March 2021

TO: State of Rhode Island
   Department of Environmental Management
   Office of Land Revitalization & Sustainable Materials Management

FROM: Jim Mullowney
   President & CEO, Pharma-Cycle LLC
   Science Advisor to the Cytotoxic Safety Council

RE: Comment Hearing on a Medical Waste Management Facility License

Offering comment in opposition to the issuance of a new license to MedRecycler-RI, Inc to treat medical waste.

As a chemist and medical waste expert, I serve as a science advisor to the Cytotoxic Safety Council and own a Rhode Island based company that safely disposes of excreted cytotoxic drugs. Many drugs used to treat cancer have their roots in chemical weapons and are DNA-altering. Any level of exposure to these dangerous chemicals can cause cancer and birth defects now and in the future.

In 2009, I gave a presentation to EPA headquarters entitled “Drugs Are Chemicals Too.” As a result of the information provided in that discussion, almost every medical waste incinerator in the U.S. was shut down. It’s a simple statement. Nothing has changed since that 2009 presentation.

Make no mistake, MedRecycler Pyrolysis will destroy any living thing which is fine for treating biological hazards that die when exposed to sunlight. The proposed incinerator does not have the same effect on chemicals.

Rhode Island air permits focus on pathogens and other living dangers. Looking at the proposed MedRecycler facility solely on this basis, of course it is safe. What is not being considered in the other dangerous chemicals that are classified by the DEM as “medical waste.”

A significant amount of this “medical waste” will contain the most dangerous chemicals ever invented. During WWII, the U.S. Navy vessel S.S. John Harvey was carrying liquid Mustard Gas (aka Mustargen, a common chemotherapy drug) was bombed in Bari Harbor in Italy, catching fire and gasifying the Mustard Gas. Thousands were killed, but it was discovered the cancer patients got better, this was the birth of chemotherapy.¹

¹ The Day of Battle by Rick Atkinson “The Entire World Was Burning” page266 - 278
These very dangerous chemicals are used very effectively to treat cancer, but as an unintended byproduct of chemotherapy treatment, chemo patients excrete up to 90% of chemo drugs in their original active form. If the chemicals remaining in cancer patients’ “medical waste” are incinerated, they will become airborne chemical weapons that threaten us and future generations. These chemicals are mutagenic (cause birth defects), teratogenic (skips a generation before causing a birth defect) and carcinogenic (cause cancer).

These chemicals are drugs. The MedRecycler system does not eliminate or destroy them.

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**EPA Regulations**

The EPA recognized the dangers of incinerating medical waste and incorporated that fact into medical waste incineration regulations. EPA regulations do not allow incineration of drugs in any form, including drugs remaining in bodily fluids.

The proposed MedRecycler facility in West Warwick is a medical waste incinerator. It will take in nearly 23% oxygen and return less than 2% oxygen in the Syngas.

Anyone who has ever lit a campfire knows that the wood itself does not burn. The gases created by the heat burn. Pyrolysis captures that gas before it catches fire. The MedReclyer facility is capturing that gas, moving it feet away, and incinerating it.

Pyrolysis has been around since the 1870’s with its beginnings in coal gasification. Those in the environmental protection world know what a disaster that process left for future generations.

This MedRecycler medical waste will use a century-old process that caused terrible damage to our environment. Their facility will put chemical weapons into the air we breathe, the air our children and families breathe, and the air future generations will breathe. They will wind up not only in our air, but in the Bay, in our soil, and in our drinking water. **And ultimately in us. The consequences are dire.**

The U.S. regulation covering medical waste incinerators (40 CFR 60.55C) was changed in 2009 when I, and many other advocates, sounded the alarm. **The regulation**
prohibits pharmaceuticals from being disposed of in a medical waste incinerator. **PERIOD.** This regulation does not discriminate as to whether that pharmaceutical is a trace residue, a bottle of pills, a vial of chemo drugs, or is contained in bodily fluids or contaminated waste from cytotoxic drugs.

**The World Health Organization**

The E.U. is leading the charge in collecting and segregating chemotherapy patient excreta in hospitals and outpatient settings because they recognize just how dangerous this chemical waste is. The U.S. is lagging in this regard. We don’t adequately educate cancer patients or enforce the regulations set forth in USP800 (see below). Hospitals and outpatients are flushing contaminated waste directly into toilets where it ultimately enters our waterways. If this MedRecycler facility is approved, cytotoxic human waste will undoubtedly be forwarded to this facility in a “red bag.” With the proposed process, the chemotherapy chemicals will be incinerated and will spew life-threatening cytotoxins out of the stack and into our air.

"Any discharge of genotoxic waste into the environment could have disastrous ecological consequences." ……WHO

**U.S. Government Regulations**

In 2019 United States Pharmacopeia ([USP](https://www.usp.org)), a regulatory body of the FDA, issued [USP800](https://www.usp.org) protecting people from cytotoxic chemotherapy drugs.

This act of Congress, [The Drug Quality and Security Act (Public Law 113-54)](https://www.congress.gov/bill/113th-congress/house-bill/54), was signed by Senators Sheldon Whitehouse, Senator Jack Reed, Representative David Cicilline and Representative Jim Langevin. These distinguished legislators are all very aware of the dangers of these cytotoxic drugs and have been given detailed presentations on the problem.
USP800 mandates that everyone who handles these chemotherapy drugs, from pharmacist to nurses to techs and even the people un-packing the boxes containing these drugs, must be protected. In fact, the regulations exceed those necessary to protect workers who are dealing with COVID. They must use TWO pair of special chemotherapy gloves. Once used, both pairs of these gloves, the box, the empty vial and every cytotoxic-drug-contaminated item must be disposed of as medical waste. That means all of the chemo-contaminated waste coming out of every hospital in within 500 miles will end up at this proposed MedRecycler facility. Subsequently the chemicals will enter the Rhode Island environment and will expose our families to extremely hazardous chemicals that cause birth defects and cancer.

USP 800 also includes protection from the cytotoxic drugs contained in urine, feces, vomit and sweat of patients. When these human excreta are collected and “red-bagged,” it will also reach the proposed MedRecycler facility to be incinerated with the same result. Chemo chemicals will be released right into our air. And if it is not collected, it still reaches our environment when it is flushed right down the toilet.

OSHA allows ZERO human exposure to chemotherapy drugs, the details of which can be found in their Hazardous Drug Policy. Ten years ago, every hospital in the country was notified of the dire consequences of exposure to these chemicals in a letter from OSHA, NIOSH and the Joint Commission on Healthcare. They take this stuff very seriously.

State of Rhode Island Regulations

In 2012, the Rhode Island Legislature formed a committee to evaluate the dangers involved with medical waste that was being flushed into toilets and subsequently entering our water. This led the Rhode Island DEM to create a new category of hazardous waste: “Extremely Hazardous Waste R006.” This regulation specifically places waste that “contains chemotherapy agents that are antineoplastic or cytotoxic, including but not limited to drugs listed in the NIOSH list of Antineoplastic and Other Hazardous Drugs” into this newly created category.

The medical waste collected and incinerated by MedRecycler will release chemotherapy-infused medical waste, identified by the DEM as “extremely hazardous waste” right into the RI air. More cancer and birth defects will be a direct result of this action.

Lack of Enforcement

The insidious nature of improper disposal of cytotoxic human waste is not limited to the Rhode Island DEM. In fact, the EPA, the FDA, Health and Human Services, the healthcare industry are agencies we rely on to protect people from the grave dangers of secondhand exposure to chemotherapy drugs. Cancer is a big business. Hospitals,
doctors, veterinarians and pharmaceutical companies reap billions taking care of patients with cancer. And with good reason. Even the U.S. Department of Defense shut down their chemical weapons incinerators because of the harmful effects on people and environment. We need to fight chemistry with chemistry, not an incinerator.

Unfortunately, the drugs used to cure cancer also cause cancer. And often the dire consequences of secondhand exposure to these dangerous chemicals aren’t seen for months or even years to come. Your doctor knows it. The hospitals know it. Pharmacists and Big Pharma know it. Unfortunately, most patients and families are unaware and are unwittingly exposing their caregivers and loved ones. Preventable cases of cancer and birth defects are continuing to happen every day.

The regulations are in place; however, they are not being enforced. Why? There is no mechanism to pay for protecting our people. Pharmaceutical companies are afraid of the liability. Insurance companies cannot get reimbursed for any safe disposal mechanism without a CMS number. And what about those who are uninsured? If only the wealthy can afford to protect their families and our environment, what happens to those who have no means to pay for safe disposal?

There are safe and reliable ways to control secondhand exposure to chemotherapy drugs while we protect our people and the environment. We can prevent many, many cases of cancer and birth defects and protect the environment in the process. We did it with secondhand smoke. Now it’s time to step up and move forward, not approve the MedRecycler facility which will return us to a doomed past.

This is and continues to be a global health crisis. Approval of the MedRecycler medical waste incinerator will not help; in fact, it will exacerbate an already dire situation.