NACWA
A Clear Commitment to America's Waters

Pharmaceuticals and Personal Care Products In the Environment:

A White Paper on Options For the Wastewater Treatment Community

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I. INTRODUCTION

New chemical detection methods and a greater focus on water quality monitoring have generated a significant interest in the pharmaceuticals, personal care products (PPCPs), and other compounds that are making their way into the nation's rivers, streams, lakes, and estuaries. Measurable amounts of medications for pain, depression, and colds; birth control pills; caffeine; hair product ingredients; cleaning supplies; and pesticides are all being detected in samples collected from U.S. waterways. Some of these products contain endocrine disrupting compounds and other contaminants that researchers fear may harm aquatic life. Increasingly sophisticated tests to monitor for groundwater and surface water contamination are revealing the presence of chemical compounds at lower and lower levels, down to nanograms per liter. The plethora of new information raises obvious questions about potential risks to human health and the environment and the role for NACWA members and the nation's publicly owned treatment works (POTWs).

As the public becomes more aware of the issue because of increased media attention, POTWs are seeking the appropriate response. Some options for responding could include public education campaigns that convey meaningful information about the quality and quantity of data, potential risk, and activities utilities and other organizations are taking to minimize contamination. The National Association of Clean Water Agencies (NACWA) and its members and affiliates are closely tracking the issue to cultivate knowledge and expertise in order to address what some see as a growing and significant challenge for the wastewater treatment community in the coming years.

This white paper is intended to provide NACWA members with a sense of the state of science on PPCPs and the major data gaps that exist; explain the increasing public and media attention this issue is receiving; and warn of a potential sleeping giant whose future is being guided by a battle between the precautionary principle and sound science. NACWA wants to ensure that any approach to address this challenge is firmly rooted in science and not dictated by public anxiety over potential risks that may never materialize. [1]

PPCPs are often described as "emerging pollutants" despite the fact that many have been around for a long time. In fact, more monitoring and better test methods have fostered an emerging *awareness* of the presence of these compounds and the need for more information about their impacts. The question at the core of this emerging issue, however, is whether concentrations of these compounds in surface waters have a negative environmental or human health impact. Representatives from several NACWA member agencies and even some EPA researchers suggested that it is the public outcry over reports of these compounds in local waterways, not scientific proof of actual harm, that could lead to required monitoring or regulation of these compounds.

[1] NACWA wishes to acknowledge the valuable contribution and insight provided by representatives from several member utilities, especially Norm Leblanc, Hampton Roads (Va.) Sanitation District; Amy Woodis, Denver Metro Wastewater Reclamation District; Joseph R. Gully, County Sanitation Districts of Los Angeles County; and Penny Hill, County Sanitation Districts of Los Angeles County.

While some research suggests possible impacts to aquatic life exposed to these compounds, no effects on human health have been detected at this time. Nevertheless, the issue could be significant for POTWs if regulations and subsequent technology standards arise out of a public perception that a problem exists, even if presumptions of potential impacts are not supported by solid scientific evidence. More importantly, operators of clean water agencies take seriously their role as stewards of the environment and the last lines of defense against contamination entering the nation's waterways from industrial and domestic sources. NACWA will work with its member agencies to develop the expertise required to be leaders on the PPCP challenge and ensure that options for addressing it are reasonable and supported by science.

Demonstrating the growing attention PPCPs are receiving, the U.S. Environmental Protection Agency (EPA) hosted a conference August 23-25, 2005, at its laboratory in Las Vegas to look into the state of science regarding PPCPs in the environment and options for addressing them. The meeting was designed to bring together the recipients of EPA's Science to Achieve Results (STAR) grants to study PPCPs as well as officials from EPA and other government agencies to discuss their findings to date, identify research gaps, and determine the steps needed to target limited resources for gaining key knowledge in this area of interest. Most agree that much more research is needed to connect the impacts to aquatic organisms of long-term and acute exposure to PPCPs. In addition, better information will help regulators and the regulated community avoid some mistakes of the past, such as those that led to a flawed whole effluent toxicity (WET) testing program.

This paper will summarize findings presented at EPA's conference and lay out some of the thinking and impressions of several representatives from NACWA member agencies who attended the meeting and generously provided the Association with their ideas. First, the paper will delve into information about the nature and types of chemicals at issue, followed by an explanation of how they end up in U.S. waterways. Then the paper will look at some of the research being conducted by EPA and university scientists, including some of the challenges they face. Finally, strategies and barriers, regulatory and otherwise, for addressing PPCPs will be discussed along with options for POTWs.

II. BACKGROUND

What Contaminants Are Being Found in the Environment?

The known chemical universe comprises about 26 million organic and inorganic compounds of which about 9 million are commercially available. Fewer than 250,000 of these compounds are inventoried or regulated worldwide, according to Christian Daughton, chief of the environmental chemicals branch of EPA's Office of Research and Development (ORD) in Las Vegas. The potential universe consists of those compounds that can be synthesized from the existing stock, a figure in the realm of 10 to the power of 60. When it comes to testing water samples for various compounds, "what you find depends on what you're looking for," Daughton said. "Those chemicals not targeted will elude detection."

Researchers estimate that about 2,000 pharmaceuticals have been approved for human use with hundreds more approved for veterinary use. Many of these can be grouped according to how they are used. These include groupings of estrogen-like compounds such as free

estrogen or 17-beta estrodial. Antibiotics and selective serotonin reuptake inhibitors (SSRIs), which include the antidepressants Prozac and Zoloft, also saturate the market along with over-the-counter painkillers, allergy relievers, and other medications. Personal care products that are found in water samples include DEET, phthalates, detergents, and an almost unlimited collection of chemicals, with little known about their potential environmental, aquatic, or human health impact.

These compounds are found in surface water, groundwater, almost all influent and effluent, and in biosolids. They are being detected in surface water intakes and in treated drinking water. Moreover, human use of pharmaceuticals is expanding and escalating, particularly as the population ages and new medications come on the market to address a variety of physical and psychological ailments.

III. HOW DO PPCPs END UP IN OUR WATERS?

This increasing use no doubt means that more of these products are ending up in the environment, both in U.S. waterways and in soils and sediments. They get there through human excretion, the flushing of unused medications, and runoff from animal feeding operations where large quantities of antibiotics and other drugs are used. However, no one has been able to rank the contribution from each of these categories of sources.

The same can be said for PPCPs in the sewer system. While households and individuals represent a huge non-regulated source of these products, other significant sources include pharmaceutical and chemical manufacturing facilities, hospitals, nursing homes, long-term care facilities, pharmacies, veterinary operations, landfill leachate, septic tank haulers, and meat processors, all of which may be scrutinized more closely for possible action under the National Pretreatment Program.

Data Gaps in Quantifying Relative Source Contributions

At the EPA conference, Mary Buzby, the director of environmental technology for Merck and Co., said the vast majority of PPCPs in the environment comes from human excretion, not the disposal of unused medications. The manufacturers themselves represent only a minute portion of the problem, Buzby said. She spoke on behalf of the Pharmaceutical Research and Manufacturers Association (PhRMA) and estimated that only about 3 percent of prescribed medications go unused.

Little research has been conducted to determine what happens to these unused medications, especially from households. PhRMA estimates, however, that nursing homes account for about a third of the medications that are not used. Most of these end up in the sewer system because nursing homes and other medical facilities must adhere to strict guidelines from the Drug Enforcement Administration (DEA) dictating that all unused controlled substances be rendered "nonrecoverable." Two health care professionals are required to witness the disposal of these medications. The easiest and cheapest way to accomplish the "observed disposal" of unused medications is by flushing them into the sewer system. In addition, Medicare requirements mandate the witnessed destruction of unused medications purchased through that program.

Many in the medical community are also concerned about the amount of unused medications. At the EPA conference, Steven Gressitt, a psychiatrist and member of the Maine Association of Psychiatric Physicians, said as many as 50 percent of patients do not take their medication properly. Consequently, he thinks the pharmaceutical industry's estimation that 3 percent of medications go unused is too low and estimates the figure may be closer to 25 percent. Research on this subject is spotty at best.

Some data on the use of medications and disposal practices exist at the local level. In King County, Washington, which includes Seattle, Dave Galvin, the chair of the Hazardous Waste Management Program, said he has data showing that patients use about 80 percent of their pain medication but only about 17 percent of their antibiotics. Clearly then, more information is needed on what consumers do with their unused medicines and what percentage of such medications is classified by the DEA as controlled substances subject to being rendered "nonrecoverable."

In Washington state, Galvin estimates that 10 percent to 25 percent of unused medications fall into this category. Another 10 percent are considered hazardous wastes subject to requirements under the Resource Conservation and Recovery Act (RCRA). PhRMA estimates that about 5 percent of medications are considered RCRA hazardous waste and 5 percent to 15 percent are non-RCRA hazardous waste.

Difficulties of Identifying Contaminants of Concern

It is clear that PPCPs come from many sources, but quantifying the contributions of these sources is difficult and contentious. Even more challenging is identifying which of these many PPCPs are of the greatest concern.

Mitchell Kostich, a researcher in EPA's Office of Research and Development lab in Cincinatti, noted that most pharmaceuticals are designed to have effects at low concentrations, unlike industrial chemicals. Moreover, there is little or no data on the ecotoxicity of most pharmaceuticals, and performing chemical analyses on all of them would be prohibitively expensive. He calls ethynylestradiol (E2) the "poster child" of the PPCP problem and said there is a "reasonable suspicion" this estrogenic compound is contributing to the presence of intersex fish and higher numbers of females in some fish populations, an issue that has garnered significant media attention. Moreover, estrogenic compounds are unique in that they are designed to block a critical species function—reproduction. If they are administered across the population, it would kill off the species. And, like many other drugs, they are used frequently and regularly over a number of years

He is working on a strategy to "triage" or prioritize pharmaceutical compounds for further research. It builds on a method similar to what is used by the European Union and the U.S. Food and Drug Administration (FDA) for estimating risks. Essentially, data on usage patterns, metabolic transformation, and physical and chemical properties are fed into models on dilution, degradation, and other factors to estimate environmental concentrations. One data gap that needs to be addressed is the "no effect" concentration on fish. Currently, the information EPA has on how chronic exposure to these compounds affects native fish is based on data extrapolated from studies of the effects these chemicals

have on mammals, Kostich said. In the meantime, EPA is developing test methods for screening chemicals in general for their endocrine disrupting potential, which will be discussed in more detail further below.

Critically, only limited evidence suggests a problem at this time with exposure to PPCPs in the nation's waterways. Research is being conducted to measure the potential risk of newly detectable compounds, information that will be critical for the proper regulation of PPCPs, if EPA determines such protections are in order to adequately and responsibly protect environmental and human health.

Studies on Biological Impacts Are Inconclusive

Several papers presented at the EPA conference focused on the biological impacts of PPCPs in the environment. Charles Knapp, a researcher at the University of Kansas, looked at fluoroquinolone antibacterials, which include the antibiotic drugs, cipro and enro. He used mesocosm and laboratory-based experiments to track mutations of a gene in the region known to confer antibiotic resistence in bacteria, evaluate the potential impact of these antibiotics on community structure, and determine their relative toxicity in a variety of test organisms. His studies showed no significant alterations in resistance gene mutations or microbial community structure in mesocosms exposed to relatively high concentrations (25 ppb) of enro. The toxicity testing revealed that blue-green and green algae as well as a simple aquatic plant were sensitive to the this class of antibiotics while higher organisms such as water fleas and fathead minnows were not affected at even very high concentrations (10 mg/L).

Marsha Black, a University of Georgia researcher, examined the acute and chronic effects of various selective serotonin reuptake inhibitors (SSRIs) on water fleas, mosquito fish, and frogs. These drugs are commonly prescribed as antidepressants and have been found to bioaccumulate in some fish tissues. Of the compounds tested, fluoxetene (Zoloft), was the most toxic although acute effects were not observed except at very high concentrations, which were not environmentally relevant—140 ppb for water fleas and 614 ppb for mosquito fish. However, chronic toxicity was observed at much lower, possibly environmentally relevant concentrations. Specifically, fish maturation and tadpole metamorphosis were delayed at 60 ppb and 9.5 ppb fluoxetene, respectively, and significant behavioral changes (lethargy) were observed in mosquito fish. Significant decreases in frog weight were observed when exposed to 0.06 ppb fluoxetene.

Jeff Armstrong, the senior biologist from the Orange County Sanitation Districts (OCSD), Fountain Valley, Calif., a NACWA member, described research his agency has conducted in collaboration with several universities and other agencies to determine whether flatfish living near their ocean outfall are showing signs of endocrine disruption. The District treats 243 million gallons of wastewater per day, most of which is discharged through an ocean outfall eight miles offshore from Huntington Beach. Their studies employed various types of biomarkers and tests, including vitellogenin (Vtg) induction, cortisol stress response, and DNA damage, to measure and compare concentrations of endocrine disrupting compounds (EDCs) near the outfall as well as at a farfield reference site. These studies found more evidence of Vtg in both male and female fish near the outfall than at the reference site as well as some DNA damage. While the studies showed that endocrine function in fish collected near the outfall was compromised, no population-level effects

were demonstrated. Sediment chemistry results found higher levels of EDCs near the outfall, which correlated with biological measures of exposure such as elevated levels of Vtg and inhibition of cortisol induction.

However, no shift in sex ratios towards feminization was observed. In fact, the hornyhead turbot population near the outfall appears slightly masculinized. Follow-up studies are being planned to examine a wider group of organisms, determine EDC levels in food items, and attempt to identify compounds in the wastewater discharge which may be the source of these effects.

IV. STRATEGIES TO ADDRESS THE PPCP CHALLENGE

Possible Regulatory Control

Some POTW representatives and EPA officials said they were highly concerned about the public outcry over reports of these compounds in local waterways. Reports in the media of test results showing pharmaceuticals and other contaminants in water samples could prompt activist groups and others to pressure government regulators into taking action prematurely that could result in monitoring requirements at the very minimum.

Ongoing research funded by EPA and other entities is intended to shed light on the subject, but without a significant boost both in funding or a dramatic shift in research priorities, the answers regarding impacts PPCPs have on the environment or public health may prove elusive.

One indication that EPA officials may be feeling pressure is their announcement at the conference that they may include some PPCPs on the third contaminant candidate list (CCL3) due out in 2008 with a draft expected in late 2006. The first CCL, published in 1998, contained 60 compounds not already regulated under the Safe Drinking Water Act (SDWA) that may have adverse health effects, may show up in public water systems, and may be regulated under the SDWA.

The second CCL was published in February 2005 and contained 51 of the original 60 unregulated contaminants. EPA performs studies on the listed compounds to establish analytical methods for detecting whether they occur in drinking water systems, determine any potential adverse health effects, and evaluate treatment technologies. The Agency would then decide whether to issue drinking water guidance, health advisories, regulations, or take no action at all.

The SDWA and the Clean Water Act tend to follow separate paths in the regulation of contaminants. Many of the compounds identified on the CCL already have water quality criteria established under the Clean Water Act. However, EPA has said repeatedly it wants to develop a strategy to merge the goals of both programs. The issue of PPCPs and other emerging pollutants demonstrates the need for such an approach.

EPA is working with the U.S. Geological Survey (USGS) to put together a database of scientific literature on PPCPs. So far the database, which is not available to the public at this time, includes more than 400 peer-reviewed articles dating from the 1970s.

Some view EPA's announcement that certain PPCPs may wind up on the 2008 CCL as evidence that the Agency may be eyeing regulation of these compounds. However, establishing reasonable regulatory limits would be a challenge given that gauging the impact of each of these compounds on human health and the environment by studying the fate, transport, mode of action, and toxicity of each individual chemical is nearly impossible. Tens of thousands of PPCPs are currently being used by the public, with more coming to market each year. Simply put, the research dollars needed for such an undertaking far exceed most research budgets. The task becomes even more daunting when dealing with complex mixtures of these chemicals that may be in various states of degradation or transformation, factors that could play out differently depending on the target species.

POTWs Seek to Avoid "WET Test Scenario"

EPA faced a similar problem in trying to regulate more conventional pollutants in the 1980s, which drove the development of the WET tests and toxicity identification evaluation (TIE) procedures which are widely used today to regulate point source discharges and surface water quality.

The concept of the WET test is simple and appealing—let the organism integrate these complex mixtures and conditions and then measure biological endpoints of concern, such as mortality, reproduction, and growth, to determine if a water sample is toxic. Once found to be toxic, the TIE procedures would be used to identify classes of chemicals or the specific chemicals themselves, responsible for the toxicity and determine appropriate treatment and/or regulatory options to remove the toxic constituents.

However, the link between WET results and environmental impact was not well established during the development of the program, particularly when only moderate effects were observed on sublethal endpoints. As a result, the current WET program is capable of detecting and predicting environmental impact in highly toxic and non-toxic samples, but moderate chronic toxicity is not very predictive of environmental condition.

The reason for this history lesson on WET is that EPA could follow a similar approach with PPCPs, but with even more urgency as a result of public concern for the presence of these chemicals in surface and groundwater. As expressed by some during breakout sessions at the conference, if the mistakes made with the WET program are to be avoided, the Agency must be patient and exercise restraint while scientists determine the risk these chemicals pose and suitable bioassays are developed which predict their environmental impact. EPA should also be prepared to abandon the current binary interpretation of bioassay results (toxic/non-toxic) because it is likely that these new assays will still contain a large degree of uncertainty regarding environmental impact, particularly when they are based upon biomarkers or only show a moderate response.

Many public agencies have begun investigating the presence and impact of these chemicals on their own out of the same public demand for information, and they are often willing to participate and contribute to this process. However, as with WET, mandatory monitoring using imperfect methods will have the unfortunate and unintended effect of preventing the needed research from being completed. As we wait for these methods to be developed and validated, it would be helpful if the Agency took time to educate and inform the

regions, states, and general public about the current situation with PPCPs, especially regarding the vast data gaps that currently exist.

Test Method Standardization Needed

Much of the data used in the research presented at the conference came from the USGS or from individual researchers using their own techniques. Currently, there are no standardized protocols for testing and analyzing PPCPs and their possible effects. While the research chemists are very confident in their data and the reliability of their methods, there has been no round-robin testing and only a few attempts at standardization.

The only paper focused on developing standardized biological methods for assessing the effects of PPCPs was presented by Joseph Tietge from EPA's Office of Research and Development describing work to date on endocrine disruption assays for screening of specific chemicals and evaluation of surface waters. The three-step approach involves first developing two relatively short-term assays for high throughput screening (Tier I), then a couple of partial or full lifecycle tests to evaluate transgenerational effects (Tier II) not targeted in Tier I to determine the predictive ability of the short-term assays. Finally, these bioassays will be field validated for surface waters through testing of effluents from wastewater discharges and CAFOs.

EPA is in the process of finalizing two Tier I methods. The first involves a 42-day fathead minnow reproduction assay to evaluate effects on the estrogenic and androgenic pathway by measuring egg production, hatch rates, blood sex steroid concentrations, histology of reproductive organs, secondary sex characteristics, and other biological markers. This test is complemented by a 21-day tadpole metamorphosis assay, which evaluates disruption of thyroid function by measuring histological changes and life stage progression in comparison to controls. Tietge briefly mentioned that the Tier II tests are also being developed and will include a two-generation fish (Medaka) and a frog reproduction and development assay.

Future research by ORD will be devoted to field validation of the Tier I and II methods and the development of other molecular endpoints (genomic, proteomic, and metabonomic), which could predict endocrine disruption in longer term tests. The hope is that these methods will increase the efficiency of screening of samples, aid in the development of predictive models for ED, and allow for extrapolation of results across species.

Other Potential Sources of Concern: Veterinary Antibiotic Use

The past two decades have also seen a dramatic rise in the number of concentrated animal feeding operations (CAFOs) and the subsequent increase in the use of veterinary antibiotics. While the number of animals has remained relatively consistent, they are confined in concentrated areas intensifying the impact on water quality. The Union of Concerned Scientists estimated in a 2001 report that livestock producers use 24.6 million pounds of antimicrobials, including antibiotics, annually for nontherapeutic purposes, such as to promote growth. In addition, antibiotics are also added to feed and water to reduce the losses of livestock to disease. Animals in confined situations are more susceptible to disease when they are crowded together prompting the need for antimicrobials.

Many argue that the impacts on the environment from pharmaceuticals used in livestock and aquaculture may be significant and warrant further research. David Graham, a researcher in the Department of Civil, Environmental, and Agricultural Engineering at the University of Kansas, said evidence is mounting to suggest that the use of antibacterial agents in agriculture is increasing the level of antibiotic resistance among microbial pathogens. His research used real-time polymerase chain reaction (PCR) to track the concentration of tetracycline resistance genes in microbes collected from surface waters and feedlot wastewater lagoons and controlled laboratory and mesocosm experiments. He concluded that resistance to tetracycline primarily occurs at the point of use rather than in the environment. Further, light plays an important role in the degradation of tetracycline as well as a reduction in the occurrence of tetracycline resistance genes downstream from the source. He will continue to research the fate and transfer of resistance genes and organisms in aquatic systems. EPA Region 10 is conducting some research in this area. In fact, several of EPA's regional offices are researching various aspects of the PPCP challenge.

Research in EPA Regions Continues

A newly-formed EPA cross-regional team called the National Regional Science Council PPCPs Team, headed by Bobbye Smith in EPA Region 9, is studying a number of issues related to PPCPs. In Region 1, EPA researchers are looking at analytical methods for steroid hormones and other EDCs in water.

Region 3 has studied intersex fish in the Potomac River and is testing the correlation between wastewater treatment plant effluents and estrogenic effects. A vitellogen gene expression assay is underway to assess the presence of estrogenic endocrine disrupting compounds. Another project is designed to look at the environmental consequences of veterinary antimicrobials.

Researchers in EPA Region 5 are developing analytical methods for alkyl and nonylphenols and are working on toxicity tests to develop water quality criteria in the future. A project to look at sewage sludge and persistent bioaccumulative and toxic compounds is also underway.
EPA Region 8 is coordinating with the University of Colorado to study the impacts on downstream fish from effluents containing EDCs. There are visual effects showing a higher number of female and some intersex fish.

Region 9 is disseminating EDC and PPCP research results to multiple stakeholder groups and participated in an EPA Office of Research and Development vitellogen gene expression study of 50 POTW effluents from across the country.

EPA Region 10 in the Pacific Northwest is looking at the potential impacts of runoff from concentrated animal feeding operations involved on nearby surface and groundwater in the vicinity of CAFOs. The regional lab is developing the capacity to perform vitellogen gene expression assays for EDCs.

Options for POTWs to Consider as Next Steps

Based on information from the Las Vegas meeting, EPA could take a top-down, "precautionary principle" approach to reducing the presence of PPCPs in the environment, but discussion centered on promoting various voluntary environmental stewardship initiatives such as pharmaceutical take-back programs.

At the moment, POTWs are assessing their options on addressing this issue. Some NACWA members strongly support take-back programs while others question the wisdom of devoting scarce resources to reduce pharmaceuticals, which may not be harmful to public health or the environment, instead of addressing other known water quality problems.

NACWA is currently looking into the possibility of working with the Product Stewardship Institute in Boston on a multi-stakeholder dialogue to develop solutions for dealing with pharmaceutical waste. Pharmaceutical take-back programs are one form of product stewardship that could be explored through such a dialogue.

Pharmaceutical Collection Programs—Benefits and Drawbacks

Another approach being experimented with at the local level is the idea of a community pharmaceutical waste collection program. Lynn Rubenstein, the executive director of the Northeast Recycling Coalition (NERC), outlined critical components for such a program modeled on household hazardous waste collection efforts. These collection programs, which can be quite complex, must take place over the course of a few hours on a designated day and require some law enforcement presence. She recommended the events be held inside and have armed police officers to provide security and take custody of the controlled substances that are collected. It is also strongly recommended that there be a pharmacist on-site to help identify and inventory the collected pharmaceuticals. Some states require that medications collected at these events follow procedures for hazardous waste disposal, including the use of proper hazardous waste containers, manifests, and transportation.

Communities undertaking these types of collections could use them as an opportunity to survey consumer disposal practices, the types of medications being disposed of and reason, and to whom the medication was prescribed. They should maintain records, including a tally of the controlled substances, which would have to be signed and overseen by a law enforcement official. Chicago has experimented with this concept and collected 1.5 tons of discarded pharmaceuticals through a collection program, according to Catherine O'Connor, of the Metropolitan Water Reclamation District of Greater Chicago.

However, community collection programs face numerous barriers, not the least of which are federal narcotics laws under the jurisdiction of DEA and the Resource Conservation and Recovery Act (RCRA), the primary law for regulating solid waste.

V. CHALLENGES TO STEWARDSHIP INITIATIVES

DEA Regulations to Eliminate Drug Diversions

Vicki Seeger, a representative from the DEA's Office of Diversion Control, discussed that agency's efforts to reduce the amount of prescribed narcotics that get diverted for illegal purposes. While DEA does not oppose pharmaceutical take-back programs and community collections outright, the agency wants to ensure that the opportunities for diversion of narcotics and other controlled substances are limited.

Essentially, pharmaceuticals fall into three categories: over-the-counter medications, prescription non-controlled substances; and prescription controlled substances, which are medications that have abuse potential, such as oxycontin and other addictive drugs. Drugs are diverted at all levels of distribution, but DEA tries to minimize the problem through the Controlled Substances Act, which creates a closed system for distributing medications that encompasses manufacturers, distributors, pharmacies, and physicians. Under the system, for example, distributors can take back unused drugs from pharmacies and physicians, but not patients.

These regulations establish a complex system for tracking the drugs and may also impede the development of pharmaceutical take-back initiatives and reverse distribution programs. They also impose strict requirements for how health care facilities must handle pharmaceuticals limiting their options for disposal. DEA regulations rendering most pharmaceuticals unrecoverable and requiring that two health-care professionals witness their disposal are examples and one area where revisions should be considered. Whether this revision can be accomplished administratively or will require congressional action remains to be seen.

DEA is aware of current regulatory limitations and is considering changes to facilitate the disposal of waste pharmaceuticals. Some POTW representatives said they hope such changes will serve to broaden disposal options and move away from the overused practice of flushing.

RCRA Challenges to Managing Pharmaceutical Wastes

RCRA presents its own regulatory barriers to take-back programs and municipal collection initiatives. Under that law, common medications such as epinephrine, warfarin, lindane, and nine chemotherapy agents are classified as hazardous waste if discarded and must adhere to strict requirements regarding transport, storage, manifesting, and incineration. The law has not been updated since the 1970s nor kept pace with the huge number of compounds entering the market since then that could potentially be subject to RCRA requirements. For example, more than 100 toxic chemotherapy agents can be legally flushed or disposed of in landfills, according to Charlotte Smith, president of PharmEcology Associates in Brookfield, Wis. PharmEcology consults with the pharmaceutical industry on waste disposal practices and other regulatory issues. In many cases, she said, health care providers are aware of the hazards and seek more responsible disposal options, though not always the most environmentally sound ones.

Even after all RCRA-classified drugs and chemotherapy agents are destroyed at RCRA-approved incinerators, another 85 percent are still disposed of in sewers or landfills. These

include endocrine disruptors, anti-depressants, antibiotics, and anticholesteremics, according to Smith. Moreover, the vast majority of states have not even begun to look at the issue of how hospitals, long-term care facilities, and clinics dispose of pharmaceutical waste. California and Washington are two exceptions. They require all pharmaceutical waste that does not meet specific toxicity levels to be incinerated. Minnesota's hazardous waste rules cover about 15 percent of the drugs on the market and encourage incineration for the rest.

Smith argues that it is not appropriate to regulate pharmaceutical waste through a model designed to address industrial hazardous waste. One obvious reason is the sheer number of pharmaceuticals. It would be unrealistic to expect every nurse to know which of more than 2,000 medications administered by a hospital are considered hazardous waste when discarded. EPA should issue guidance clarifying how these wastes can be efficiently managed. Eventually, she said, regulations should be adopted to clarify a rational decision-making process for "this significant source of environmental contamination." In the meantime, the agency should promote voluntary, collaborative approaches to pharmaceutical waste identification, management, and minimization, Smith said at the conference.

Treatment Options of PPCPs

The EPA conference had limited discussions on treatment options to remove PPCPs from wastewater. Some work showed that longer sludge age helped reduce some compounds but was ineffective for others. The same held true for powdered activated carbon (PAC). Membrane filters coupled with long sludge age and/or PAC provided the optimum removal for the compounds evaluated. Composting also showed positive results. However, it appears that the most effective treatment option depends on the compound and the targeted limit.

J.C. Davis, the public information officer for the Las Vegas Valley Water District, pointed out that what are considered adequate removal limits today will change tomorrow as detection capabilities advance. Thus, it is important to determine safe levels for specific compounds and communicate them to the public. The presence of a newly detected contaminant, regardless of how minute or insignificant, can trigger alarm among a misinformed public.

A strong public education program would go a long way to alleviate this often excessive concern and also could be used as a tool to reduce the amount of medications that get flushed into the sewer system. Public education campaigns could involve a number of approaches. Some at the EPA conference suggested a labeling program not unlike those used to educate consumers about household pesticides. Other options include providing disposal information on medicine bottles or on a separate leaflet accompanying a prescription. Another option includes public education campaigns by POTWs through "bill stuffers" to inform customers about the risks associated with flushing unused medications.

VI. CONCLUSION

While the technical information from the EPA conference was informative, it was clear that EPA is under pressure to begin monitoring for certain PPCPs as soon as possible and potentially regulate these compounds despite a lack of evidence that, with a few notable exceptions, these compounds are having an environmental impact. Much of the impetus to begin monitoring appears to be coming from EPA regions as well as various states that are trying to address public concerns about the mere presence of these compounds in their surface waters or groundwater supplies.

EPA should approach this issue in a cooperative manner with the regulated community. The options range from doing nothing at all to imposing costly regulations that ultimately may show little environmental benefit. In between these extremes are opportunities for collaboration and innovation, including community collections, product take-back programs, and aggressive public education campaigns. The thought of a regulated approach at this time could slow progress on much needed research to find answers to the numerous questions that are out there.

Before regulation of these contaminants can be reasonably contemplated, EPA must develop meaningful biological endpoints. Otherwise the Agency would simply be wandering down an inchoate path to more and costly regulation with uncertain outcomes.

Many regulators, researchers, and some in the regulated community agree that the best approach is to remove these chemicals at the source rather than after disposal. To that end some POTW officials said take-back programs may offer the most cost effective solutions in many situations depending upon the degree to which unused materials contribute to the source and the reduction needed to mediate any problem. Others questioned their usefulness if the majority of the problem stems from human excretion rather than the disposal of unused PPCPs.

To be sure, much more information is needed before broad national strategies for addressing the problem are implemented. In the meantime, NACWA will work with its member utilities and other organizations that are doing environmental research to take the results and develop options for minimizing risks and communicating these strategies to the public.

For example, NACWA can take a leadership role in engaging the federal government, including EPA and FDA, and encourage these agencies to consider water quality impacts as a regular component of their decision-making process regarding the approval of drugs or chemicals for commercial use. The Association has already done this in its recent letter to EPA commenting on the Agency's process for approving certain pesticides for commercial use and urging it to take into consideration potential impacts to water quality. Minimally, there is a need to ensure consistent monitoring of and participation in PPCP-related policy. NACWA may want to consider setting up a special workgroup, or least cultivate an issue leader, to collect information, coordinate strategies, and be involved in the development of any policy relating to PPCPs. The Association's Communications and Public Policy Committee should be an integral part of any strategy NACWA undertakes to help provide the public with accurate information about this important topic.