Prepared Statement

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Introduction

Chair Bordallo, and members of the committee, thank you for your interest in this critical issue and for inviting me to testify before you today. My role on this panel is to provide insight and hopefully an understanding about the sources of estrogen disruptors and other pharmaceuticals entering our water supply via the disposal of pharmaceutical waste. As an interesting note, in 2008 greater than 72 million prescriptions were written for estrogen based products in the United States (source Drug Topics June 2009)

My interest in the topic of pharmaceutical waste disposal interestingly enough was brought on by a visit to my hospital in September 2004 by the region 7 US EPA. Our hospital was randomly selected for a survey. Upon inspection by the US EPA agent it was determined that Methodist Hospital was in violation of the Resource, Conservation and Recovery Act (or RCRA) of 1976 which states that listed hazardous chemicals (in our case known as drugs) must be segregated, itemized and disposed of via a USEPA approved incinerator. Those drugs which are so classified must be disposed of pursuant to strict standards so as to prevent their introduction into the environment. Taking the opportunity to better understand RCRA and the required elements I utilized the EPA inspector to walk me through the RCRA requirements and the major issues surrounding the proper disposal of pharmaceutical waste. Upon our discussion I found it interesting the agent noted that the list of chemicals within RCRA has not been updated since 1976 and we both came to the same conclusion that there are far more toxic chemicals (or drugs) that have been approved since 1976 requiring no more than simple disposal through the landfill or even more concerning the ability to pour unused portions down the drain. Some of these agents although not listed on the original 1976 RCRA list have been classified by International Agency for Cancer Research as being known human carcinogens. Interestingly enough, through the Methodist Hospital visit we found out we were not alone in our violation. EPA's Region 2 conducted a pilot program between 1998-2004 to determine the extent of any disposal problems. Thirty-seven hospitals were asked to volunteer information about waste disposal practices. The results showed that these 37 hospitals had disposal violations which would have resulted in $8.9 million in fines if this had been an actual enforcement action. The number one hospital violation was the failure to properly identify what materials were hazardous waste according to

RCRA's list.

According to the EPA Region 2 study, the reasons for failed compliance with RCRA requirements included inadequate resources, knowledge and training, and poor recordkeeping. Another EPA study showed 71% of hospitals did not have a formal environmental management system and 72% lacked a comprehensive knowledge of waste management regulations.

Since that initial visit with the USEPA at Methodist Hospital, I have spent the past few years educating pharmacists on my experience with the EPA and the proper disposal of pharmaceutical wastes based on current regulations. I have been active in establishing national surveys to better understand the scope of the problems surrounding the management of this waste in addition to trying to understand the current practice models.

An interesting fact has emerged from my presentations and survey's, there truly is a lack of formal didactic programs established today for educating pharmacist or other healthcare providers on the current regulations surrounding pharmaceutical wastes as noted in the 2002 EPA survey of region 2. So it really is not surprising that the current disposal practices noted in the surveys of hospitals, Veteran's Administration Hospitals, long-term care facilities, and Veteran's homes for unwanted or unused pharmaceuticals is directly into our water system via the sewering of medications and indirectly through leachate from the land filling of medications.

These practices are in line with the landmark series on pharmaceuticals in our nation's water supply by the Associated Press in 2008, which ran nationwide in hundreds of newspapers and was reported in major television and radio outlets. Two main sources of waterway pharmaceutical contaminants were identified: you and I through the natural excretion of drugs along with inappropriate disposal of unwanted medications, and, secondly the healthcare industry including hospitals and long-term care facilities through disposal practices.

The March 2008 Associated Press article summarized a five month investigation into pharmaceuticals in the environment and outlined the following facts secondary to a United State Geological survey:

- The drinking water in 24 major cities serving 41 million people was contaminated by waste pharmaceuticals.
- More than 100 different pharmaceuticals have been detected in surface waters. And although not tested for, does not mean that there are not other agents. It only means that only 100 different types were tested for.
- Pharmaceuticals permeate aquifers deep underground, which is the source of 40% of the nation's water supply.
- While scientists do not know with certainty the effects of long term exposure to low levels of pharmaceuticals in water, or the cumulative effects of mixtures of drugs, substantial evidence shows adverse impacts on blood cells and kidneys, that some drugs may be cancer accelerants (particularly for breast cancer), and that recycling water may concentrate the drugs. Some scientists worry about special human effects since these drugs, including powerful cancer treating drugs, were designed to

act on the body at low concentrations. For many scientists, the cause and effect relationships are clear.

- Pharmaceuticals in the environment are linked to reproductive problems (male fish growing female organs and female fish growing male organs), reproductive failures, kidney failure, stunted growth, and death in fish and wildlife, including endangered and threatened species. Again, the cause and effect relationships are clear.

In the Second AP article written in September 2008 the AP found that:

- Hospitals and health care facilities dump 250 million pounds of waste pharmaceuticals into the environment each year. Primarily through sewering and the land filling.
- This may only be the tip of the iceberg because few of the country's 5,700 hospitals and 45,000 long term care facilities keep data on how much pharmaceutical waste they generate due to the complexities associated with capturing this type of data **(please refer to Graphic #1)**
- More than 365 medicines are controlled by the U.S. Drug Enforcement Administration that, to prevent diversion, effectively requires that these waste drugs be disposed of on site, which often defaults to sewering the unwanted or unused portions;
- Other federal guidelines, including FDA guidelines, state that many waste pharmaceuticals should be flushed down the toilet. However, the EPA did converse with the FDA in 2008 to state that this practice has never been advocated by the EPA and since then the FDA has required manufacturers to not list sewering as a means of disposal by the public.
- Currently, the White Houses policy of the proper disposal of unwanted pharmaceuticals by the public includes mixing the medications with coffee grounds or kitty litter in a zip lock baggy or sewering if it is a specialized controlled substance. Since the public has a high volume of unwanted pharmaceuticals these recommendations will indeed add to the already present concentrations in our environment. In addition, without
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Other independent studies have suggested that the single largest identifiable source of pharmaceutical waste in the environment is hospitals and health care facilities, accounting for 27% of the total (hospitals alone account for 12%). These wastes are typically far more toxic than wastes from home medicine cabinets or waste excreted by people because hospital pharmaceuticals are routinely administered in higher concentrations. Rather than being partially metabolized by the human body and then excreted in a minute concentration of the original form, health care facilities handle the concentrated and most hazardous forms of these medications. Often time they are 'legally' poured down the drain or disposed of directly to landfills.

When looking at the scope, U.S. hospitals annually purchase greater than 3.9 billion vials, bottles, and syringes of injectable pharmaceuticals – enough to circle the earth 2.5 times. A typical hospital handles over 700,000 containers of this hazardous pharmaceutical waste annually. You may ask where does pharmaceutical waste come from in health care? Pharmaceutical waste is generated for many reasons including when multi-dose drug containers are opened but not completely used, changes in the patient's condition require medications to be discontinued, operating room/emergency room drugs are opened in anticipation of possible emergency use but are never

administered, and the patient is moved to a new area of the hospital. Typically, when a patient is moved, for example from the Emergency Room or Operating Room to an Intensive Care Unit or a medical floor, new medications are administered and previous ones disposed of.

Significantly, the Department of Health and Human Services projects drug utilization will nearly triple between 2001-2011 as the population ages, with hospital pharmaceutical use increasing significantly thus leading to increases in the amount of wastes and the number of containers with residue pharmaceuticals. In addition, as medicine progresses, more and more toxic therapies will be developed to help champion our battles against cancer and other human parasites. Without simplified and regulated mandates for pharmaceutical waste in the healthcare industry, this toxic waste will continue to be disposed of as municipal waste, where the drugs go to a landfill and can leach into groundwater, or the wastes are dumped down the drain and end up in wastewater treatment plants not designed or equipped to render the waste safe.

Current Pending Regulations

Currently, RCRA has been on the books since 1976 and has mandated healthcare facilities to appropriately segregate manifest and assure proper disposal of hazardous drugs. This applies to private hospitals, Veteran Affairs facilities, and the department of defense hospitals. As discussed earlier in my testimony, although the law has been in effect since 1976, most healthcare facilities are not in compliance. Since they are not in compliance, our efforts today is how do we get these facilities into compliance? This could be achieved through the USEPA via education and the enforcement of current regulations. To date congressional activities have involved studying the problem of pharmaceuticals in the environment versus the enforcement of the current regulations.

Over the past year there has been some momentum gaining on the hill as it pertains to formally addressing pharmaceutical waste. The first is the Drug Free Water Act of 2009 which was introduced into the House on January 7, 2009 and requires an EPA Task Force study the proper disposal of unused drugs. The first phase of this program is an aggressive survey of all healthcare facilities to fully identify the scope and to identify best practices that can be relayed on other facilities. The estimated date of the survey is quarter 4 of 2009. In addition to this proposed legislation is the USEPA has for comment the proposal to classify the RCRA listed drugs/chemicals as Universal Waste. The hope of this proposal was to ease the process of segregation, however, this proposal does nothing to update the current list from 1976 as to what is hazardous and it does not eliminate the need for these agents to be disposed of in the manner outlined by RCRA. In fact the universal waste rule could lead hospitals who currently do not comply with or understand RCRA to use the rule as a means to avoid RCRA compliance believing that if they give pharmaceutical waste to a waste hauler that this would allow them to be in compliance. The net result could be an increase cost to hospitals due to the waste hauler having to classify all of this waste as mixed hazardous waste pursuant to the RCRA mixture rule, thus commanding a premium price. Another unintended consequence could be facilities choosing not to segregate their pharmaceutical waste and using inexpensive means of disposal such as sewering and land filling.

The next two acts allow for clarification of the controlled substances act for formal programs for the public to safely dispose of unwanted pharmaceuticals. The Safe Drug Disposal Act of 2009 was introduced into the House on February 25, 2009 for the purpose of amending Controlled Substances Act to provide for the disposal of controlled

substances by ultimate users and care takers through State take-back disposal programs and to amend the Federal Food, Drug and Cosmetic Act to prohibit recommendations on drug labels for the disposal by flushing. And in the Secure & Responsible Drug Disposal Act of 2009 introduced into the House on March 5, 2009 to amend the Controlled Substances Act to enable consumer take-back programs.

I commend the introduction of these acts as a means to the beginning of addressing the proper disposal of pharmaceutical wastes. However, not having a sustainable take-back program available to the public to take unused/unwanted medications back to their pharmacies like it is done with the federally funded Canadian, United Kingdom and Australia programs, leaves our country vulnerable to systems that propagate diversion and accidental poisonings. Today's national poison centers are often left to answer questions from the public on how to deal with unwanted medications with either zip lock bagging with kitty litter or coffee grounds or sewering. Whereas, directing the public back to their local pharmacies to properly secure and destroy these medications makes more sense as a sustainable public safety program and one that needs to be looked at seriously for funding.

The healthcare industry needs simplified regulations that make logical sense and not based on the 1976 standards. The process needs to be simple and easy to educate and should simply be 'no pharmaceutical waste in the sewer or in landfills, period'. However, this type of policy will take federal funding to achieve and is a great investment into two of the Obama Administration initiatives: healthcare reform with an ecological spin.

Conclusion

The US Geological Survey highlighted by the Associated Press's series has given us a baseline from 2002 of the current pharmaceutical contaminant levels of our nation's water supplies. As the US population ages and more and more people are placed on pharmaceuticals, compounded with a lack of a sustainable US program for management of unwanted pharmaceuticals, we can only see these contaminate concentrations rise. Compounding this issue is the current practice of recycling water as being done in the drought stricken Southwest regions which has the propensity to concentrate these contaminates to a higher and potentially therapeutic levels. One may try to speculate what a 'safe concentration' is for these agents and to that we know that we really do not know.

But what we do know is that the impact currently that these agents have had on fish and their siblings is an alarming concern and one that has the potential to change the ecological stature of not only our fish but mankind.

Chair Bordallo, members of the Committee, thank you very much for inviting me to share my experience today.