800 Task Force Minutes **November 7, 2017**

-Discussion of "inclusion list" from group 2 or 3 that could be considered for alternative risk assessment stratisfication. (parameters to be determined by task force group)

-Medications to be included:

- Estradiol, Medroxyprogesterone, progesterone, testosterone, methimazole, finasteride, fluconazole, oxytocin, tretinoin, clonazepam, colchicine, spironolactone, and

-outside entity (U of U Drug Information and IMC Drug Information) to analyze and review list

-What is in the published literature to define exposure risk from these agents?

-Is there anything published in the literature that examines risk reduction by use of PPE?

-Discussion UPhA compounding of HD exposure survey

27 responses; only 40.7% have powder containment hoods

-Set up meeting with DOPL (Mark Steinagel/Jennifer Zaelit) for budget proposal to have Drug Information Centers analyze risk for certain HDs on the NIOSH list

-Jim and Trip will make a proposal for a legislative bill to cover the cost of outside entity to review the literature of hazardous drug exposure for certain medications to be on the "inclusion list" to opt out of full 800.

Jim and Trip met with Mark Steinagel on December 19th to gain insight on options to cover the cost associated with the proposed review of the "inclusion list" by the outside entity. Mark Steinagel stated that a legislative bill would not be necessary and that the State would grant us $50,000 for the 800 review that the task force is requesting. This is outstanding progress and news for our endeavors with how to best proceed with adoption of our 800 and hazardous drug handling within our State. A big thanks to Mark Steinagel and the State for helping us move this forward.

-See attachment: 800 Recommendations to the Board by the Compounding Task Force

Mark your calendar for February 7th and 8th ACHC PCAB accreditation and USP 800 workshop in SLC

****Next meeting scheduled for Tuesday January 16th, 2018 at U of U College of Pharmacy at 7 am****

800 recommendations to the Board of Pharmacy by the Compounding Task Force

State enforcement of 800 by December 2019;

By December 2018

All pharmacies:

Must have a designated HD representative

Must have a HD list for their facility

Must have at least a powder containment hood

Must follow all PPE requirements within the chapter (to be discussed in more detail)

Must follow the cleaning, disinfecting and decontamination steps within the chapter

Changes to 800: Recommendations deal only with Group 2 and 3 of the NIOSH list

Section 2: List of Hazardous Drugs

Box 1: Containment Requirements

*Drugs on the NIOSH list that must follow the requirements of this chapter:

-Any HD API with the exception of the approved risk analysis category list

-Any antineoplastic requiring HD manipulation

*Drugs on the NIOSH list that do not have to follow all the containment requirements of this chapter if an assessment of risk is performed and implemented include:

-Final dosage forms of compounded …….

-HD API from group 2 or 3 of the NIOSH list that have been approved for a risk analysis category list

This list includes the following medications:

Estradiol, medroxyprogesterone, methimazole, progesterone, finasteride, fluconazole, oxytocin, tretinoin, clonazepam, colchicine; spironolactone, and (we as a task force should go thru meds on the list one by one to determine the approved list). Outside entity (drug information of IMC and U of U) to review issues related to exposure of the above medications. Task force will make a proposal for a legislative bill to cover the cost of this research.

**If an entity chooses to opt out of full 800 the facility must have a medical survelliance program; Intial and every 2 years; questionnaire would be suffice to show trends; also recommend we have a pilot study with certain parameters to report. Then we revisit 800 in 2020 for update.

**IF entity chooses to opt out of full 800 and perform a risk assessment for alternative containment strategies certain items must be followed:

- Must follow all PPE requirements
- Must follow all cleaning, disinfecting, and decontamination steps
- Must have a powder containment hood (vented to outside?)
- Must have a medical survelliance program
- BPR would be to store all medications from the "inclusion list" in a clearly marked area and to use the same utensils and equipment (including powder containment hood if possible)

*****Goal to remove all shoulds and only have "Must" included in our Rules to establish clarity and have less gray areas for pharmacies and inspectors.

*****After 800 Rules are established, task force would like to work with DOPL inspectors and investigators to create an inspection form and discuss educational opportunities to enhance compliance

****USP has delayed the implementation date of USP 800 to December 1, 2019****