

**MINUTES**  
**UTAH ADVISORY PHARMACY COMPOUNDING EDUCATION COMMITTEE**  
**ELECTRONIC MEETING**  
**MARCH 25, 2021 | 9:00 A.M.**  
**HEBER M. WELLS BUILDING**  
**SALT LAKE CITY, UT 84114**

**DUE TO COVID-19, NO PUBLIC ANCHOR LOCATION WAS PROVIDED.**  
**PUBLIC ATTENDANCE BY PHONE**

**CONVENED:** 9:04 A.M.

**ADJOURNED:** 10:28 A.M.

**DOPL STAFF PRESENT ELECTRONICALLY:**

**Bureau Manager:** Jennifer Falkenrath

**Pharmacy Inspector:** Sharilee McIntyre

**Board Secretary:** Jennifer Johnson

**Pharmacy Inspector:** Travis Drebing

**Pharmacy/Health Program Specialist:**  
Jim Garfield

**Pharmacy Investigator:** Jennifer Healey

**COMMITTEE MEMBERS PRESENT ELECTRONICALLY:**

**Chair:** Matthew Higley, PharmD.

Hali O'Malley, PharmD.

**Vice Chair:** Chris Cox, PharmD.

Christopher Kane, PharmD.

Jeremy Olsen, PharmD

**COMMITTEE MEMBERS NOT PRESENT:**

Adam Taintor, MD

Casey Sayre, PharmD

**GUESTS ATTENDED ELECTRONICALLY:**

Jeanne Brennan

Rocky Parker

Lauren German

MitHil Shah

McKenzie Hammon

Bart Smith

Note: Others may have attended but were not identified.

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**AMINISTRATIVE BUSINESS:**

**CALL MEETING TO ORDER**

**Dr. Higley called the meeting to order at 9:04 A.M.**

**APPROVE DECEMBER 17, 2020, MEETING MINUTES**

*Refer to audio for specifics (Audio) (00:03:00 – 00:05:35)*

**The Committee reviewed the minutes.**

**Dr. Cox made a motion to approve the minutes with corrections**

**Dr. O'Malley seconded the motion.**

**The Committee motion passed.**

## **DISCUSSION ITEMS:**

### **FDA MOU DISCUSSION**

*Refer to audio for specifics (Audio) (00:05:41 -00:38:30)*

**Dr. Higley reviewed information regarding the FDA MOU and stated some feedback had been provided from the public.**

**Dr. Higley stated the FDA MOU affects those pharmacies that ship more than 5% of drug product out of the state. For those states that chose to not sign the FDA MOU, their pharmacies would no longer be allowed to ship more than 5% of drug product out of the state. The deadline to sign the FDA MOU is October 2021.**

**Dr. Higley stated the FDA MOU has several provisions regarding reporting of adverse events or complaints related to the compounded products, as well as reporting pharmacies that ship more than 50% of their yearly compounded product.**

**Dr. Higley discussed information provided by NABP regarding surrounding states not wanting to sign or not being able to sign due to legal reasons or issues with those states rules and regulations. Dr. Higley stated he does not believe there are any legal reasons that would prevent Utah from signing, but stated Utah is waiting to sign at this time while additional information is being gathered.**

**The Committee reviewed concerns submitted by pharmacies within the community. One of the biggest concerns is the impact it would have on pharmacies if Utah chooses not to sign preventing pharmacies from being able to ship more than 5% of their compounded product outside of the state.**

**Ms. Falkenrath stated the FDA will be having a virtual listening session April 7<sup>th</sup>, April 8<sup>th</sup>, and April 9<sup>th</sup> from 2:00 PM – 4:00 PM (EST), which is 12:00 PM -2:00 PM (MST), if any of the Committee members were interested in attending. There is a registration process and Ms. Falkenrath will need to let the FDA know if any Committee members from Utah will be attending.**

**The Committee stated they would like to draft a letter of concern to the FDA regarding the concerns Utah has with the MOU ahead of the virtual listening session. Ms. Falkenrath stated the letter would need to be provided by Tuesday, March 30, 2021, and would need review and approval from the Board of Pharmacy.**

**The Committee indicated because a decision does not have to be made until October of 2021, they would like to take this time to gather additional information as well as see if there is an outcome regarding the lawsuit filed against the FDA over the MOU.**

**The Committee will plan to discuss any updates regarding the FDA MOU at the next Advisory Pharmacy Compounding Education Committee meeting scheduled for June 24, 2021. There will be an additional meeting scheduled for September as well and by that time Utah should hopefully have more information to make a decision to sign or not by the deadline of October 2021.**

## **INSANITARY CONDITIONS**

*Refer to audio for specifics (Audio\_01) (00:38:37 – 00:46:20)*

**Dr. Higley stated he presented the document Dr. Jeremy Olsen drafted to the Board of Pharmacy (BOP). Dr. Higley stated the BOP liked the draft document but stated they wanted the document to state the facts regarding the regulations and differences between USP <795>, <797>, and the Insanitary Conditions document and not appear as though the Committee is making recommendations on how to operate.**

**Dr. Higley discussed the changes he made to the document based on the BOP feedback. The Committee stated they like the changes made and discussed other areas that need to be updated.**

**Dr. Higley stated the BOP would like to publish the document in the next quarterly newsletter.**

**Ms. Falkenrath stated articles for the May newsletter need to be submitted by April 1<sup>st</sup>, 2021.**

**Ms. Falkenrath stated the BOP would need to approve the final draft of the document before it could be added to the next newsletter.**

**Dr. O'Malley made a motion to approve the updated *Insanitary Conditions* document and present to the BOP for approval.**

**Dr. Cox seconded.**

**The Committee motion passed.**

**Dr. Higley and Dr. O'Malley stated they would be available to present the document at the upcoming BOP meeting.**

## **BIO-IDENTICAL HORMONES**

*Refer to audio for specifics (Audio) (00:46:25 – 1:09:00)*

**The Committee discussed the report provided by National Academies of Sciences, Engineering, and Medicine (NASEM) regarding Bio-Identical Hormones.**

**Dr. Higley stated the FDA asked NASEM to look at Bio-Identical Hormones. NASEM generated a 300 page report regarding their recommendations. One area of recommendation stated any pharmacy dispensing Bio-Identical Hormones must provide patients with standardized package inserts with warnings and additional information about the product being compounded and not approved.**

**Dr. Higley stated a lawsuit has been filed against the FDA regarding the NASEM Report.**

**The Committee discussed the information associated with the lawsuit and NASEM Report recommendations.**

**Questions, comments, and concerns were discussed.**

**Ms. Falkenrath stated the BOP received the request for review of the NASEM report from Dr. Mark Munger from the University of Utah. The BOP has asked for the Advisory Pharmacy Compounding Education Committee to review the recommendations of the NASEM report to determine if and determine if there were any patient safety concerns that need be addressed and if any changes to regulation need to be made.**

**Dr. Higley stated the NASEM report is only a recommendation and is a non-binding report. Those who involved in compounding, already do a lot of what is recommended in the report and at this time he does not feel there is not a requirement for action.**

**Dr. Cox stated he sees a lot of issues with the NASEM report and is uncomfortable making recommendations and is strongly opposed to the NASEM report recommendations**

**Dr. O'Malley stated she too had major concerns with the NASEM report.**

**Additional questions, comments, and concerns were discussed.**

**Ms. Falkenrath stated she would need to have an official motion made regarding the Committee's recommendations on the NASEM Report.**

**Dr. Cox made a motion the Advisory Pharmacy Compounding Education Committee does not accept the NASEM report recommendations and Utah does not need to make changes to the regulations.**

**Dr. O'Malley seconded the motion.  
The Committee motion passed.**

**Dr. Higley stated this information will be provided to the BOP at their next Board meeting.**

**USP <800>**

*Refer to audio for specifics (Audio) (1:09:30 – 1:24:19)*

**Dr. Cox stated he wanted this added to the agenda in order to get an update on where things are at with USP <800>.**

**Dr. Higley stated at this time it's his understanding information is back to the drawing board and a new USP <795> and <797> Committee has been created. To his knowledge USP <800> is complete it just cannot be adopted or enforceable until the new versions of USP <797> and <795> are adopted and implemented by Utah.**

**Dr. O'Malley stated the Utah BOP adopted USP <800>, language had been modified, but implementation was being tabled due to the appeals that had been filed against USP <795> & <797>. Dr. O'Malley stated there were also discussions with redoing the NIOSH tables.**

**Ms. Falkenrath stated the rules had been drafted and were awaiting the Division Directors signature when the Division was notified about the USP <795> & <797> appeals. At that time the decision was made to hold off on approval until the appeals process was resolved.**

Ms. Falkenrath stated if the NIOSH tables are being redone this will require how the rules are written. Ms. Falkenrath stated every time USP <795> and <797> are identified in rule it has to be incorporated by reference. This means it has to be defined as to what version of USP <795> and <797> Utah has adopted each time the rules are drafted.

The Committee stated they will plan to discuss at a future meeting especially when the final version of the new approved USP <795> and <797> are released.

Additional questions and comments were discussed.

**NEXT SCHEDULED MEETING: Thursday, June 24, 2021**


**ADJOURNED:** Meeting adjourned at 10:28 A.M.

Note: These minutes are not intended to be a verbatim transcript but are intended to record the significant features of the business conducted in this meeting. Discussed items are not necessarily shown in the chronological order they occurred.

06/24/2021  
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Date Approved

(ss)   
\_\_\_\_\_  
Matthew Higley (Jun 24, 2021 14:49 MDT)  
Dr. Matthew Higley, Chairperson  
Advisory Pharmacy Compounding Education  
Committee

06/24/2021  
\_\_\_\_\_  
Date Approved

(ss)   
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Jennifer Falkenrath (Jun 24, 2021 16:20 MDT)  
Jennifer Falkenrath, Bureau Manager  
DOPL