Legal Backgrounder

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MEDICINES AND THE ENVIRONMENT: LEGAL AND REGULATORY STORMS AHEAD?

By

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Approximately 2000 pharmaceuticals have been approved for human use and hundreds more for veterinary use. Thousands of tons of these pharmaceuticals are produced each year and, not surprisingly, significant amounts find their way into the environment. In fact, a 2001 report by the activist group Union of Concerned Scientists estimates that livestock producers use as much as 24.6 million pounds of antimicrobials, including antibiotics, annually for non-therapeutic purposes such as to promote growth.

The extent to which these substances are finding their way into the environment is documented by a U.S. Geological Survey ("USGS") study of 139 streams in 30 states. That study found human and veterinary drugs, hormones, and other substances in 80% of the streams. 83% of the substances found were pharmaceuticals or hormones. Although these results are not representative of all waterways because samples were taken downstream from urban areas and areas of livestock production, these numbers, coupled with the implications of the research detailed below, have caused some observers to wonder if we are on the threshold of a new regulatory era. The question is what, if anything, is the appropriate response.[1]

The punctuation mark to the USGS report is being supplied by studies of individual waterways. A Baylor University researcher found accumulated pharmaceuticals, including anti-depressants and estrogen, in fish and clams living downstream from a wastewater treatment plant discharging into Texas' Pecan Creek. The estrogen, likely coming from birth control pills and hormone replacement therapy, was causing male fish to develop female characteristics, which could reduce populations by rendering the males unable to breed. The impact of anti-depressants on the fish's natural fear of predators, and the possible resulting impact on population levels, is under continuing study. In Maryland's Potomac River, researchers discovered male bass actually producing eggs. The suspected cause: human hormones escaping from sewage treatment plants. A Colorado biologist found similar problems in some Colorado rivers where the ratio of male to female fish is seriously skewed. Fish in Nebraska's Elkhorn River living downstream from cattle feedlot operations appeared to be affected by the male and female hormones given to the animals and entering the river as feedlot effluent. Male fish had one-third less testosterone than normal and females had 20% less estrogen, but 45% more testosterone, than fish above the feedlot discharge. A University of Wisconsin researcher exposed minnows to a popular anti-cholesterol drug at levels just above that found in local streams. The seven day experiment was stopped after one day because the fish were struggling to survive. Johns Hopkins University researchers found that popular anti-depressants being released into waterways can cause female fish to not spawn. USGS found carbamazepine, a popular anti-epileptic drug, is widely present in our waterways. Researchers at the University of Guelph found this drug kills benthic

[1]Although this LEGAL BACKGROUNDER focuses on pharmaceuticals in the environment, scientific studies are also documenting the presence in the environment of chemical residues from personal care products. The same issues which arise regarding pharmaceuticals in the environment also arise with respect to personal care products.

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organisms. Still other researchers have found evidence that certain hormones in our waterways may accelerate the growth rate of some cancers.

While the research is still in its infancy and much needs to be done before absolute conclusions about population level impacts can be drawn, the issue is quickly becoming far less abstract and subject to dispute than other issues such as global warming. In fact, studies at the University of Minnesota and at Canada's Trent University indicate that some hormones can affect aquatic life at almost infinitesimal concentrations, in the parts per trillion range. And our scientific ability to detect chemicals at ever smaller levels is steadily increasing. A Johns Hopkins University research team has developed a test capable of detecting one gram of pharmaceutical in one billion litres of water.

For pharmaceutical companies, wastewater treatment facilities, animal feedlot operators, and others, the question becomes just how much data and certainty is required before existing regulatory mechanisms kick in. For example, the Endangered Species Act ("ESA") requires that federal agencies (including agencies approving the use of pharmaceuticals and hormones) "insure" that any action they take or authorize is not likely to adversely affect species protected by the ESA. Indeed, ESA issues may already be present in Nevada where a USGS toxicologist detected elevated levels of pharmaceuticals and hormones in waterways downstream from Las Vegas and a very large decrease in sperm production in three species of fish, including the endangered razorback sucker. Experienced ESA attorneys are all too well aware of how little proof of impact is required before the ESA's "insure" no harm standard triggers regulatory controls. In one ESA case, a federal judge upheld a finding that fishing was adversely affecting an ESA-protected species even though there was no evidence that fishing was causing any impact. The logic, using the ESA's insure no harm standard, was that fishermen catch fish, the listed species eat fish, and, therefore, there must be an adverse impact from fishing. Apply that reasoning to pharmaceuticals in the environment and it is not a very long leap before the ESA can be brought to bear on protected species such as the razorback sucker and other listed species of fish, including virtually all the salmon and steelhead species in the Pacific northwest.

And what if the U.S. Environmental Protection Agency ("EPA"), pursuant to its authority under the Safe Drinking Water Act ("SDWA"), sets contaminant levels for pharmaceuticals or hormones detected in waterways from which drinking water is taken. Already, EPA is under pressure to use its SDWA authority to address pharmaceuticals in the environment. EPA could also set effluent discharge limitations under the Clean Water Act ("CWA") to protect human health and the environment. Using its authority under the Resource Conservation and Recovery Act ("RCRA"), EPA has listed several common medications and nine chemotherapy agents as hazardous waste if discarded. But there are more than 100 toxic chemotherapy agents which are not yet RCRA regulated. If regulated substances are released into the environment, as those terms are understood under Superfund and the Clean Water Act, can we look forward to cleanup orders and claims for natural resource damages under those laws? The answer is probably yes.

The question is who is legally responsible. Is it the pharmaceutical companies whose sole role is the development of drugs to treat diseases? Is it the doctors who prescribe the medicines? Is it the patient who flushes unused medicines down the toilet? Is it nursing homes, hospice workers, and hospital staff who, upon a patient's passing, are required by federal law to destroy controlled substances and who often do so by flushing them down the toilet? Is it concentrated animal feeding operations which administer hormones and antibiotics to the animals? Is it municipal waste treatment plants which are faced with the task of treating sewage and wastewater containing partially metabolized drugs and unused drugs flushed down the toilet? All of these persons and entities are engaged in perfectly lawful activities and provide a valuable service to consumers. Indeed, the pharmaceutical industry states that the vast majority of detected pharmaceuticals in the environment result from patients taking their medicine and passing the medicines that are not fully metabolized as waste down the sewer. Concerned environmental groups, however, assert that waste treatment facilities need to do a better job of removing pharmaceuticals and that the release of hormones and pharmaceuticals from animal feedlots needs to be better controlled.

Even though all of the groups producing and using these drugs are engaged in lawful activities, being

engaged in a lawful activity has not proven a bar to cleanup liability under Superfund or to claims for natural resource damages. Congress declared that someone had to be responsible for cleaning up and restoring the environment, even if the company, or its predecessor, was in full compliance with all applicable laws when the material was released into the environment, and even if the substance was not considered to be hazardous when it was released. Being engaged in a lawful and societally important activity also has not been a bar to regulation under the ESA's "insure" no harm standard. And when do SDWA standards become applicable since many of our citizens get their water from waterways which may contain residual pharmaceuticals and hormones? Drinking water standards do not exist for 81 of the 95 chemicals detected in the USGS study of 139 waterways in 30 states. At what point does the requirement to prepare a full environmental impact statement under the National Environmental Policy Act ("NEPA") apply to each and every decision to authorize the use of pharmaceuticals and hormones for the treatment of humans and animals or to permit the operation of wastewater treatment plants? Congress, various federal regulatory agencies, and the courts, under pressure from environmental groups or crusading state attorney generals, can be expected to wrestle with these questions and issues. Indeed, sufficient information is likely present to support creative lawsuits by environmental activists – lawsuits which, in the absence of preemptive government action, will lead to regulation by adjudication.

One need not look far to find a precedent for potential lawsuits. For example, an Illinois municipal water district which owns and operates a plant providing water to municipal residents and businesses has sued the manufacturers of certain herbicides demanding that the manufacturers clean up all residue from a substance which has found its way into the source of the drinking water and also pay for the costs of installing and operating additional water treatment systems to guarantee the removal of any residue from this herbicide. What makes this case significant is that the plaintiff does not allege the herbicide is being used unlawfully or contrary to the manufacturer's instructions. Nor are there any allegations of a violation of the safe drinking water standards established by EPA or the State of Illinois. Rather, the plaintiff, citing various studies allegedly demonstrating adverse human health impacts of herbicide residue at concentrations less than the existing safe drinking water standards, asserts that the federal and state standards are not protective of human health. The plaintiff then asserts that the herbicide manufacturers are guilty under state law of trespass, nuisance, negligence, and releasing "contaminants" into the environment solely because residue from the herbicide has come to be located in water owned and used by the plaintiff. While this case does not involve pharmaceuticals or personal care products, one can imagine creative attorneys using similar and related theories. And, as noted above, one need not be too creative to invoke the ESA, or to demand action under various hazardous waste management and cleanup statutes if a substance is listed as a regulated substance.

Potentially affected industries should also not neglect the driving force of public opinion as a spur to legal and regulatory action. An October 2005 Harris Interactive poll found that Americans rank water pollution as the country's number one environmental problem, ahead of such blockbuster issues as global warming.

Already, federal agencies are reacting. At an August 2005 ESA-sponsored conference on pharmaceuticals and personal care products in the environment, EPA officials announced the agency may include a significant number of pharmaceuticals and personal care products on the third candidate contaminant list published pursuant to the Safe Drinking Water Act. The draft list is expected to be published this year and finalized in 2008.

EPA and USGS are also collaborating to assemble a database of relevant scientific literature on pharmaceuticals and personal care products in the environment. Meanwhile, USGS researchers, as part of the agency's Emerging Contaminants Project, have developed specific analytical methods for measuring the presence of these substances in the environment and have undertaken a broad monitoring program. Not to be outdone, at least five EPA regional offices are undertaking studies to document the presence and effect of pharmaceuticals and personal care products in the environment. And a December 2005 report by the Environmental Working Group, an activist organization, asserts that millions of Americans are drinking

water containing a myriad of contaminants which may act individually or synergistically to harm human health.

However, before citizen lawsuits become a reality and regulatory mechanisms are brought to bear, preventative steps should be considered. Provisions in RCRA and in Drug Enforcement Administration regulations which are designed to protect the public from the improper discharge or disposal of medical waste and controlled substances may, in reality, be encouraging medical professionals and the public to flush unused pharmaceuticals in toilets or drains. Reviewing the unintended effects of these existing regulatory programs and establishing new programs which encourage medical professionals and consumers to return unused pharmaceuticals instead of flushing them into the sewers can only be a plus for the environment. The State of Maine, for example, provides for the collection of unused pharmaceuticals through the use of prepaid mailers. Required incineration may also be a viable alternative to the disposal methods which are too often used today.

Assisting waste treatment plants in developing and employing improved waste treatment technologies will also help. Yet, for areas such as the Florida Keys which rely on septic systems, this initiative may not be helpful. Although this could be an enormously expensive option, reaching into the tens of billions of dollars, the European Union is giving this option serious consideration because of their concerns about addressing the effects of pharmaceuticals in the environment.

Perhaps Congress should reflect on the history of asbestos problems and, before pharmaceuticals in the environment lead to a national liability crisis, consider the creation of a liability fund used for research, the implementation of new technology, cleanup and restoration, and, if necessary, victim compensation. Such a program would give participants the certainty of no liability in exchange for a fixed payment, or schedule of payments, into the fund. But the difficulties of calculating the appropriate size of any such fund should not be underestimated and the costs, if borne exclusively by industry, could be ruinous.

Knowledge is also a powerful tool. Research identifying the precise scope of the problem and the possible antidotes may shed much needed light on what are appropriate responses to an important emerging issue.

While there is no consensus on the extent of the problem or an appropriate response, what is clear is that absent some preventative action or actions, the day is approaching when the already documented presence of pharmaceuticals in the environment leads Congress, the Environmental Protection Agency, or state agencies to take action. Absent such action, or perhaps notwithstanding such actions, the day is also approaching when citizens and activists or state Attorney Generals will demand action and go to court to apply existing regulatory mechanisms, even if no one thought of pharmaceuticals in the environment when these regulatory systems were created and regardless of whether these regulatory programs are well suited to addressing the issue of pharmaceuticals in the environment.

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