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ADDRESSING PHARMACEUTICALS AND PERSONAL CARE PRODUCT CONTAMINATION: A UNIQUE OPPORTUNITY TO LINK SCIENCE TO ACTION

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ABSTRACT

Too often, well-intended environmental improvement strategies fail or result in unintended negative consequences because the problem and proposed solutions were not fully and objectively measured and analyzed. Whether due to government agencies with compartmentalized technical disciplines or inadequate consultation with key business and community stakeholders, the problem often fails to get solved or has unintended but negative side effects. With respect to emerging contaminants (EC), such as trace pharmaceutical and personal care product contaminants (PPCP) in wastewater, government programs are already being implemented and many more are being discussed and proposed – sometimes without a scientific basis for expected environmental or human health protection or improvement and without objective evaluation to measure or demonstrate effectiveness.

By addressing environmental issues with a multi-disciplinary technical approach to identify the source contributions of PPCP levels in waterways by implementing a pilot program to address human behavior in a community, we may prevent wasted efforts and unwanted side effects, and provide opportunities to optimize environmental improvements. Absent this approach, government agencies (and thus citizens in general) may waste millions of dollars implementing pollution control strategies, later found to be ineffective (at best), if not counterproductive (at worst). We suggest starting the discussion with a proposal to implement a broad-based stakeholder advisory group, including public and private sector researchers; local, state, and federal government representatives; health-care providers; pharmaceutical manufacturers; water suppliers; wastewater treatment utilities; and other relevant representatives. We propose developing a stakeholder-based program to refine the research agenda to investigate the relative source contributions of PPCP, and what pollution prevention strategies are most effective.



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INTRODUCTION

Since the publication of *Our Stolen Future* (Colburn, 1996), the issue of emerging contaminants (EC), trace amounts of pharmaceuticals and personal care products found in waterways, has received more attention from the U.S. federal government, universities, researchers, and communities across the nation. More evidence over the past 12 years has been uncovered on a wider array of chemical pollutants and possible adverse environmental effects resulting from their environmental fate. In 2006, the *Environmental Science and Technology* call to the scientific community for research on the “emerging” issue led to a valuable collection of papers that helped set the stage for the complexity and potential seriousness of contaminants that, while they themselves are not really “emerging”, so much as the technology and visibility of the issue are. More advanced analytical methods have led to the low-level detection of organic contaminants, such as pharmaceuticals, antibiotics and fluorochemicals. Unfortunately, while a substance can be identified at parts per billion levels, this technology does not offer a clear link to whether the chemical is persistent or has potentially deleterious human, wildlife, or toxic ecological effects (Field et al., 2006). Some alarming evidence of EC effects have been surfacing for years however, if you know where to look. Professor David Norris of the University of Colorado found that the fish population downstream of wastewater treatment plants in Boulder Creek were disproportionately female, and nonfemale fish had developed both male and female organs (Peglar, 2005). These findings are similar to studies done in Lake Mead, Florida, and the Great Lakes, where similar reproductive issues occur in fish, alligators, and birds (Peglar, 2005). Studies conducted on the lower Potomac River as well as on Boulder Creek have also provided evidence of hermaphroditic or inter-sex smallmouth bass and other smaller fish in waters that showed readable levels of endocrine disruptors (Avasthi, 2007. Also, Woodling, et al, 2006). Several of these studies were able to duplicate their results in laboratory tests. Studies in Great Britain have shown very similar results (Briggs, 2000). The presence of estrogens and estrogen-mimicking chemicals from pharmaceuticals, personal care products like lotions, shampoos, and cleansers are thought to be to blame for the endocrine disruption and resulting sexual deformities. Endocrine disrupting compounds can also be found in pesticides and their residuals, fire retardants, plasticizers, and other common chemicals and their byproducts. Norris notes that these environmental contaminants may also have a correlation to human health and demographics, particularly concerning the rising rates of breast cancer, early onset of puberty in girls and the slowly shifting ratio of males to females born in the U.S., all of which can be attributed to estrogenic effects (Field et al., 2006).

However, there is very little quantified evidence for the effects of long-term, low-dose exposure to endocrine disruptors on such human health problems such as cancer, early onset of puberty, and other medical issues associated with elevated hormone levels. Many concentrations of contaminants are below regulatory limits, and are not known to be harmful in such low amounts. In fact, one desk-based study out of Great Britain suggests that EC levels detected in drinking



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water were so low that they should not be considered harmful at all (Watts, et al, 2007). However, scientists are not sure what exactly the human health impacts are, and which drugs, or combination of drugs, and at what level they may become toxic (Frazier, 2005). In spite of this uncertainty, many experts and concerned citizens have begun to call for adherence to the precautionary principle, and with good reason. Simply because all of the science is not yet definitive does not mean that there is no threat to humans or wildlife. As it stands now, “Current regulatory practices give chemical manufacturers the benefit of the doubt. Substances can be removed from the market only if their health impacts can be demonstrated with scientific certainty. This burden of proof needs to be shifted.” (Colburn, n.d.)

Removing EC from waterways or preventing their occurrence is not something policy or wastewater treatment plants are currently set up to achieve. So, to avoid finger pointing and mandates on wastewater treatment plants or household products and individual medicine consumption, no clear policy strategies exist to address what the Institute for Environmental Solutions (IES) feels is the real issue; human behavior.

Prevention strategies such as pharmaceutical take-back programs (in which either events are held to collect and dispose of unused pharmaceuticals and toxic household chemicals according to current local regulations, or ongoing collections are held locally or through the mail) have become popular in recent years. It is critically important that strategies such as this are backed with sound science to ensure they are accomplishing the desired goal of reducing EC levels in the environment, without unwanted side effects. If take-back programs are the only mitigation strategy and they do not result in measurable reductions in contaminants, they may lead consumers or community leaders to believe the contamination is being adequately addressed when, in fact, the problem is not being solved.

To make real progress in developing and implementing pollution prevention strategies, a critical first step is to engage the full range of stakeholders, from consumers to product manufacturers to the scientific community, in characterizing the problem and working toward multiple sound and effective strategies. The best time to begin to address our chemical footprint on the environment was perhaps thirty years ago; the second best time is now. This paper is intended as a call to scientists, government agencies, and other stakeholders to come together and develop initial steps that can link sound science to effective action in our communities.

AMBIGUITIES AND CHALLENGES

While the knowledge base concerning EC is expanding, there are still large gaps in the overall picture of this type of pollution. The chemicals associated with emerging contaminants and their attendant by-products are found in a wide variety of consumer, industrial, and agricultural products, which number in the thousands. These chemicals often find their way to bodies of



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water. Advances in trace chemical detection technologies have made the quantification of contamination possible. Though detection technology does not tell us where specific chemicals originated and how they made it into the water, several researchers have clearly defined and mapped the possible routes that EC take into ground and surface water. PPCP originate with individual or household use (e.g., metabolic excretion of drugs, disposal of unused drugs, use and disposal of personal care and other household products, or underground leakage from sewage systems), hospital or industrial waste, and agricultural releases, and most often end up running through a sewage treatment plant. They may then be transported back to waterways, taken up by plants, or being affected by sunlight and UV rays (Daughton, 2004). However, more research to determine the relative contribution of each of these sources and source categories to the water contamination would be extremely valuable for developing prevention strategies. Trace contamination appears to act on aquatic life as endocrine disrupting compounds, affecting demographic patterns and individual sexual characteristics. What is less clear is which of the trace contaminants is causing these effects. Whether the effects are caused by a combination of contaminants or if they are cumulative impacts due to long-term, low-level exposure is unknown. According to experts like Dr. Theo Colburn of the not-for-profit organization, The Endocrine Disruption Exchange (TEDX), this is a key hurdle for those of us addressing the EC challenge. “Traditional toxicology often assumes that there is some level of exposure, a threshold, beneath which small amounts of a contaminant have no effect. New research has demonstrated that endocrine disrupting compounds violate this assumption, that there is literally no threshold of effect for an endocrine disrupting compound when it is added to a hormone system that is already active.” (Colburn et al., n.d.) The issue is that traditional toxics supposedly impact the body by starting or stopping a process by overwhelming the body's defense system. In this case, the body can defend itself against chemical assaults up to a certain level of exposure.

Endocrine disrupting chemicals, on the other hand, are adding to or subtracting from chemical signals that are directing processes already underway.

Even less clear is the seriousness of the impact of emerging contaminants on the wider environment as the impacts on aquatic life transfer to other ecosystems and wildlife. Links between EC and their resulting effects on humans are surfacing in many ways as national and international researchers pinpoint evidence through case studies. For example, one of the most prevalent effects of drugs in our water systems is antibiotic resistance (Wall, 2005). Since the twentieth century, the use of synthetic, manufactured antibiotics has revolutionized medicine, reducing fatalities from once very threatening diseases. However, this use has led to overuse, and the bacteria are fighting back. According to one expert, “Among microbes, the Darwinian evolution is alive and well. The fittest organisms, the survivors, became resistant to antimicrobial drugs.” (Vandevelde, as cited in Wall, 2005) Now, diseases like pneumonia and tuberculosis are resurfacing with strains resistant to antibiotics. Over-prescribing by doctors, patient requests for antibiotics, and widespread agricultural use may be causes for concern. While the agricultural



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industry strongly refutes the idea that widespread antibiotic use in caged animal feeding operations (CAFO) are to blame for antibiotic resistance, over 40% of antibiotics used in the U.S. are for farm animals. Research at the University of Illinois discovered bacteria with genes resistant to tetracycline (an antibiotic used on humans and animals) found in groundwater up to one-sixth mile away from a CAFO (Wall, 2005). While the research done to this point is promising, these areas need to be explored more fully to foster a more complete understanding of the full range of impacts on humans.

Due to the synthetic nature of many of these emerging contaminants, the strategy for addressing this issue would be to use the plethora of existing science to inform the development of national pollution prevention, mitigation, and treatment programs. However, in the absence of the information establishing direct links between individual, commercial and industrial behavior and EC levels, and the evidence of this link to exact human and ecological effects, pollution prevention programs could be implemented targeting the wrong products, chemicals, consumers or businesses. This might result in dollars wasted and unintended side effects. Many pollution treatment strategies have the potential to reduce the concentration of many EC in wastewater. It will be critical for researchers to continue characterize which strategies are effective on which chemicals and at what unit cost, as new technology and equipment can be prohibitively expensive.

PUBLIC POLICY CONSIDERATIONS

Due mainly to the recent attention to EC on aquatic life in the media, there is growing pressure on public officials to “do something” about this issue. Public officials often seek quick and publicly palatable solutions to very complex problems. This issue has the potential for ‘feel-good’ solutions to be implemented that are actually ineffective and end up being a waste of time and resources. For example, one-day pharmaceutical take-back programs or household chemical round-up events may be a band-aid solution with no measurable effect on levels of contamination. This has the potential to result in the misconception that potential problems are being addressed when they are not. According to the Bay Area Pollution Prevention Group ([BAPPG] as cited in IISG, 2007), “Event based collection events are an inefficient way to have residents properly dispose of medications, since the events require an enormous amount of resources including outreach, advertising and staff time to organize and table the event.” However, there are several compelling reasons to hold such events. Namely, that the associated press, information and education can raise public awareness of the issue and their potential role in the solution. As communities realize that flushing unused medication, rinsing soaps down the drain and using toxic household chemicals on a regular basis can negatively affect the whole ecological system, behavior can begin to shift toward alternative products, and perhaps alternative medicine and natural health treatment.



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One big unknown relevant to public policy consideration is the relative sources and strengths of each trace contaminant and how they affect aquatic life and ecosystems. Considering that EC are found in a wide array of products, such as pharmaceuticals, personal care products, plasticizers, fire retardants, and fertilizers, many of these and their associated industries could be adversely affected by misguided, ineffective, or unnecessarily costly pollution abatement policies. Since the goal of addressing this issue is to promote knowledge as well as to ensure a safe and healthy environment, and not to foster unnecessary and counter-productive confrontation with any stakeholder in this issue, bringing sound science into the policy debate and development would help to avoid the alienation of impacted parties. Major challenges to effective public policy and pollution control strategy development include the following issues.

Nontraditional Nonpoint Sources

The most “convenient” pollution to control is directly traceable to a defined source. EC are generally not traceable to a specific source, even if impacts can be identified downstream of a wastewater treatment plant because the cocktail of contaminants come from so many sources, and can be chemically altered under various treatment methods (e.g., chlorination of acetaminophen causes products like Tylenol to transform into toxic compounds; Bedner and Maccrehan, 2006). Where we can link EC pollution to a source, it is generally a nonpoint source, such as agricultural runoff which may directly impact nearby streams. In other environmental arenas, such as air pollution, history shows a clear pattern where major point sources and traceable pollutants were the first to be regulated. Control technology was effectively developed and implemented. When air pollution persisted (and sometimes increased) in spite of point source controls, regulators reluctantly looked to controlling area (dispersed) sources and to developing control and prevention methods to reduce pollution that was not traceable to a single source. EC will challenge the most innovative of pollution prevention and control strategy developers.

As noted above, not only must the sources be determined, but the relative contributions of the sources must also be determined to then develop scientifically effective mitigation strategies.

A Vicious Circle: Lack of Defined Cause and Effect Relationships, Increased Drug Use and Disposal

Consistent with nonpoint sources of environmental contaminants, EC identified in streams and wastewater treatment plant discharges have the potential to present human health and environmental concerns. But the concerns have not been fully quantified and the link from the presence of EC to human health and ecosystem threats has not been adequately made. Steadily improving analytical capabilities are making the detection of more trace contaminants possible. This alone does not indicate that contamination levels are necessarily increasing, but there is



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evidence that suggests that this may be the case. The U.S. Centers for Disease Control and Prevention looked at 2.4 billion drugs prescribed in visits to doctors and hospitals in 2005. Of those, 118 million were for antidepressants. The use of antidepressants has skyrocketed over the last decade; adult use of antidepressants almost tripled between the periods 1988-1994 and 1999-2000. Between 1995 and 2002, the use of these drugs rose 48% (Cohen, 2007).

Many psychiatrists see this statistic as good news - a sign that Americans now feel comfortable asking for help with psychiatric problems. However, for the fish, frogs and other aquatic life (and possibly nonmedicated humans) this is not such good news. Evidence of Prozac was found in the brains, livers, and muscles of bluegill caught downstream of the Pecan Creek Water Reclamation Plant in Denton, Texas (Walton, 2005). Aquatic toxicologist Marsha Black found that low levels of common anti-depressants like Prozac cause development problems in fish, and metamorphosis delay in frogs (Walton, 2005). Delays and development problems lead to diminishing species; if tadpoles do not complete their metamorphosis by the time water levels drop, they will die. As critical species are removed, imbalances in the aquatic ecosystem take place.

The problem with antidepressants, hormone altering chemicals like birth control pills, estrogen replacement therapy, steroids, combined with antihistamines and aspirin, vitamins and Viagra, is that only a fraction is absorbed by the user. The rest is flushed down the toilet, resulting in bioaccumulation of which we are only beginning to see the impacts (Uhler, 2008). The possibility exists that accumulation in species low on the food chain can result in complex reactions on species higher up the food chain and in offspring, even at low concentrations.

New advances in hormone therapy, such as the Evra patch for birth control, now may lead to direct disposal of hormones in the environment. The patch can be discarded with other household waste, allowing hormones to find their way into the ecosystem. Even if they are disposed of in a protective foil pouch as recommended in the U.S., there is no guarantee that there will be no release of hormones. This is an example of how regulatory systems, rather than proven science, have more influence over how EC may make their way into the environment, because ecological exposure to contaminants is directed by disposal laws and waste management for a given community. Potential hormone release after disposal also points to a need for our legislative framework to address the full life cycle of a drug (Elston, 2004).

POLICY RESEARCH TO ADDRESS CHALLENGES

Increases in American drug use can be attributed to many causes, including increasingly stressful lifestyles with unhealthy eating and exercise habits. However, one other possible cause deserves a critical look; increased television drug ads and product placement. Since advertising laws were loosened around 2000, television advertisements for prescription drugs have skyrocketed. Pharmaceutical companies effectively spend millions of dollars each year on direct ads and on



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product placement within popular television dramas like House, ER and Scrubs. A University of British Columbia study found that more people are asking doctors for specific drugs by name, based on a television ad they saw and, in 75% of cases, they got them (Johnson, 2002).

Another problem may be that as soon as a drug hits the market, advertising begins, often before long-term effects are identified (Mintzes as cited in Johnson, 2002).

Further and more extensive scientific research points to a growing urgency for dealing with EC with multiple concurrent approaches such as human behavior, and policy related to promotion, disposal and product ingredients. One way to avoid the pitfalls in policy development would be to adopt a multi-disciplinary, technical, and stakeholder-based approach to that policy development.

To this point, many of the pollution control and abatement laws and regulations have been reactive in nature, as environmental agencies, research personnel, and citizen activists perceive a relatively large problem and work to alleviate these pollution-based problems by implementing a top-down regulatory solution. This process has indeed resulted in reductions of pollution overall, yet the inflexibility of such a top-down system has meant that unnecessary adversarial relations have developed between environmental and public health agencies charged with implementing these plans and the businesses that must comply with them. Furthermore, a ‘one-size-fits-all’ approach to pollution abatement has resulted in less than efficient pollution control activities. This inflexibility and inefficiency cannot be solely ascribed to the actions of government agencies, as they are also a result of preconceived notions as to the sources of pollution. This can pose a major stumbling block in dealing effectively with issue such as emerging contaminants. Care needs to be taken to ensure that ‘obvious’ or deep-pocketed targets of pollution abatement schemes are only targeted if they are actually the major sources of EC. For example, the 1987-88 Denver Brown Cloud Study was implemented because local government and environmental groups were focusing blame on the power plants as the major source of air pollution in the metro area. The power plants and their suppliers went to the Governor to get a postponement of legislation until a scientific study with stakeholder involvement could be done to objectively determine the major sources. The study found that contrary to popular belief, the power plants were an insignificant source of the Brown Cloud (Lyons, 1990). Proceeding with the originally proposed strategies to control the power plants would have cost the metro area, conservatively, \$30 million/year in increased electricity costs and done nothing to reduce the pollution problem. As a result of the study, major sources and several control strategies were identified that were tens if not hundreds of times more effective and less costly (Lyons, 1990).

Policy Based on Science

An urgent need exists to find, test, and implement sound scientific cost-effective solutions to



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complex environmental problems. By addressing environmental issues with a multi-disciplinary technical approach, one can prevent waste and unwanted side effects and provide opportunities to optimize environmental improvements. Too often, well-intended environmental improvement strategies fail or result in unintended negative consequences because the problem and proposed solutions were not fully and objectively measured and analyzed. The oxygenated fuels program implemented in Denver in the late 1980s illustrates this point. The State of Colorado put this program into action in the Denver metropolitan area in an effort to reduce carbon monoxide (CO) air pollution emissions from automobiles. Organic compounds which contained oxygen atoms, such as ethers and alcohols, were blended with gasoline to, theoretically, increase complete combustion of the fuel and reduce CO emissions. In 1989, the Colorado State Legislature mandated an independent performance audit of the program. The audit found that the program cost consumers between \$25 and \$30 million per year (in 1992), with a cost per ton of CO reduced between \$1,000 and \$1,300. The analysis showed that lower technology strategies could reduce more pollution at a lower cost (less than \$100 per ton; PRC, 1992). In subsequent years, other communities adopted oxygenated gasoline programs and then found that the primary compound used to add oxygen to the gasoline, methyl tertiary butyl ether (MTBE), caused widespread groundwater contamination when it leaked from underground fuel tanks (EP, 2002). In 2003, public water providers in 17 states sued 12 oil companies for cleanup costs. The oil companies recently agreed to pay \$423 million in addition to the cleanup costs to settle the suit (NY Times, 2008).

Whether due to stove-piped government agencies with compartmentalized technical disciplines or inadequate consultation with key business and community stakeholders, it happens quite frequently that the problem is not effectively solved. However, as in the Brown Cloud Study mentioned above, because all stakeholders were involved, no one stakeholder group could claim that the study results were biased, unscientific, or did not address their concerns.

Public policy to address environmental problems is most effective when it is based on sound, independent, and objective scientific analysis – although this is often not the easiest approach. Emerging contaminants is an environmental problem which needs such analysis. One of the most important issues to address concerning EC is that current toxicant policy is based on the concept that higher levels are thought to be more toxic, but this is not necessarily true, especially with endocrine disruptors.

The analysis to develop effective public policy needs to begin with definition and understanding of a key problem – the relative source contributions of contaminants. This is just as important as research related to the most prevalent or most potent drugs, endocrine disruptors, and their ecological effects.

Several opportunities and new technologies exist to address EC levels. Further research may be



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useful in determining their effectiveness, but some seem promising as first steps. For example, urine separation devices on toilets would significantly reduce the loading of the wastewater and would allow recycling of the nutrients, as most pharmaceuticals are excreted in urine (Ternes et al., 2004). Labeling of PPCP would inform the consumer and allow them to make an informed choice, as well as influence manufacturers in removing potentially harmful ingredients (Ternes et al., 2004). This would presumably work much like the recent requirement to labeling trans-fats on pre-packaged food, which has led manufacturers to find alternatives to hydrogenated oils. A supported, nationwide effort is needed to identify the major and most potent PPCP in various communities, improve misguided or ineffective policy, and guide effective, proper disposal of PPCP.

Stakeholder Approach

A stakeholder-based, multi-disciplinary, and technical approach can be very valuable in driving the research agenda related to EC. With thorough background research at the outset of a project designed to address EC, combined with stakeholder involvement, a wide array of information and concerns relating to as many facets of the issue as possible can be compiled to use as a baseline for the definition of the problems the issue presents. Taking a stakeholder approach helps to avoid excessive confrontation and adversarial relationships between equally relevant and important stakeholders or stakeholder groups. Being as inclusive as possible in meaningfully engaging stakeholders helps to foster acceptance of potential solutions that need to be investigated further.

Some states have implemented this stakeholder approach to policy solutions. For example, Maine recently passed LD 1826, *An Act to Encourage the Proper Disposal of Expired Pharmaceuticals*, effective July 2005. Senator Bromley (DCumberland County) worked with more than 20 interested parties representing stakeholder groups from public health officials to environmental groups to law enforcement to discuss the legislative action (Small Flows Quarterly, 2004).

However, proper disposal methods may only be a small step in mitigating EC. Involving stakeholders in the process of identifying source contributions of contaminants in a community on a project basis will require an understanding of the factors that motivate members of these groups. Targeting issues of importance to each stakeholder allows one to find effective means to engage individuals in joining the collaborative effort to tackle the challenge of emerging contaminants. For example, the motivation for a pharmacist to participate would be different than the motivation for a local university researcher. Once a relationship is established, stakeholders should have the opportunity to network and find additional benefits from meetings and other avenues of communication. Meetings are just one way that stakeholders have the opportunity to have their opinions and comments heard and to make a difference in their



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community. Collaborative working groups can be established as needed to work on specific issues and to address the specific needs and priorities of groups of stakeholders. Working groups may be comprised, for example, of stakeholders or partners from concerned citizen groups, or household product manufacturers and involved researchers from local nonprofit groups such as Consortium for Research and Education on Emerging Contaminants (CREEC), might establish a research agenda for utilizing nontoxic ingredients, or the effect of consumer reduction on a certain chemical on EC levels.

Educational outreach information developed in collaboration with key stakeholders can help to bring participants to a common level of understanding. Printed and electronic communication tools, presentations and discussions can provide important technical and environmental information. Comprehensive background research, consultation with regional and national experts, and organization of scientific and regulatory information is needed.

POTENTIAL STRATEGIES TO SUPPORT EFFECTIVE POLICY DEVELOPMENT

Baseline Information

Before possible solutions can be attempted, baseline data for source contributions of contaminants in a community need to be assembled to be able to accurately gauge the efficacy of each individual approach to pollution mitigation. When considering EC in water and how to compile baseline information, it may be effective to do the initial studies at places high in the watershed to avoid as much anthropogenic pollution as possible. Since the potential sources of emerging contaminants are very diverse, working with more of headwater source would help to identify which of the varied pollution abatement activities are effective. For example, implementing a pharmaceutical take-back program might need a supplemental education program if the greater source of EC happened to be fertilizers. This baseline data on source contributions of an individual community can be compiled by water quality tests being taken upstream of the pilot community, at the entry to the wastewater treatment plant, and then perhaps downstream of the water treatment facility to identify levels of removal.

Accessible Database

An electronic database similar in style to Wikipedia (the free on-line encyclopedia) could offer the stakeholders and the public access to scientific data on EC research, data, and projects. It could allow scholars and outside experts to contribute additional edited definitions, articles, and current information to an e-library. The specific concept is to allow the dissemination of information to the general public and sharing of information among stakeholders and researchers while gaining supplemental information from additional sources. Contributors could submit information and articles in a submission page that would be peer-reviewed. Qualified work



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would then be filed within the database. Stakeholders would be included in all phases of the process. Educational awareness of the database would be provided to the public on how to properly use the database for their benefit. The specific areas that the database would cover could include (but are not limited to): human health risk, ecological risk, technological advancement in trace pharmaceutical isolation and removal, mitigation processes, analytical methods, and results. While building on the numerous positive aspects of the public access Wikipedia concept, it is important to note that the proposed technical database would not allow unedited access. Rather, it will be “gated” by an objective, science-based organization such as IES, to assure the high standards of scientific peer review.

The Internet provides amazing new opportunities for access to information. However, thoughtful and organized information on important scientific issues is not readily available for free. Providing access to reliable and comprehensive information consolidated in one location would be a powerful asset in effectively tackling the challenge of trace pharmaceutical (emerging) contaminants.

Potential outcomes of this database include: increased public awareness of the human health and ecological risks of EC; centralized access to vast data and information on EC; regulatory information on what actions are being taken to mitigate the contamination of local waterways from trace pharmaceuticals; and information on what potential methods may be useful in the isolation and elimination of pharmaceutical residual in wastewater.

Pilot Test Programs

It is not practical or realistic to wait until science and technology developments have established firm answers to the questions of the sources, impacts, and mitigation strategies of EC before developing approaches to the problem. However, it is vital that experimental control and mitigation pilot projects be developed with monitoring and measurements to determine the effectiveness of the effort both in total life cycle costs and in environmental benefits. Independent objective scientific evaluation of the programs is essential.

One of the critical challenges of the EC issue is identifying individual contaminants. This pilot program would start with addressing what humans are contributing, so that analysis can be focused to identify potential correlations, within a reasonable budget. The pilot includes the following tasks:

Pilot Source Identification Program:

Some states and communities have implemented programs that aim to reduce the amount of these contaminants entering the environment through implementation of pharmaceutical take-back programs and other waste diversion efforts. The actual methods vary and include a mail-in



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program, the depositing of pharmaceutical and personal care products at previously designated household hazardous waste collection centers, and allowing pharmacies to accept pharmaceuticals at their counters for later disposal. Because the largest sources and seriousness of the contaminants have not yet been established, IES proposes a pilot program to identify the relative source contributions of EC levels. It is important to recognize that, while a pharmaceutical take-back program may be a visible response to the challenge of trace contaminants in wastewater, it may not provide significant or measurable reductions in wastewater contamination. Thus it is critically important to develop a program that involves cost-effective public education building on efforts in other areas and pursuing parallel efforts to address this complex challenge. Pilot program tasks would include:

- Establish a Stakeholder Steering Committee, to serve as the Board of Directors for the project, made up of representatives for key stakeholder groups. The Steering Committee helps to establish goals, objectives, project plan and environmental testing agenda required for a successful pilot program.
- Develop a broad-based Stakeholder Advisory Committee to provide feedback to the goals, objectives, and communication efforts of a proposed program.
- Establish Peer Review Committee to provide technical review, insight and guidance.
- Implement pilot project: 1) conduct community survey and focus group process - a community-based evaluation to identify individual household and local pharmaceutical, personal care and household product use and disposal habits, 2) conduct statistical analysis and environmental testing to identify correlations between PPCP use, disposal and existing contamination.
- Analyze results of surveying and environmental testing.
- Report on results, develop recommendations and establish future research agenda.
- Collaborate with stakeholder committee to develop relevant educational strategies, information, materials, and programs.

Pollution Prevention

The diversity of points of discovery of EC suggests that trace contamination in streams is a pervasive condition. Effective pollutant removal at the point of impact may be cost-prohibitive. Pollution prevention starting with changes in human behavior may be the most technically and cost-effective strategy to reduce EC in the environment. Therefore, it is important to begin determining where the various sources of EC are, and which contribute the most to pollution, both in quantity and potency. Limited research has been done to investigate and develop pollution prevention strategies that address not only proper disposal, but responsible use and alternative methods for cleaning, disinfecting, and even, health care.



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There are challenges to achieving significant reductions of EC in the environment through pollution prevention. Generations of changes in human behavior, such as we have experienced in the reduction of cigarette smoking, may be required. However, the fundamental pollution prevention approach has the potential to be the least costly and most effective.

Public Information

The final piece of this collaborative approach requires that community members not only represent a valuable part of any stakeholder group, but that they are presented with accessible, sound scientific information so that they can make informed decisions about how they interact with the natural environment. Like all stakeholder groups, if representative citizen organizations are included in a project to tackle EC from a human behavior standpoint, the public will be more likely to adopt recommendations. In fact, having all stakeholder groups represented ensures that local business owners work with local government, educators, hospital administrators, and others, and become informed, engaged, and supportive individuals who eagerly embrace results and take the message back to their respective communities.

Information dissemination and communication may need to address the fact that objective scientific analysis and results may be disappointing. Sound independent research may yield results that contradict popular understanding. The science may point to contaminant sources and impacts that are bad news for businesses, manufacturers, government agencies, or individuals (i.e., may indicate a need for alternative ingredients, disposal, and investment in new technology or additional effort). However, the stakeholder process which involves all parties from the beginning, presents unbiased facts and no agenda, allows skeptics to come forward early in the process, and have their concerns addressed. This process can turn former skeptics into a program's biggest supporters.

CONCLUSION

As the green movement gains momentum in the U.S. and popular press urges people to stop using plastic bottles to avoid contamination from bisphenol-a (a known endocrine disruptor), timing is critical to make the public, companies and government aware of their chemical footprint and take responsibility to start identifying what their impact is and to finding a way to reduce the impact. While there is still some lack of understanding of the magnitude of EC, it does not mean the issue can be ignored, but rather the precautionary principle should apply, as trace levels of contaminants in almost all parts of the country, including in pristine areas (Cornwall, 2008) and disturbing evidence in wildlife, or in groups of people exposed by accident or through medicine have been identified. Often, laboratory research on the health impacts of EC test compounds one or a few chemicals at a time and is thus not directly representative of the real world. "No one is exposed to just one chemical. Our exposures come in mixtures whose



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compositions depend upon our life style, where we live, our age and many other factors.” (Colburn et al., n.d.) Laboratory tests that look for the combined effects of different chemicals reveal complex interactions; sometimes additive, sometimes synergistic, and sometimes a canceling effect. These experiments, which rarely involve more than a few chemicals simultaneously, do not compare to the uncontrolled "experiments" that are taking place in humans and wildlife today. Typical exposures involve several hundred chemicals simultaneously (Colburn et al., n.d.).

As analytical and removal techniques improve and are widely used and evaluated, policy changes will occur. Effective pollution prevention should be top of the list. This can be achieved by evaluating and addressing human behavior through a science-based stakeholder approach to strategy and pilot project development, and a regimen of independent scientific monitoring and evaluation. Through a combination of existing science, future studies and supportive effort from communities, governments and businesses, we can link science to action to prevent PPCP contamination and improve the environmental state of our waterways and wildlife.

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