

# Pharmaceuticals in the Environment: Something Can Be Done

## GUEST COLUMN

With 250 million pounds of pharmaceutical waste disposed of annually, health and environmental impacts must not be ignored, writes **George Mannina Jr.** of Nossaman

A nationwide study on water quality published in 2002 by the U.S. Geological Survey found 80 percent of 139 streams in 30 states contained pharmaceutical or hormone waste. In March 2008, the Associated Press reported that its five-month investigation of pharmaceuticals in the environment discovered over 100 waste pharmaceuticals in the drinking water of 24 cities serving 41 million Americans.

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 different drug mixtures, the evidence suggests potentially serious impacts. German and Swiss scientific and environmental agencies found certain pharmaceutical waste hinders kidney and immune system processes in fish and mammals. Italian researchers found pharmaceutical contaminants can inhibit human embryonic cell growth. Other scientists believe certain waste pharmaceuticals in water can cause human breast

cancer cells to multiply more rapidly. Still other researchers found a positive association between low level arsenic exposure and the onset of diabetes. Other studies found that waste pharmaceuticals in water cause male fish to develop female organs and vice versa, a decline in reproductive rates in mussels, and kidney failure in birds. Thus, although there is no definitive study of the individual and cumulative effects of waste pharmaceuticals in the environment, the available studies clearly suggest impacts.

By volume, the largest source of pharmaceutical waste is you and me. We excrete drugs that are not fully absorbed and we often dispose of expired drugs in our medicine cabinets down the toilet or in the trash where they may leak into groundwater from landfills. But the single most identifiable source of waste drugs in the environment is health care facilities. The AP investigative team reported hospitals and health care facilities dump 250 million pounds

of waste pharmaceuticals into the environment each year.

Drugs prescribed for patients may not be fully used for many reasons, including that the patient recovers before all are used, or dies; the drugs are not effective, or the patient has an adverse reaction, and drugs need to be changed; or the doctor prescribes a dosage smaller than the package amount sold by manufacturers and the remainder becomes waste.

The AP estimate of 250 million pounds of pharmaceutical waste disposed of into the environment by health care facilities each year may only be the tip of the iceberg. Few of the country's 5,700 hospitals and 45,000 long-term care facilities keep data about the volume of pharmaceutical waste they produce. Significantly, these wastes are typically far more concentrated and toxic than the wastes we excrete and the wastes from home medicine cabinets. Power-

See Page 7 — PHARMACEUTICALS

**Continued from page 1**

ful oncology drugs are just not found in home medicine cabinets and some of these drugs are known carcinogens, at any concentration, when healthy individuals are exposed.

Each year, U.S. hospitals are estimated to purchase over 3.5 billion vials, bottles, and syringes of pharmaceuticals that are classified as hazardous. A typical hospital handles over 700,000 containers of this hazardous pharmaceutical waste annually. Add up the numbers and U.S. hospitals could be handling and disposing of 5 billion containers of pharmaceutical waste annually.

To properly dispose of this waste, hospital health care providers must know the correct disposal protocol for each pharmaceutical. But there are over 160,000 National Drug Codes. Overworked hospital staff cannot be expected to remember which of the 160,000 are hazardous much less the different disposal protocols. Adding to the confusion, the Food and Drug Administration does not require a hazardous symbol for drug labels as is done with other chemicals.



**GEORGE J. MANNINA JR.** is a partner at Nossaman's Washington D.C. office. He has significant experience in environmental litigation including demonstrated expertise with oceans and fisheries law, the Endangered Species Act, Superfund's natural resource damages program, and the Clean Water Act. He can be reached at (202) 887-1491 or [gmannina@nossaman.com](mailto:gmannina@nossaman.com).

An Environmental Protection Agency study between 1998-2004 surveyed the pharmaceutical waste disposal practices at 37 hospitals that volunteered for the study. EPA found these 37 hospitals had pharmaceutical waste disposal violations that would have resulted in almost \$9 million in fines if this had been an actual enforcement action. The number one reason for the violations was that doctors, pharmacists, and nurses did not know what was required by federal law for pharmaceutical waste disposal.

The Resource Conservation and Recovery Act (RCRA) already regulates the disposal of hazardous wastes, including pharmaceutical wastes. Yet EPA has done little to educate hospitals about their RCRA responsibilities — and has done even less to enforce the law. The Bush Administration decided the best it could do was design a survey of hospitals asking about waste disposal. Just asking the questions would help hospitals and other health care facilities to understand what wastes are RCRA regulated and what RCRA requires. Sadly, the Obama Administration stopped the survey and has done nothing more about the issue of pharmaceuticals in the environment. Instead, EPA is pressing forward with a Bush Administration proposal called the Universal Waste Rule, which could unintentionally result in hospitals not segregating and properly disposing of their hazardous waste but instead, lumping their wastes together as if all are non-hazardous. These wastes would then end up in our landfills and waterways.

This applies to Veterans Administration and Department of Defense hospitals as well. EPA has already fined some VA hospitals, which reportedly includes Kansas and California VA hospitals, for improperly disposing of hazardous pharmaceutical waste.

Congress passed RCRA in 1976, however, the list of pharmaceuticals considered hazardous has never been updated. Since 1976, thousands of new drugs, including powerful oncology drugs and other chemicals, have become available to improve our healthcare. EPA has never looked at whether the disposal of these new chemicals should be regulated under RCRA to prevent them from being flushed down the drain or sent to landfills. EPA should do so.

The Food and Drug Administration should stop telling people that it is okay to dispose of unused drugs by flushing them down the drain. And the Drug Enforcement Administration should figure out how pharmaceuticals classified as controlled substances can be disposed of other than by flushing them down the toilet. How many of us have had a loved one pass away under hospice care? One of the first things the hospice nurse does is dispose of the painkillers and other controlled drugs by flushing them down the toilet, often with family members as witnesses. The hospice caregiver is doing that which is required by the DEA. No one disputes the importance of the DEA's mission to prevent controlled substances from being sold on the street, but surely the DEA and EPA can devise a way to accomplish the DEA's important mission without undermining the EPA's equally important mission of preventing our waterways from being contaminated by hazardous waste pharmaceuticals.

Although some people argue that we shouldn't do anything about waste pharmaceuticals until we know the exact extent of the problem,

and while comprehensive studies will define the total scope of what should be done, it would seem intuitively obvious that adding substances like arsenic and powerful oncology drugs that are designed to kill things and not break down in water is probably not a good thing.

## **The single most identifiable source of waste drugs in the environment is health care facilities.**

---

Years ago, we learned to properly dispose of paints and chemicals in our houses. We can also be taught to properly dispose of waste pharmaceuticals in our medicine cabinets. Our medical care professionals who dedicate their lives to helping people need to be educated about existing legal requirements and given the tools to properly manage pharmaceutical waste.

One thing that can be done right now is to educate health care professionals about RCRA's requirements so that hospitals and health care facilities can take the necessary steps to properly dispose of

pharmaceutical wastes. This country's medical care professionals are in the business of helping people. They do not want to be in the business of creating new patients. An industry-EPA environmental education program will go a long way to address this problem - but any such program must be followed by appropriate enforcement so that we know education is followed by action.

We also need to establish public take back programs so unused and outdated pharmaceuticals can be returned to a hospital, community drug store, or otherwise. Some states, notably Maine and Iowa, have established take back programs that need to be expanded throughout the country.

Legislation now being considered in Congress generally seeks to study the problem. We can all benefit from additional studies to determine the full extent of the problem, but we should be taking steps now to prevent known problems from becoming worse. We should be enforcing existing RCRA requirements to prevent arsenic, carcinogens, and other hazardous substances from entering the environment and we should be fixing regulations that encourage such disposal. Addressing this problem is good not only for human health and the environment but may also have positive effects on national health care costs. The full accounting for, and proper management of, pharmaceutical waste will provide valuable information about the actual amount of drugs used. If the health care industry had better estimates of the amount of drugs that lie unused in medicine cabinets and are disposed of at health care facilities, then drug production rates, dosage amounts, and package sizes might better match actual usage, thus reducing overall drug costs.