Form	☑ Tablet / Capsule ☑ Oral Liquid (commercial) ☐ Compounded liquid ☐ Pre-filled syringe ☑ Solution/powder for injection ☐ Other:
NIOSH Category:	☐ Table 1: Antineoplastic Drugs that only require packaging or counting ☑ Table 2: Non-antineoplastic Drugs ☐ Table 3: Reproductive Toxin Drugs
Description of Packaging	☑ Final dosage form, ready for dispensing directly to patient (*i.e., unit dose, unit-of-use*) ☑ Bottle of [tablet/capsule/liquid] to be repackaged ☐ Other:
Description of Required Manipulation	☑ None (product available in ready-to-dispense package) ☑ Repackaging only (e.g. counting; transfer container) ☐ Other:
Risk of Exposure	☑ Skin contact Exposure risk minimal, risk is associated with ingestion not due to routine handling ☐ Ingestion ☐ Inhalation ☐ Injection ☐ Other (specify):
Alternative Containment Strategies and/or Work Practice	**[Engineering Control** *(i.e., BSC, containment isolators, CSTDs, temporary designated prep. area)***]**
	[Administrative Control *(i.e., educational materials, acknowledgement form, training)***]** Hazardous Drug Acknowledgement of Risk Form
	[PPE Strategies *(i.e., gloves, gowns, booties, head cover, face shield, eye protection, respirators)***]** Chemotherapy Gloves only for any handling

Developing a HD List

- NIOSH list meant to be a starting point
  - Official NIOSH list is from 2016
- Vigilance around new medications, **vaccines** approved under BLA etc.
- **Internal risk assessment** should drive your HD List

Pop Quiz

An entities hazardous drug list may be different from the NIOSH hazardous drug list

True

Pop Quiz

The NIOSH 2020 list is comprehensive and ready for implementation

False