



May 4, 2015

United States Pharmacopeia Convention
CompoundingSL@usp.org

To whom it may concern,

The College of Psychiatric and Neurologic Pharmacists (CPNP) thanks the USP Compounding Expert Committee for the changes made in the most recent draft of USP General Chapter 800 Hazardous Drugs – Handling in Healthcare Settings. We appreciate your willingness to accept input and work with stakeholders to minimize unintended adverse impact from the chapter. The elimination of the more onerous storage requirements for non-antineoplastic drugs is a major improvement. We have reviewed the most recent draft and have suggestions to further clarify the chapter and address the concerns of our membership.

CPNP is the professional society of pharmacists who specialize in providing care for persons with psychiatric and neurologic conditions. Our members serve in a variety of roles including as clinical pharmacists (public and private), managers and directors of pharmacy, academia, state mental healthcare and in industry. The mission of CPNP is to advance the reach and practice of neuropsychiatric pharmacists. CPNP recognizes the importance of protecting healthcare workers from hazardous medications and supports the intent of the chapter.

CPNP continues to oppose the use of the NIOSH Hazardous Drugs List for classification of a medication as hazardous. In our previous letter regarding the initial draft of USP General Chapter 800, we detailed the problems with the NIOSH List. We ask that USP reconsider the use of the NIOSH list and the appropriateness and necessity of including non-cytotoxic/non-antineoplastic agents such as psychiatric medications under the same handling regulations as cytotoxic chemotherapy.

CPNP has previously expressed concerns to the National Institute for Occupational Safety and Health regarding inclusion of certain psychotropics on the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012. It is the position of CPNP that risk to healthcare workers from routine exposure to these non-cytotoxic medications is minimal, even when individual doses are divided or crushed. In fact, hundreds of thousands of family members, assisted living staff and health professionals have been exposed to some of the maintenance medications for chronic conditions (such as psychiatric medications including risperidone, ziprasidone, divalproex, valproic acid, clonazepam, phenytoin, carbamazepine, paroxetine, topiramate) on the NIOSH list for decades without the detection of significant toxicity of the type that prompted USP to develop Chapter 800. This lack of evidence further justifies their exclusion from Chapter 800.

CPNP supports the classification of medications that present acute or chronic occupational hazards due to a high likelihood of contact sensitivity or causticity as hazardous drugs. This would include drugs for which manufacturer's labeling recommend precautions and that are designated as known or probable carcinogens (by International Agency for

Research on Cancer and National Toxicology Program). Unnecessary and substantial burdens would be placed upon healthcare facilities if medications are classified as hazardous only through extensive extrapolation.

If USP is unwilling or able to develop its own list using the transparent and scientifically rigid procedures for which it renowned, CPNP would offer a compromise. We recommend that USP specifically exempt non-antineoplastic agents on the NIOSH list from the following sections of USP General Chapter 800:

- Section 7 Personal Protective Equipment
- Section 7.1 Gloves
- Section 7.2 Gowns
- Section 7.3 Head, Hair, Shoe, and Sleeve Covers
- Section 7.4 Eye and Face Protection
- Section 7.5 Respiratory Protection
- Section 8 Hazard Communication Program
- Section 10 Receiving
- Section 11 Labeling, Packaging, and Transport
- Section 13 Administering
- Section 15 Deactivation/Decontamination, Cleaning, and Disinfection
- Section 16 Spill Control

We would further recommend that the requirement for maintaining medical surveillance records (quantities of HDs handled, etc.) be eliminated for non-antineoplastic agents. We do acknowledge that compounding is the highest risk activity related to HDs and we would be agreeable to the applicability of that section to all HDs.

CPNP is of the opinion that these changes would greatly enhance the clarity of the chapter and reduce the unintended consequences of its implementation. We remain concerned that the current version of the chapter will divert limited resources away from patient care and towards implementation, increase the stigma related to psychiatric medications and mental disorders and frighten those with chronic disorders (as well as their caregivers) thereby reducing adherence to safe and effective treatment.

USP is an internationally respected standards setting organization that is renowned for its scientific approach and its transparency in developing standards. CPNP urges USP to carefully examine the science behind the non-antineoplastic portions of the NIOSH List and the degree to which practicing health professionals from diverse care settings have input into its development and maintenance. Any list that USP incorporates into its standards should meet the same level of rigorous science, transparency and opportunity for widespread health professional input as a USP standard.

Thank you for your review and thoughtful consideration of these comments.

Sincerely,



Raymond C. Love, PharmD, BCPP, FASHP
President-Elect, College of Psychiatric and Neurologic Pharmacists