To;

Editorial staff

RE: **USP800 and the requirement to collect Cytotoxic Chemotherapy Drugs excreted in the Patient’s Sweat, Urine, Feces and Saliva.**

Dear Editor

It has been a long process to convince the regulators and the people responsible for healthcare safety that;

(1) Chemo drugs that are excreted by the patient are the same chemicals and deserve the same respect

(2) this is a real problem that is killing people that are exposed to these chemicals and causing birth defects in future generations

(3) that there is a way to fix it.

We believe that part of the resistance to their acknowledgment is the institutional fear of the liability for their past actions by sending patient’s home to expose their families, ( same as sending them home with a bag of chemo in their pocket) and part is the heavy cost both in dollars and in systemic change that the solution requires.

It is our strong opinion that neither of these reasons to slow roll the reform process are legitimate and in fact we believe is a systemic moral failure. We understand that the money is not limitless but the cost per lives saved for a 2 to 3% increase in the cost of some types of cancer care, particularly when those lives are in many cases family members, children, and caregivers of those cancer patients is not so high that it should be a bar to implementation of the new protocols.

USP 800 takes a very big step in the right direction by acknowledging and codifying the problem with the language they use it is now impossible for pharmacist and hospitals to deny the reality of the environmental risk of cytotoxic drugs. USP 800 does not explicitly impose a solution but foresees the issue any pharmacist who does not want to be in the crossfire’s the massive new era of litigation and regulatory pressure will have new protocols in place by the December 1, 2019 deadline. Anyone who ignores that deadline will find themselves and the hospitals they work for paying a very steep price over the next 5 to 10 years.

So a minute ago I said that USP 800 doesn’t “impose a solution” that merits explanation and clarification because this is at the heart of the debate right now. USP does in fact impose a solution and for the most part they get it right, they recognize the dangers these treatments pose they recognize and actually mandate various protocols that will limit the risk of these treatments to third parties and to the environment they make explicit standards that anyone who works under USP 800 must follow.

What we try very hard to do, however, is to make the standards clear without crossing the line that would exceed what they might view as their reach. They have not generally in the past, had to deal with an issue that bleeds over so heavily from the hospital environment into the home environment. Maybe with radiation, maybe with contagious outbreaks generally, but not with outpatient individuals. They were walking a delicate line and probably for the two reasons we first mentioned above. Their constituents face massive legal liability, and explicit statement of what they are saying implicitly in USP 800 would be a class action lawyers dream and the cost to implement a solution is a healthcare insurer or government payers nightmare.

We understand why they walk that line – there would be pillared otherwise, but we are thrilled that in USP 800 they delicately but undeniably make the case that we have been making for a decade now. With USP 800 the Rubicon has been crossed and the pharmacist in the hospital systems can no longer slow role their acknowledgment of the problem and the necessity of the solution. December 1, 2019 is a hard deadline and USP 800 tells them that they better be ready.

I have attached the following link to an article in the trade journal for people that pump septic systems and the dangers to the workers cleaning out a septic system destroyed by the human waste from a patient on Chemo. The dangers are the same as to the Pharmacist and in most cases the exposure is much greater. This is the link <https://www.pumper.com/online_exclusives/2019/01/septic-tanks-can-hold-dangerous-levels-of-chemo-drugs> .

It is fairly obvious that the property is impacted and the well water contaminated, will the pharmacist’s malpractice insurance cover the cost of clean-up and the damage to the family and caregivers?

I am also attaching the following;

Correspondence I received on July 25,2018;

1. Letter dated July 24, 2018 from [The Joint Commission](../USP%20800%20legal/Pharma-Cycle%20Joint%20Commission.pdf) on the topic of an online course I was giving on USP 800 and containing the human waste. The Joint Commission is the most powerful organization in Healthcare.
2. Letter dated July 19, 2018 from [USP headquarters](../USP%20800%20legal/Pharma-Cycle%20re%20800%20Course.pdf). USP is the most powerful organization in Pharmacy.

The significance of the timing of the letters shows the importance of the topic and it is at the highest level in both organizations.

1. Letter from [Cameron & Mittleman LLP](../USP%20800%20legal/2809242-Response%20to%20USP%20-%20Alexander%2C%20K%202018-8-1.PDF) responding to both The Joint Commission and USP. I highly recommend you read the letter carefully as it points out the significance of this landmark standard in protecting the health all people exposed to Cytotoxic Chemotherapy drugs. A key statement in the response reads;

“we also agree that in and of itself USP 800 does not contain a mandate of collection of patient excretion outside of healthcare facilities. USP 800 does not, however, exist in a vacuum, and effectively imposes that very requirement. From Hippocratic oath forward healthcare providers do not have the luxury of taking only limited readings of the sort of guidance USP 800 offers”

1. Letter dated September 5, 2018 from [USP in response](../USP%20800%20legal/2857807-Letter%20from%20USP%209-5-2018.pdf). The significance of this letter is that it states “We maintain the position that <800> does not effectively impose the requirement to collect excreta outside of healthcare facilities.” Our position is that it does impose the collection of excreta inside of healthcare facilities and that home healthcare makes the patient’s home a healthcare facility.

We have further commented on USP 797 and expect our concerns to be addressed in the upcoming revision.

We hope to be included in your publication and would be happy to answer any questions.

Sincerely

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