

August 2011

# ENVIRONMENTAL HEALTH

## Action Needed to Sustain Agencies' Collaboration on Pharmaceuticals in Drinking Water

U.S. Government Accountability Office

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## Why GAO Did This Study

Drinking water in some metropolitan areas contains concentrations of pharmaceuticals, raising concerns about their potential impact on human health. The Safe Drinking Water Act (SDWA) authorizes the Environmental Protection Agency (EPA) to regulate contaminants, including pharmaceuticals, in public drinking water systems if they may adversely affect human health among other criteria. Pharmaceuticals may enter drinking water supplies from several pathways, including discharge from wastewater facilities. GAO was asked to provide information on the (1) extent to which pharmaceuticals occur in drinking water and their effects, if any, on human health; (2) U.S. and other countries' approaches to reducing their occurrence; and (3) challenges, if any, that EPA faces in determining whether to regulate pharmaceuticals. GAO reviewed federal and peer-reviewed reports, and surveyed a nonprobability sample of five U.S. programs designed to properly dispose of pharmaceuticals. We selected these programs based on geographic diversity and program characteristics. We also researched such programs in two countries, and interviewed scientists and agency officials.

## What GAO Recommends

GAO recommends that the Administrator of EPA establish a workgroup or other formal mechanism to coordinate research on pharmaceuticals and other contaminants in drinking water. EPA agreed with the recommendation.

## ENVIRONMENTAL HEALTH

### Action Needed to Sustain Agencies' Collaboration on Pharmaceuticals in Drinking Water

## What GAO Found

Research has detected pharmaceuticals in the nation's drinking water. National and regional studies by the U.S. Geological Survey, EPA, and others have detected pharmaceuticals in source water, treated drinking water, and treated wastewater; but the full extent of occurrence is unknown. The concentrations detected for any one pharmaceutical were measured most frequently in parts per trillion. Research has not determined the human health effects of exposure to these concentrations of pharmaceuticals in drinking water. However, federal research has demonstrated the potential impact to human health from exposure to some pharmaceuticals found in drinking water, such as antibiotics and those that interfere with the functioning and development of hormones in humans.

Some states and local governments as well as the Drug Enforcement Administration have taken actions that could reduce the extent to which pharmaceuticals occur in drinking water. These efforts have primarily been through drug take-back programs to encourage proper control and disposal of pharmaceuticals. Additional efforts have been adopted in Europe following the European Union's directive in 2004 requiring member states to have appropriate collection systems for unused or expired medicinal products. In addition to collection systems, Sweden also encourages actions such as writing small initial prescriptions to reduce the amount of pharmaceuticals that are disposed of if patients switch to a different pharmaceutical course.

EPA faces challenges in obtaining sufficient occurrence and health effects data on pharmaceuticals and other contaminants in drinking water to support analyses and decisions to identify which, if any, pharmaceuticals should be regulated under SDWA. EPA is collaborating with the Food and Drug Administration and U.S. Geological Survey on research to help obtain such data but these efforts are largely informal. EPA officials said there is no formal mechanism, such as a long-term strategy or formal agreement, to manage and sustain these collaborative efforts. A recently expired interagency workgroup, which EPA co-chaired, initiated work on a research strategy to identify opportunities that will enhance collaborative federal efforts on pharmaceuticals in the environment, but its draft report did not contain key details about how the agencies will coordinate such collaborative efforts. GAO previously identified key practices for enhancing and sustaining collaboration among federal agencies, some of which may help clarify such coordination, such as establishing the roles and responsibilities of collaborating agencies; leveraging their resources; and establishing a process for monitoring, evaluating, and reporting to the public the results of the collaborative research efforts.

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### Abbreviations

ADI	acceptable daily intake
BPA	bisphenol A
CENRS	Committee on Environment, Natural Resources, and Sustainability
DEA	Drug Enforcement Administration
DOI	Department of the Interior
DOJ	Department of Justice
EDC	endocrine disrupting chemical
EPA	Environmental Protection Agency
EU	European Union
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
OSTP	Office of Science and Technology Policy
NSTC	National Science and Technology Council
PIE	Pharmaceuticals in the Environment
RCRA	Resource Conservation and Recovery Act of 1976
RUM	Return Unwanted Medicines
SDWA	Safe Drinking Water Act
USGS	U.S. Geological Survey

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**G A O**

Accountability \* Integrity \* Reliability

**United States Government Accountability Office**  
Washington, DC 20548

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August 8, 2011

The Honorable Brad Miller  
Ranking Member  
Subcommittee on Energy and Environment  
Committee on Science, Space and Technology  
House of Representatives

The Honorable Edward J. Markey  
House of Representatives

In 2008, in response to increasing information arising from the scientific community, the news media reported that pharmaceuticals had been detected in the drinking water of 24 major metropolitan areas across the United States.<sup>1</sup> The concentrations detected were measured most frequently in parts per trillion. The reports raised concerns about the potential impact of these pharmaceuticals on human health and the environment. Pharmaceuticals are a particular concern because they are designed to interact with human or animal physiology.<sup>2</sup> Much is known about the therapeutic uses of pharmaceuticals, but little is known about their potential risk to human health from long-term exposure through drinking water. According to scientists, pharmaceuticals may enter the environment and ultimately drinking water supplies in various ways, such as through the elimination of human and animal waste, disposal of unused medicines down the toilet or drain, veterinary drug usage, hospital waste disposal, and industrial discharges.

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<sup>1</sup>This report uses the term “drinking water” to refer to treated drinking water—the water that has been treated before it enters homes or businesses. We use the term “source water” to refer to the water in rivers, lakes, ground water, and other water bodies that may be the source of drinking water before treatment or that may be consumed without being treated. We also use the term “effluent” to refer to treated wastewater.

<sup>2</sup>This report uses the term “pharmaceutical” to refer to active pharmaceutical ingredients (API) and related chemicals such as metabolites. According to the Food and Drug Administration, an API is a substance that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. A metabolite is a substance that is the product of biological changes to a chemical.

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Federal, state, and local governments, and other countries have taken actions to reduce the extent to which pharmaceuticals enter the environment through programs that encourage the proper disposal of unused and expired pharmaceuticals. These programs are known as take-back programs and in the United States they are also tied to efforts to reduce drug abuse or accidental poisoning by removing expired medicines from homes.

The Environmental Protection Agency (EPA) has the authority to regulate some pharmaceuticals under several statutes, including its responsibility for regulating the nation's drinking water under the Safe Drinking Water Act (SDWA). Pharmaceuticals are regulated by other agencies, including the Food and Drug Administration (FDA) and in some cases the Drug Enforcement Administration (DEA), but not as contaminants in drinking water.

To help understand the human health and ecological effects of pharmaceuticals in the environment, a workgroup of federal scientists was established in 2006 to identify and prioritize research to better understand the risk from pharmaceuticals in the environment and to recommend areas for federal collaboration to address those priorities. The workgroup, known as the Pharmaceuticals in the Environment (PiE) workgroup, produced a draft report in the spring of 2009 that was never finalized or publicly released.

In this context, you asked us to review the scientific literature and assess efforts to address pharmaceuticals in drinking water. Our objectives were to (1) provide information on the extent to which pharmaceuticals occur in drinking water and the effects, if any, that their occurrence has on human health; (2) describe the approaches taken in the United States and in other countries to reduce the extent to which pharmaceuticals occur in drinking water; and (3) identify challenges, if any, that EPA faces in determining whether any pharmaceuticals should be regulated under SDWA, actions EPA is taking to address these challenges, and options for addressing such challenges in the future.

To identify the extent to which pharmaceuticals occur in drinking water and their potential effects on human health, we reviewed federal and peer-reviewed reports, including (1) studies by the U.S. Geological Survey (USGS), (2) articles in scientific journals, and (3) the PiE workgroup's draft report. We also interviewed scientists and other officials from federal agencies, as well as representatives from the pharmaceutical industry. Additionally, we attended an October 2009 academic conference

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on hormones and related compounds in the environment. To describe the approaches taken in the United States and in other countries to reduce the extent to which pharmaceuticals occur in drinking water; we reviewed literature and spoke with experts; from these efforts, we identified consumer take-back programs as the primary approach to reducing occurrence in the United States. We selected a nonprobability sample of five U.S take-back programs to provide geographic and program diversity; the information from these programs is not generalizable to all take-back programs and offers examples of how these programs can operate . We also chose to describe efforts by Sweden and Australia to reduce the occurrence of pharmaceuticals in drinking water. We selected Sweden because it engages in a variety of activities to reduce the occurrence of pharmaceuticals in drinking water. We selected Australia because it has a national take-back program. To identify challenges, if any, that EPA faces in determining whether any pharmaceuticals should be regulated under SDWA, actions EPA is taking to address these challenges, and options for addressing such challenges in the future, we reviewed documentation related to EPA's implementation of SDWA and interviewed EPA and other federal officials knowledgeable about challenges EPA is facing in implementing SDWA. We also reviewed the PiE workgroup's 2009 draft report and interviewed workgroup members and Office of Science and Technology Policy (OSTP) officials. We also reviewed our own work on practices that can help enhance and sustain interagency collaboration. A more detailed description of our scope and methodology is presented in appendix I.

We conducted this performance audit from January 2010 through August 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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## Background

This section presents information on (1) the ways in which pharmaceuticals may enter drinking water, (2) pharmaceuticals in drinking water as a contaminant of emerging concern, (3) the degree to which relevant environmental statutes regulate pharmaceuticals, and (4) the establishment of the PiE workgroup.

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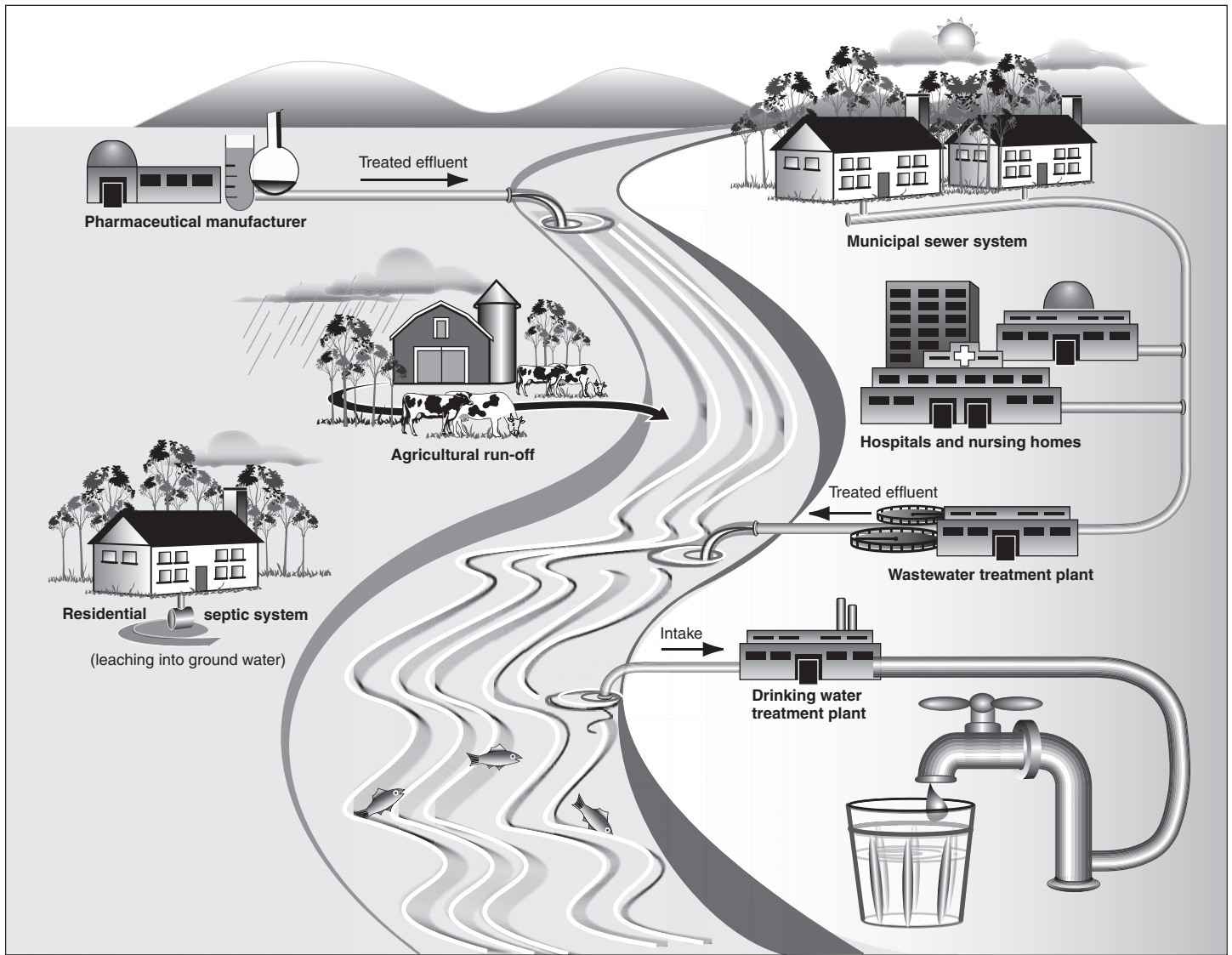
## Pharmaceuticals May Enter Drinking Water through Different Pathways

Scientists have identified numerous pathways by which pharmaceuticals may enter the environment and ultimately drinking water supplies. According to USGS scientists, the main source of human pharmaceuticals in the environment is likely treated wastewater from households, industry, and commercial facilities. Biosolids from wastewater treatment plants applied to land as fertilizer may also be a source of human pharmaceuticals in the environment. Septic systems may be a source of human pharmaceuticals in ground water. A potential source of veterinary pharmaceuticals is agricultural facilities where large numbers of food-producing animals (such as chickens, cattle, and swine) are treated with pharmaceuticals. The pharmaceuticals enter the environment either directly from waste storage structures as a result of accidents or weather conditions, or through the application of manure and liquid waste to croplands.

Figure 1 illustrates the different pathways by which pharmaceuticals may enter drinking water supplies.



**Figure 1: Examples of Pathways through which Pharmaceuticals May Enter Drinking Water Supplies**



Source: GAO.

## Pharmaceuticals in Drinking Water Are a Contaminant of Emerging Concern

EPA considers pharmaceuticals in drinking water to be a contaminant of emerging concern (also called emerging contaminants). The term is not defined in regulation, and EPA does not maintain a list of contaminants that are considered contaminants of emerging concern. In this report, the term refers to a wide range of contaminants for which the risk to human health

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and the environment associated with their presence, frequency of occurrence, or source may not be known. In some cases, the release of contaminants of emerging concern into the environment has likely occurred for a long time but may not have been recognized until new detection methods were developed. In other cases, the synthesis of new chemicals or changes in the use and disposal of existing chemicals can create new sources of contaminants of emerging concern. Other contaminants of emerging concern can include personal care products (e.g., sunscreen, antibacterial soap, synthetic musks); chemicals used in industry (e.g., flame retardants, stain resistant coatings); and chemicals used in agriculture (e.g., pesticides that may act as endocrine disrupting chemicals (EDC)).<sup>3</sup>

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### The Degree to which Relevant Environmental Statutes Regulate Pharmaceuticals

Most pharmaceuticals are not currently regulated under EPA programs implementing key environmental laws. SDWA, the Resource Conservation and Recovery Act of 1976 (RCRA) and the Clean Water Act provide EPA with authority to regulate pharmaceuticals meeting certain criteria in drinking water, waste, and wastewater discharges.

#### The Safe Drinking Water Act

Under SDWA, EPA is authorized to regulate contaminants, including pharmaceuticals, meeting certain criteria in public drinking water systems. In 1996, Congress amended SDWA to require EPA to select for consideration those unregulated contaminants that present the greatest public health concern, evaluate their occurrence and the potential health risks associated with them, and decide whether a regulation is needed for at least five contaminants every 5 years. This regulatory determination process includes EPA's publication in the *Federal Register* of a preliminary decision on whether the agency will propose a drinking water regulation for each contaminant evaluated—called a preliminary regulatory determination—and provides for a public comment period, followed by a final decision, or regulatory determination, also published in the *Federal Register*. The 1996 amendments also require EPA to identify and publish a list every 5 years of unregulated contaminants for drinking water that may require regulation—called the Contaminant Candidate List. The Administrator must decide whether to regulate at least five of the

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<sup>3</sup>EDCs are chemical compounds found in some pharmaceuticals, food, and consumer products, or occur naturally in the environment. EDCs can interfere with the functioning and development of hormones in humans and animals and can produce adverse developmental, reproductive, neurological, and immune effects.

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contaminants on the candidate list every 5 years.<sup>4</sup> These decisions are called regulatory determinations. SDWA specifies that EPA is to regulate a contaminant if the Administrator determines that

- the contaminant may have an adverse effect on the health of persons;
- the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and
- in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

Since 1996, EPA has completed two regulatory determination cycles—in 2003 and 2008. During this time, EPA conducted 20 regulatory determinations and found that none met the criteria requiring regulation. In 2011, EPA made an out-of-cycle regulatory determination, concluding that perchlorate, an ingredient in rocket fuel and other products that can interfere with the normal functioning of the thyroid gland, met the criteria requiring regulation.<sup>5</sup> EPA has made no regulatory determinations for pharmaceuticals. EPA published the third candidate list in October 2009 but has not yet made any regulatory determinations or completed the third regulatory determination cycle.<sup>6</sup>

To determine which contaminants to include on the third candidate list, EPA developed a multistep process, based on available data, to characterize occurrence and adverse health risks a contaminant may pose to consumers of public water systems.<sup>7</sup> Starting with a list of almost 26,000 unique chemicals, EPA identified a universe of about 6,000 potential drinking water contaminants for consideration based on the availability of occurrence and health effects data. Of these, 287 were

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<sup>4</sup>The Administrator may also regulate contaminants not on the Contaminant Candidate List if the criteria for regulation are met, but to date has not done so.

<sup>5</sup>76 *Fed. Reg.* 7762 (Feb. 11, 2011).

<sup>6</sup>74 *Fed. Reg.* 51850 (Oct. 8, 2009).

<sup>7</sup>EPA used a different approach to determine which contaminants to include on the first and second candidate lists. See 73 *Fed. Reg.* 9628, 9631 (Feb. 21, 2008).

pharmaceuticals. Then, using the available data, EPA employed successively more detailed evaluations—as well as expert opinions and comments from the public—to identify the 116 contaminants that it included on the third candidate list—12 of these contaminants are pharmaceuticals.<sup>8</sup> Table 1 identifies the 12 pharmaceuticals.

**Table 1: Pharmaceuticals on the Third Contaminant Candidate List**

Pharmaceutical	Use
17alpha-estradiol	An estrogenic hormone used in pharmaceuticals
Equilenin	An estrogenic hormone used in pharmaceuticals
Equilin	An estrogenic hormone used in pharmaceuticals
Erythromycin	Used in pharmaceutical formulations as an antibiotic
Estradiol (17-beta estradiol)	An estrogenic hormone used in pharmaceuticals
Estriol	An estrogenic hormone used in veterinary pharmaceuticals
Estrone	An estrogenic hormone used in veterinary and human pharmaceuticals
Ethinyl estradiol (17-alpha ethynylestradiol)	An estrogenic hormone used in veterinary and human pharmaceuticals
Mestranol	An estrogenic hormone used in veterinary and human pharmaceuticals
Nitroglycerin	Used in pharmaceuticals, in the production of explosives, and in rocket propellants
Norethindrone (19-norethisterone)	A progestronic hormone used in pharmaceuticals
Quinoline	Used in the production of other substances, as a pharmaceutical (antimalarial), and as a flavoring agent

Source: EPA.

Notes: According to FDA, estriol, estrone, ethinyl estradiol, and mestranol are not listed as approved for veterinary use in the United States but it is possible that these pharmaceuticals are or have been used as such, for example, for research purposes or as investigational new drugs. Although not identified as use by EPA, according to FDA, estradiol and erythromycin are approved for veterinary use.

In a May 2011 report, we identified systemic limitations in EPA’s implementation of the 1996 amendments’ requirements for determining whether additional contaminants in public drinking water warrant regulation and made 17 recommendations to EPA for implementing the requirements in a way that better assures the public of safe drinking water. Among other things, we recommended that EPA (1) develop criteria and a process for identifying those contaminants on its candidate list that present the greatest

<sup>8</sup>For additional information on the process EPA used to develop the third Contaminant Candidate List and the contaminants on that list, see <http://www.epa.gov/ogwdw/ccl/ccl3.html>.

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Resource Conservation and Recovery Act

public health concern and (2) develop a coordinated process for obtaining both the occurrence and health effects data that may be needed for the agency to make informed regulatory determinations on these priority contaminants.<sup>9</sup> EPA did not agree to adopt these recommendations and generally took the position that no further steps are needed.

RCRA established federal requirements and EPA regulatory authority for “cradle-to-grave” management of hazardous wastes, as well as a program for state oversight of nonhazardous solid waste with federal minimum regulations for landfills. RCRA and its implementing regulations establish several means by which waste may be deemed hazardous, including specifically being listed by EPA as a hazardous waste or by exhibiting one of the following four characteristics: toxicity, ignitability, corrosivity, or reactivity. According to EPA’s August 2010 draft guidance and a proposed rule concerning management of hazardous pharmaceutical wastes in the *Federal Register*, more than 30 active pharmaceutical ingredients are considered listed hazardous wastes under RCRA.<sup>10</sup> In addition, other pharmaceuticals may be considered to be hazardous waste when disposed if they have certain characteristics (e.g., they are likely to leach concentrations of any 1 of 40 different toxic chemicals in amounts above the specified regulatory levels). Examples of these chemicals that have pharmaceutical uses include: arsenic, barium, cadmium, and chloroform. EPA has estimated that about 5 percent of all pharmaceutical waste is hazardous waste.<sup>11</sup>

The disposal of pharmaceuticals meeting the RCRA hazardous definition is generally subject to RCRA requirements, such as reporting, using a manifest, and disposing of the waste in approved ways, such as through hazardous waste incineration; however, household trash is exempted. Noting that implementing existing regulations may be difficult for healthcare facilities such as hospitals and nursing homes and that the streamlined

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<sup>9</sup>GAO, *Safe Drinking Water Act: EPA Should Improve Implementation of Requirements on Whether to Regulate Additional Contaminants*, [GAO-11-254](#) (Washington, D.C.: May 27, 2011).

<sup>10</sup>EPA Office of Water, *Guidance Document: Best Management Practices for Unused Pharmaceuticals at Health Care Facilities*, Draft (August 2010): table 1, 14-15. EPA, Proposed Rule, Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 *Fed. Reg.* 73520, 73522 (Dec. 2, 2008).

<sup>11</sup>EPA Office of Water, *Guidance Document: Best Management Practices for Unused Pharmaceuticals at Health Care Facilities*, Draft (August 2010): 18.

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requirements would help avoid mismanagement, in 2008 EPA proposed to add hazardous waste pharmaceuticals to the Universal Waste Rule, which simplifies RCRA requirements for certain hazardous wastes. Under the proposed rule, manifests would not be required and other requirements may be simplified. EPA estimated the rule could affect over 600,000 entities. According to EPA's Web site on the proposed rule, stakeholders commenting on the proposal expressed concerns that including hazardous pharmaceutical wastes under the Universal Waste Rule would eliminate some requirements, such as notification and use of a manifest, that currently apply to such wastes. EPA officials also told us the agency has begun considering additional regulatory options to address these and other issues but that EPA has no projected date for issuing a final rule.<sup>12</sup>

## Clean Water Act

The Clean Water Act is the primary federal law concerning pollution of the nation's waters. Under the act, EPA is required to establish and revise national water quality criteria that accurately reflect the latest scientific knowledge about the effects of pollutants on aquatic life and human health. These criteria represent maximum concentrations that would not cause an unacceptable effect on aquatic life and represent the levels at which specific chemicals are not likely to adversely affect human health. Criteria are elements of state water quality standards, expressed as constituent concentrations, levels, or narrative statements, representing a quality of water that supports a particular use. When criteria are met, water quality will generally protect the designated use.<sup>13</sup> States, or in some instances EPA, use these criteria to adopt and revise water quality standards for designated uses—such as drinking, swimming, or fishing—for water bodies. States may use EPA's national criteria, modify them to site-specific criteria, or adopt other scientifically defensible criteria. States are required, as part of 3-year reviews, to adopt water quality standards for each of the toxic pollutants for which EPA has promulgated water quality criteria. Water quality standards play a critical role in the act's

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<sup>12</sup>EPA noted it has also funded and assisted in the development of a guidance document to help healthcare facilities develop and implement hazardous pharmaceutical waste management plans.

<sup>13</sup>40 C.F.R. § 131.11 (2011). Most water quality criteria are expressed as numeric or quantitative-parameters. For example, national recommended water quality criteria for toxic pollutants are numeric and specify the precise, measurable levels of particular chemicals or conditions allowable in a water body. When numerical criteria cannot be established, such as when pollutants cannot be precisely measured, narrative criteria are used to express a parameter in a qualitative form.

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framework, potentially affecting effluent<sup>14</sup> limitations dictated by permits and requirements for state reporting and pollution control planning.

Regarding permits, EPA and delegated states administer the Clean Water Act's National Pollutant Discharge Elimination System program, which limits the types and amounts of pollutants that industrial and municipal wastewater treatment facilities may discharge into the nation's surface waters. Facilities such as municipal wastewater treatment plants and pharmaceutical plants require a permit if they discharge into surface waters. Certain agricultural facilities—known as concentrated animal feeding operations—also need a permit, but other agricultural operations do not. EPA and delegated states issue discharge permits that are to set conditions in accordance with technology-based effluent limitations EPA established for various categories of discharges. EPA has issued effluent limitation regulations for pharmaceutical manufacturing facilities as well as pretreatment regulations applicable when these facilities discharge into a publicly owned wastewater treatment plant. These regulations currently do not include limitations for any pharmaceutical constituents in wastewater; rather, the regulations set limitations for conventional pollutants, priority toxic pollutants, and selected nonconventional pollutants—mainly solvents used in manufacturing. Similarly, EPA's regulation for concentrated animal feeding operations does not contain specific limitations for veterinary pharmaceuticals.

At present, EPA has not developed specific water quality criteria under the Clean Water Act for most pharmaceuticals; hence, there are no water quality standards for most pharmaceuticals, and permits do not contain any limitations for them. EPA's current national criteria include one pollutant identified as being used as a pharmaceutical—lindane.<sup>15,16</sup> In January 2010, the Center for Biological Diversity, a nonprofit environmental organization, petitioned EPA to revise its water quality criteria for lindane,

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<sup>14</sup>Effluent refers to wastewater discharged into the environment. Typically, effluent is treated and discharged from wastewater treatment plants, which may receive wastewater from such entities as households, factories, or commercial establishments.

<sup>15</sup>Lindane is also known as gamma-hexachlorocyclohexane ( $\gamma$ -HCH), gammexene, and Gammalin. As a pharmaceutical, lindane is used in shampoos and creams to treat lice and scabies (mites).

<sup>16</sup>According to EPA officials, another pollutant for which EPA has issued national criteria – malathion – has pharmaceutical applications.

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and to establish water quality criteria for 34 other pharmaceutical and personal care products. EPA told us the agency is considering the petition and expects to issue a response by mid 2011. If EPA were to establish water quality criteria for one or more additional pharmaceuticals, then states would need to adopt water quality standards reflecting the new or revised criteria, and the standards would be considered in permit decisions as well as in states' water quality management plans.

In August 2010, EPA's Office of Water released a draft guidance document for health care facilities, *Best Management Practices for Unused Pharmaceuticals at Health Care Facilities*. The nonbinding document recommends management practices, such as methods to reduce the quantity of unused pharmaceuticals, and explains applicable disposal requirements for those pharmaceuticals that are hazardous. EPA's goal for the guidance document is to keep pharmaceuticals out of U.S. waters, particularly by minimizing their disposal into sewers. According to agency officials, EPA expects to issue a final guidance document by the end of 2011.

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### Workgroup Addressing Pharmaceuticals in the Environment Was Established within the National Science and Technology Council

The PiE workgroup was established in 2006 by the Committee on Environment, Natural Resources, and Sustainability (CENRS), Toxics and Risk Subcommittee, an executive branch entity under the National Science and Technology Council (NSTC).<sup>17</sup> NSTC is a council of cabinet-level officials chaired by the President and managed by the Director of OSTP.<sup>18</sup> The purpose of the workgroup was to identify and prioritize research needed to better understand the risk from pharmaceuticals in the environment and to recommend areas for federal collaboration to

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<sup>17</sup>NSTC was established by Executive Order in 1993. NSTC has multiple committees to address its broad responsibilities regarding the scientific and technical work of the executive branch. For example, CENRS advises and assists NSTC on federal research and development related to environment, natural resources, and sustainability. The Toxic and Risks Subcommittee is one of several subcommittees of CENRS.

<sup>18</sup>Congress established OSTP in 1976 with a broad mandate to advise the President and others within the Executive Office of the President on considerations of science and technology in federal policy, plans, and programs. OSTP is also charged with leading interagency efforts to develop and implement sound science and technology policies, among other things.



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address those priorities.<sup>19</sup> The workgroup, which was intended to be temporary, was staffed by scientists from eight federal agencies.<sup>20</sup> EPA, FDA, and USGS scientists served as co-chairs. In May 2009, the PiE workgroup produced a draft report but it was never finalized because of a disagreement between OSTP and the workgroup over what should be included in the final report.

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## Pharmaceuticals Have Been Found in Drinking Water, but Their Prevalence and Effects on Human Health Are Largely Unknown

Although research has confirmed the presence of pharmaceuticals in drinking water throughout the nation, the full extent of their occurrence is unknown. Research on the human health effects of exposure to these pharmaceuticals is largely unknown but the effects of some compounds have raised concern among some scientists, the public, and policy makers.

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### Research Has Confirmed the Presence of Some Pharmaceuticals in Drinking Water

Research has detected pharmaceuticals in the nation's drinking water. National and regional studies have generally detected pharmaceuticals in source water, treated drinking water, and treated wastewater; but the full extent of occurrence is unknown. The concentrations detected were measured most frequently in parts per trillion.

### Studies Have Detected the Occurrence of Pharmaceuticals in Source Water

As part of its Toxic Substances Hydrology Program, USGS conducted four reconnaissance studies that were national in scope (national reconnaissance studies) to study the occurrence and distribution of emerging contaminants, including pharmaceuticals, in the environment. For each study, USGS chose to sample water from locations that it

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<sup>19</sup>*Charter of the Working Group on Pharmaceuticals in the Environment, Toxics and Risk Subcommittee, Committee on Environment and Natural Resources, National Science and Technology Council* (May 2006).

<sup>20</sup>The eight agencies were the U.S. Department of Agriculture, the Department of Commerce's National Oceanographic and Atmospheric Administration, EPA, the Department of Health and Human Services' Centers for Disease Control and Prevention, FDA, and National Institute for Environmental and Health Sciences; and the Department of the Interior's Fish and Wildlife Service and USGS.

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believed were more likely to have pharmaceuticals and other contaminants present.

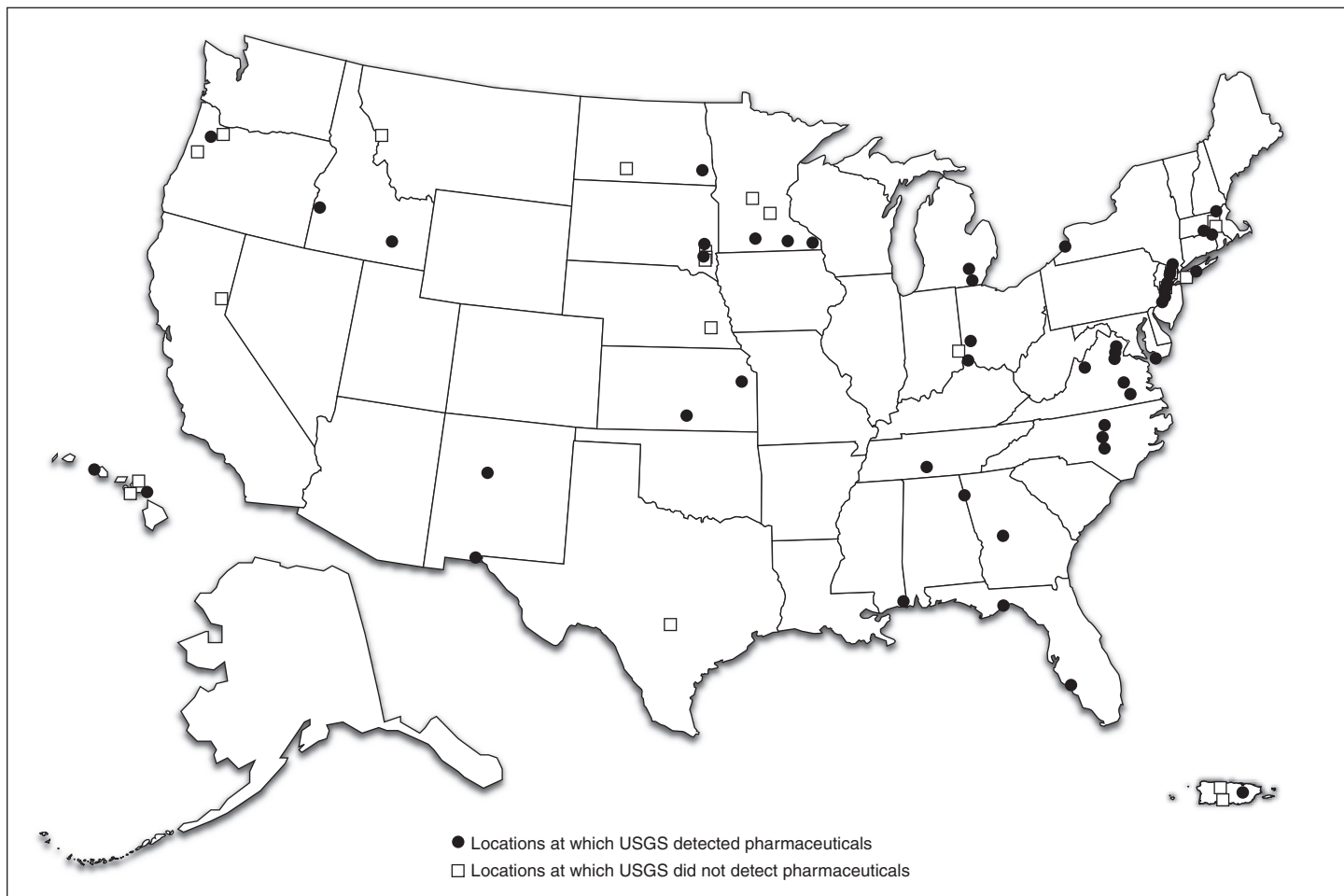
One study specifically focused on untreated source water used by public drinking water systems. For example, samples were collected from wells and near surface water intakes that supplied the water systems. For this study, USGS collected water samples from 74 locations in 25 states and Puerto Rico in 2001. These locations provide drinking water to populations ranging from one family to over 8 million.<sup>21</sup> The study reported testing for the presence of 100 contaminants, including 36 pharmaceuticals.<sup>22</sup> USGS found that 53 of the 74 locations had one or more pharmaceuticals in the water, and 40 percent of the pharmaceuticals analyzed were detected at one or more of these locations. Figure 2 shows the location of sample sites and the sites at which USGS detected pharmaceuticals.

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<sup>21</sup>Focazio, M.J.; Kolpin, D.W.; Barnes, K.K.; Furlong, E.T.; Meyer, M.T.; Zaugg, S.D.; Barber, L.B.; Thurman, M.E., "A National Reconnaissance for Pharmaceuticals and Other Organic Wastewater Contaminants in the United States – II) Untreated Drinking Water Sources," *Sci Total Environ*, 402(2-3) (2008): 201-216.

<sup>22</sup>USGS selected these contaminants using the following criteria: known or suspected usage, toxicity, potential hormonal activity, persistence in the environment, and results from previous studies.

**Figure 2: Locations at which USGS Sampled Untreated Sources of Public Drinking Water and Those at which It Detected Pharmaceuticals**



Source: GAO; map (MapArt).

Figure 3 shows the pharmaceuticals that USGS reported detecting in its study of untreated sources of public drinking water.

**Figure 3: Pharmaceuticals USGS Detected at Untreated Sources of Public Drinking Water.**

Category of pharmaceutical	Number of sites with selected pharmaceuticals in untreated sources of public drinking water	Type of pharmaceutical	Typical use
<b>Nonprescription drugs</b>	0 10 20 30 40 50 60 70 80 90 100 26	Cotinine	Nicotine metabolite
	17	1, 7-dimethylxanthine	Caffeine metabolite
	6	Acetaminophen	Antipyretic
	6	Caffeine	Stimulant
	1	Ibuprofen	Anti-inflammatory
<b>Prescription drugs</b>	16	Carbamazepine	Anticonvulsant
	4	Diphenhydramine	Antihistamine
	3	Dehydronifedipine	Metabolite of nifedipine, an antianginal
	2	Codeine	Analgesic
	1	Diltiazem	Antihypertensive
	1	Fluoxetine	Antidepressant
<b>Veterinary and human antibiotics</b>	6	Erythromycin-H2O	Erythromycin metabolite
	5	Enrofloxacin	Antibiotic
	5	Trimethoprim	Antibiotic
	2	Sulfamethoxazole	Antibiotic
	1	Azithromycin	Antibiotic
	1	Ciprofloxacin	Antibiotic
	1	Sarafloxacin	Antibiotic

Source: USGS.

Notes: A metabolite is a substance that is the product of biological changes to a chemical. For example, cotinine is the metabolite produced in the body after nicotine has been consumed. According to FDA, while caffeine, caffeine metabolites, and nicotine are in nonprescription drugs, caffeine and its metabolites are most likely from the urine of persons imbibing caffeine-containing beverages and nicotine metabolites are most likely from the urine of smokers. Also, antipyretic medication reduces fever.

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The other three national reconnaissance studies that USGS conducted focused on (1) surface water,<sup>23</sup> (2) ground water,<sup>24</sup> and (3) stream sedimentation.<sup>25</sup> The four USGS national reconnaissance studies tested for a similar, but not identical, suite of pharmaceuticals and other contaminants and all of the studies reported detecting pharmaceuticals and other contaminants.

In addition to its national studies, USGS has undertaken a number of local and regional studies as part of its reconnaissance effort to provide information on the sources, occurrence, and transport<sup>26</sup> of contaminants of emerging concern, including pharmaceuticals. These studies have reported similar results—finding pharmaceuticals in source water. For example, in a 2009 study, USGS, in cooperation with the Oregon Department of Environmental Quality and Deschutes County Environmental Health Division, collected and analyzed water samples from ground water near La Pine, Oregon.<sup>27</sup> The study reported detecting 8 of the 18 pharmaceuticals for which it tested. The study also reported testing for and finding other contaminants.

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<sup>23</sup>Kolpin, D.W.; Furlong, E.T.; Meyer, M.T.; Thurman, E.M.; Zaugg, S.D.; Barber, L.B.; Buxton, H.T., "Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance," *Environ. Sci. Technol.*, 36(6) (2002): 1202-1211.

<sup>24</sup>Barnes, K.K.; Kolpin, D.W.; Furlong, E.T.; Zaugg, S.D.; Meyer, M.T.; Barber, L.B., "A National Reconnaissance of Pharmaceuticals and Other Organic Wastewater Contaminants in the United States – I) Groundwater," *Sci Total Environ*, 402(2-3) (2008): 192-200.

<sup>25</sup>Furlong, E.T.; Ferrer, I.; Glassmeyer, S.; Cahill, J.D.; Zaugg, S.D.; Werner, S.L.; Kinney, C.A.; Kolpin, D.W.; Kryak, D., "Distributions of organic wastewater contaminants between water and sediment in surface-water samples of the United States" (in Proceedings of the 3rd International Conference on Pharmaceuticals and Endocrine Disrupting Chemicals in Water, Minneapolis, Minn., National Ground Water Association, Mar. 19-21, 2003).

<sup>26</sup>Transport refers to the movement of a contaminant within the environment.

<sup>27</sup>Hinkle, S.R.; Weick, R.J.; Johnson, J.M.; Cahill, J.D.; Smith, S.G.; Rich, B.J., *Organic Wastewater Compounds, Pharmaceuticals, and Coliphage in Groundwater Receiving Discharge from Onsite Wastewater Treatment Systems Near La Pine, Oregon: Occurrence and Implications for Transport*, U.S. Geological Survey Scientific Investigations Report, 2005-5055 (2005): 98.

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In addition to USGS, other research groups have conducted studies to detect pharmaceuticals and other contaminants in source water, with results that are similar to those of USGS. Specifically:

- The New York City Department of Environmental Protection reported finding pharmaceuticals and personal care products in the low, part-per-trillion range in a 2010 study of the Catskill, Croton, and Delaware untreated source waters that contributed to New York City's water supply.<sup>28</sup>
- The National Water Research Institute funded a study testing for 50 contaminants such as pharmaceuticals and organic wastewater contaminants in three watersheds supplying drinking water to more than 25 million people in California.<sup>29,30</sup> The study analyzed 126 samples taken from 32 locations at various points in the watershed, including upstream and downstream from wastewater treatment plant discharges over a 1-year period, from April 2008 through April 2009. Overall, at least 1 contaminant was found in all but one of the samples. The study further reported that concentrations of contaminants were higher downstream of the wastewater treatment plants and concluded that the plant discharges were likely the main source of these contaminants in the environment.

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<sup>28</sup>NYC Department of Environmental Protection, *Occurrence of Pharmaceutical and Personal Care Products (PPCP) in Source Water of the New York City Water Supply* (New York, N.Y.: May 26, 2010).

<sup>29</sup>The National Water Research Institute (NWRI) is a nonprofit organization founded in 1991 by a group of California water agencies in partnership with the Joan Irvine Smith and Athalie R. Clarke Foundation to promote the protection, maintenance, and restoration of water supplies and to protect public health and improve the environment. NWRI's member agencies include Inland Empire Utilities Agency, Irvine Ranch Water District, Los Angeles Department of Water and Power, Orange County Sanitation District, Orange County Water District, and West Basin Municipal Water District.

<sup>30</sup>Y. Carrie Guox and Stuart W. Krasner, Metropolitan Water District of Southern California, La Verne, California; Steve Fitzsimmons, Greg Woodside, and Nira Yamachika, Orange County Water District Fountain Valley, California. *Source, Fate, and Transport of Endocrine Disruptors, Pharmaceuticals, and Personal Care Products in Drinking Water Sources in California*. A special report prepared at the request of the National Water Research Institute Fountain Valley, California, May 2010.

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## Studies Have Also Detected Occurrence of Pharmaceuticals in Treated Drinking Water

Although USGS studies have focused on source water, other studies have detected pharmaceuticals and other emerging contaminants in treated drinking water. For example:

- A 2008 study funded by the American Water Works Association Research Foundation and the WaterReuse Foundation tested for 51 potential contaminants including 20 pharmaceuticals and pharmaceutical metabolites in drinking water in 19 drinking water treatment plants across the United States.<sup>31,32</sup> The study reported detecting 9 of the 20 pharmaceuticals and metabolites at all of the locations tested.<sup>33</sup> These plants provide drinking water for over 28 million Americans.
- EPA funded a 2010 meta-analysis of 48 publications and found that 54 active pharmaceutical ingredients and 10 metabolites have been detected in treated drinking water.<sup>34</sup> The analysis notes that of the 64 substances that have been detected, only 36 have corroborative data from at least a second study.<sup>35</sup>

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<sup>31</sup>According to its Web site, the American Water Works Association Research Foundation is a member-supported, international, nonprofit organization that sponsors research to enable water utilities, public health agencies, and other professionals to provide safe and affordable drinking water to consumers. Its stated mission is to advance the science of water to improve the quality of life.

<sup>32</sup>According to its Web site, the WaterReuse Foundation is an educational, nonprofit public benefit corporation that serves as a centralized organization for the water and wastewater community to advance the science of water reuse, recycling, reclamation, and desalination.

<sup>33</sup>Benotti, M.J.; Trenholm, R.A.; Vanderford, B.J.; Holady, J.C.; Stanford, B.D.; and Snyder, S.A., "Pharmaceuticals and Endocrine Disrupting Compounds in U.S. Drinking Water," *Environmental Science and Technology*, 43(3) (2009): 597-603.

<sup>34</sup>Daughton C.G., "Pharmaceutical Ingredients in Drinking Water: Overview of Occurrence and Significance of Human Exposure," in ACS Symposium Series 1048, *Contaminants of Emerging Concern in the Environment: Ecological and Human Health Considerations*, ch. 2, Rolf Halden (ed.) (Washington, D.C.: American Chemical Society, November 2010).

<sup>35</sup>The study's analysis cautioned that the data cannot be considered statistically representative of any particular locale and that with very few exceptions; each of the 48 publications was very limited in scope. The analysis further cautions that the published studies employed various methods of analysis and quality control measures; and that no attempt was made to determine the veracity of the actual identification of targeted pharmaceuticals.

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Studies Have Also Detected Occurrence of Pharmaceuticals in Treated Wastewater

In addition to source and treated drinking water, USGS and others have tested the effluent of wastewater treatment plants and animal feeding operations, two sources that are thought to be significant contributors of contaminants to streams and other sources of drinking water. Specifically:

- *Treated wastewater.* A 2005 study by USGS and EPA collected water samples upstream and downstream of wastewater treatment plants at 10 different locations totaling 40 sampling sites across the United States.<sup>36</sup> The agency tested for the presence of 110 chemicals, including industrial wastewater compounds and pharmaceuticals and related chemicals. Specifically, the study reported finding nonprescription pharmaceuticals in over 40 percent of the samples; prescription, nonantibiotic pharmaceuticals in over 30 percent of samples; and antibiotics in fewer than 10 percent of all samples. The study's results demonstrated an increase in the frequency of detection and concentration of most of the pharmaceuticals, and other chemical compounds, in the treatment plants' effluent as compared to water samples collected upstream of these plants; however, the chemical concentrations and occurrences decreased downstream from the treatment plants.
- *Animal feeding operations.* A study published in 2002 reported finding concentrations of antimicrobial agents in surface and ground water near large-scale poultry and swine farms, and concluded that animal waste likely acted as a source for antimicrobial residues in nearby water resources.<sup>37</sup> Specifically, the study noted that livestock receive antimicrobials both in therapeutic and nontherapeutic doses (i.e., in their feed), and that these compounds can be excreted into the environment.<sup>38</sup>

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<sup>36</sup>Glassmeyer, S.T.; Furlong, E.T.; Kolpin, D.W.; Cahill, J.D.; Zaugg, S.D.; Werner, S.L.; Meyer, M.T.; Kryak, D.D., "Transport of Chemical and Microbial Compounds from Known Wastewater Discharges: Potential for Use as Indicators of Human Fecal Contamination," *Environ Sci Technol*, 39(14) (2005): 5157-5169.

<sup>37</sup>Antimicrobials are drugs used to treat infections by micro-organisms such as bacteria and viruses and include drugs such as synthetic and natural antibiotics.

<sup>38</sup>Campagnolo, E.R.; Johnson, K.R.; Karpati, A.; Rubin, C.S.; Kolpin, D.W.; Meyer, M.T.; Esteban, J.E.; Currier, R.W.; Smith, K.; Thu, K.M.; McGeehin, M., "Antimicrobial Residues in Animal Waste and Water Resources Proximal to Large-Scale Swine and Poultry Feeding Operations," *Sci Total Environ*, 299(1-3) (2002), 89-95.



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- *Pharmaceutical manufacturing facilities.* A 2010 USGS study of emerging contaminants in wastewater treatment plant effluents found that wastewater treatment plants that receive discharge from pharmaceutical manufacturing facilities had 10 to 1,000 times higher concentrations of pharmaceuticals (including opioids, muscle relaxants, and a barbiturate) than typically found in wastewater effluents. Maximum concentrations of some pharmaceuticals were in the part per million range.<sup>39</sup>

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### Research Has Not Determined the Human Health Effects of Pharmaceuticals in Drinking Water, but Some Research Raises Concerns

Research has not determined the human health effects of exposure to pharmaceuticals in drinking water. However, some research has demonstrated the potential impact to human health from exposure to some pharmaceuticals found in drinking water, such as EDCs and antibiotics.

### Research Has Not Determined the Human Health Effects of Pharmaceuticals in Drinking Water

Uncertainty persists regarding whether pharmaceuticals in drinking water pose a risk to human health, and research has pointed to different conclusions.<sup>40</sup> For example, in its April 2008 testimony before the Senate Committee on Environment and Public Works,<sup>41</sup> the Pharmaceutical Research and Manufacturers of America, a trade association for the leading research-based pharmaceutical and biotechnology companies, cited a peer-reviewed study for which it provided financial support that concluded there was no demonstrable health risk to exposure to 26 pharmaceuticals detected by USGS in one of its national reconnaissance

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<sup>39</sup>Phillips, P.J.; Smith, S.G.; Kolpin, D.W.; Zaugg, S.D.; Buxton, H.T.; Furlong, E.T.; Esposito, K.; Stinson, B., "Pharmaceutical Formulation Facilities as Sources of Opioids and Other Pharmaceuticals to Wastewater Treatment Plant Effluents," *Environ. Sci. Technol.*, 44 (13) (2010): 4910-4916.

<sup>40</sup>While each of the studies cited in this report are limited in geographic scope and not generalizable to all public drinking water systems or sources of drinking water in the country, they still offer valuable insights. Please see the specific research citation for additional information.

<sup>41</sup>Statement by Alan Goldhammer, Ph.D., Deputy Vice President, Regulatory Affairs; Pharmaceutical Research and Manufacturers of America, before the Senate Environment and Public Works Committee, Subcommittee on Transportation Safety, Infrastructure Security, and Water Quality, "Pharmaceuticals in the Nation's Drinking Water: Assessing Potential Risks and Actions to Address the Issue" (Apr. 15, 2008).

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studies.<sup>42,43</sup> The study reached its conclusions by comparing an estimate of human exposure from drinking water and/or ingesting fish for each pharmaceutical to the acceptable daily intake (ADI) for that pharmaceutical. ADI is an estimate of the daily amount of pharmaceuticals that can be ingested by a healthy adult of normal weight and that should not result in an adverse health effect. In this instance, the ADI was derived from data developed by pharmaceutical manufacturers when testing the effectiveness and safety of a therapeutic dose of the pharmaceutical.

Other research has emphasized the absence of data and lack of knowledge regarding the health effects of pharmaceuticals in the environment. For example, research funded by EPA notes that risk assessments based on benchmarks such as ADIs generally conclude that there is negligible risk from exposure to pharmaceuticals through drinking water but that benchmark levels such as ADI are orders of magnitude higher than the exposure levels and may not take into account less obvious, nontherapeutic effects.<sup>44,45</sup> This research notes that despite the lack of empirical data linking pharmaceuticals in drinking water to adverse human health effects, the issue remains one of interest because of the unanswered questions concerning low-dose exposure to contaminants of emerging concern, including but not limited to pharmaceuticals. Some of the most significant unanswered questions identified in the research are:

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<sup>42</sup>Schwab, B.W.; Hayes, E.P.; Fiori, J.M.; Mastrocco, F.J.; Roden, N.M.; Cragin, D.; Meyerhoff, R.D.; D'Aco, V.J.; Anderson, P.D., "Human Pharmaceuticals in U.S. Surface Water: A Human Health Risk Assessment," *Reg. Toxicol. Pharmacol.*, 42(3) (2005): 296-312.

<sup>43</sup>Kolpin, D.W.; Furlong, E.T.; Meyer, M.T.; Thurman, E.M.; Zaugg, S.D.; Barber, L.B.; Buxton, H.T., "Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance," *Environ. Sci. Technol.*, 36(6) (2002): 1202-1211.

<sup>44</sup>Daughton C.G., "Pharmaceutical Ingredients in Drinking Water: Overview of Occurrence and Significance of Human Exposure," in Rolf Halden (ed.), ACS Symposium Series 1048, *Contaminants of Emerging Concern in the Environment: Ecological and Human Health Considerations*, ch. 2, Rolf Halden (ed.) (Washington, D.C.: American Chemical Society, November 2010).

<sup>45</sup>Daughton, C.G., "Pharmaceuticals as Environmental Pollutants: The Ramifications for Human Exposure," in the *International Encyclopedia of Public Health*, vol. 5, Kris Heggenhougen and Stella Quah (eds.) (Oxford: Academic Press, 2008): 66-102.

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Some Research Has Raised Concerns about EDCs and Antibiotics

- What is the potential for biological effects of long-term, low-dose exposure to pharmaceuticals, including for sensitive subpopulations<sup>46</sup> such as children and in utero exposure?
- What are the effects of mixtures of pharmaceuticals, both additive and interactive?
- How do pharmaceuticals interact with the many other contaminants—both man-made and naturally occurring—that may be present in drinking water?
- Are there transgenerational effects (i.e., present in successive generations)?

The human health effects of pharmaceuticals in drinking water have not been conclusively shown, but research showing an impact on aquatic life raises concerns about two classes of pharmaceuticals—EDCs and antibiotics. Some of the concern about EDCs in drinking water stem from studies that have documented the abnormalities associated with aquatic life exposed to EDCs in rivers and lakes. Specifically, scientists have expressed concern because of both the significance of the abnormalities and the effects of contaminants on animals, which can be indicative of similar effects on humans. For example:

- A 2007 study reported that 75 percent of male smallmouth bass in certain areas of the South Branch of the Potomac River basin had ovarian tissue in their gonads.<sup>47</sup> The study concluded that a combination of EDCs was likely to have caused the feminization of the male fish. Although the authors note that the actual EDCs responsible for the abnormalities could not be determined, they suggest that a combination of contaminants could be the cause and noted that the additive effects of many EDCs have been demonstrated even when each compound present is below the threshold of detectable effects.

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<sup>46</sup>Such subpopulations, which may be at greater risk for adverse health effects from exposure to drinking water contaminants, may include infants, children, individuals with kidney or liver diseases or weakened immune systems, and the elderly.

<sup>47</sup>Blazer, V.S.; Iwanowicz, L.R.; Iwanowicz, D.D.; Smith, D.R.; Young, J.A.; Hedrick, J.D.; Foster, S.W.; Reeser, S.J., 2007, "Intersex (Testicular Oocytes) in Smallmouth Bass from the Potomac River and Selected Nearby Drainages," *Journal of Aquatic Animal Health*, 19(4) (2007): 242-253.

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The authors further noted that reproductive abnormalities in fish are frequently associated with human wastewater effluent, which contains synthetic estrogens found in birth control and hormone replacement medications.

- In another 2007 study by EPA and the Canadian government, researchers reported conducting a 7-year whole-lake experiment to test the effects on fathead minnows of chronic exposure to a synthetic estrogen used in some birth control pills.<sup>48</sup> The researchers reported a collapse in the population of fathead minnows in the experimental lake and concluded that the results from the study demonstrate that continued introduction of estrogens and estrogen mimics to the aquatic environment through municipal wastewaters could decrease the reproductive success and sustainability of fish populations.
- According to a 2004 research study, fish exposed to effluent from a cattle feedlot in Nebraska experienced reproductive abnormalities, including reduced testes size in male fish and a lower level of estrogen in female fish.<sup>49</sup> The study reported the use of androgens in growth implants in the feedlot as one possible cause of the abnormalities.

Not all EDCs found in drinking water, however, are pharmaceuticals. Other contaminants, such as industrial chemicals and products, as well as naturally occurring hormones found in plants and excreted by different species, can also act as EDCs. Because other chemicals have also been shown to have potential endocrine-disrupting effects, the extent to which pharmaceutical EDCs contribute to detected abnormalities is unclear. For example, bisphenol A (BPA), a nonpharmaceutical EDC, is used to make polycarbonate plastics that are used in products such as compact disks, baby bottles, plastic dinnerware, eyeglass lenses, and toys. In its paper reporting 2003-2004 National Health and Nutrition Examination Survey

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<sup>48</sup>Kidd, K.A.; Blanchfield, P.J.; Mills, K.H.; Palace, V.P.; Evans, R.E.; Lazorchak, J.M.; Flick, R.W., "Collapse of a Fish Population after Exposure to a Synthetic Estrogen," *Proceedings of the National Academy of Sciences of the United States of America*, 104(21) (2007): 8897-8901.

<sup>49</sup>Orlando, E. F.; Kolok, A. S.; Binzick, G. A.; Gates, J. L.; Horton, M. K.; Lambright, C. S.; Gray, L. E.; Soto, A. M.; Guillette, L. J., "Endocrine-Disrupting Effects of Cattle Feedlot Effluent on an Aquatic Sentinel Species, The Fathead Minnow," *Environ. Health Persp.*, 112(3) (2004): 353-358.

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findings, the Centers for Disease Control and Prevention found BPA in more than 90 percent of the urine samples representative of the U.S. population 6 years of age and older.<sup>50</sup> Another commonly occurring nonpharmaceutical EDC is atrazine, the most commonly used herbicide in the United States. In a 2003 study, scientists established a probable chain of causation between exposure to small concentrations of atrazine and the formation of female reproductive organs in frog testes.<sup>51</sup>

A second class of pharmaceuticals that has raised concern about the potential for health effects is antibiotics. In addition, some scientists are concerned about antimicrobial resistance resulting from interactions among chemicals, genes, microbes, animals, and humans in the environment. For example, some studies have demonstrated that bacteria exposed to pharmaceutical antibiotics and other antimicrobial agents in the environment have increased resistance to pharmaceutical antibiotics. However, the studies do not identify the extent to which pharmaceuticals or other antimicrobial agents contribute to these resistant bacteria. For example, triclosan and triclocarban, which are antimicrobials found in antiseptics, can contribute to antimicrobial resistance.<sup>52</sup> We recently issued a report that, among other issues, discusses scientific evidence supporting the association between antibiotic occurrence in the environment and an increase in resistance among bacteria.<sup>53</sup>

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<sup>50</sup>Calafat, A.M.; Ye, X.; Wong, L.Y.; Reidy, J.A.; Needham, L.L. "Exposure of the U.S. Population to Bisphenol A and 4-tertiary-Octylphenol: 2003–2004." *Environ. Health Perspect.*, 116(1) (January 2008): 39-44.

<sup>51</sup>Hayes, T.; Haston, K.; Tsui, M.; Hoang, A.; Haeffele, C.; Vonk, A., "Atrazine-Induced Hermaphroditism at 0.1 Ppb in American Leopard Frogs (*Rana pipiens*): Laboratory and Field Evidence," *Environ. Health Persp.*, 111 (2003): 568-575.

<sup>52</sup>According to studies published in 2008 and 2009, triclosan and triclocarban are also endocrine-disrupting chemicals. For example, see, Ahn, K.C.; Zhao, B.; Chen J.; Cherednichenko, G.; Sanmarti, E.; Denison, M.S.; Lasley, B.; Pessah, I.N.; Kultz, D.; Chang, D.P.Y.; Gee, S.J.; Hammock, B.D., "In Vitro Biologic Activities of the Antimicrobials Triclocarban, Its Analogs and Triclosan in Bioassay Screens: Receptor-Based Bioassay Screens," *Environmental Health Perspectives*, 116(9) (2008). Zorilla, L.M.; Gibson, E.K.; Jeffay, S.C.; Crofton, K.M.; Setzer, W.R.; Coper, R.L.; Stoker, T.E., "The Effects of Triclosan on Puberty and Thyroid Hormones in Male Wistar Rats," *Toxicological Sciences*, 107 (2009): 56-64.

<sup>53</sup>GAO, *Antibiotic Resistance: Gaps in Information Will Remain Despite HHS Taking Steps to Improve Monitoring*, [GAO-11-406](#) (Washington, D.C.: June 1, 2011).

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In addition to EDCs and antibiotics, other classes of pharmaceuticals have been found in drinking water and garnered scientific attention. Examples include chemotherapy drugs and selective serotonin reuptake inhibitors, which are a class of pharmaceuticals used to treat depression.

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## The United States and Other Countries Are Engaged in Take-Back Programs to Help Prevent Pharmaceuticals from Reaching Drinking Water

Some states and local governments, as well as DEA, have taken actions to reduce the extent to which pharmaceuticals occur in drinking water—primarily through take-back programs to properly dispose of pharmaceuticals. These efforts are often tied to efforts to reduce drug abuse or accidental poisoning by removing expired medicines from the home. Through outreach and education on proper drug disposal, EPA has also taken steps to reduce the introduction of hazardous pharmaceutical waste into water supplies. Other countries—including Sweden and Australia—have undertaken additional efforts to reduce the occurrence of pharmaceuticals in drinking water.<sup>54</sup>

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## Consumer Drug Take-Back Programs Are Found Across the United States, and Congress and Others Are Considering Additional Efforts

Federal agencies do not have comprehensive data on the number of take-back programs across the United States, but EPA and the Product Stewardship Institute, Inc. collectively identified 25 states that have had one or more take-back programs.<sup>55,56</sup> In addition, DEA has held two nationwide take-back programs—in September 2010 and April 2011—and a third is planned for October 29, 2011.

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<sup>54</sup>For additional details on pollution prevention, source control, and other environmental stewardship measures see: Daughton, C.G., “Drugs and the Environment: Stewardship & Sustainability,” National Exposure Research Laboratory, Environmental Sciences Division, U.S. EPA. Las Vegas, Nevada, report NERL-LV-ESD 10/081, EPA/600/R-106 (September 2010). Available at <http://www.epa.gov/nerlesd1/bios/daughton/APM200-2010.pdf>.






<sup>55</sup>The Product Steward Institute, Inc. is a nonprofit environmental organization whose members include 45 states, 70 local governments, and other stakeholders, and whose mission is to reduce the adverse health and environmental impacts of consumer products.

<sup>56</sup>The states are Arkansas, California, Colorado, Connecticut, Delaware, Florida, Idaho, Illinois, Indiana, Iowa, Kentucky, Maine, Massachusetts, Michigan, Missouri, New York, Oklahoma, Ohio, Oregon, Pennsylvania, Texas, Utah, Vermont, Washington, and Wisconsin.

Take-back programs are organized by a wide variety of stakeholders, including environmental groups, those with interests in preventing prescription drug abuse, and government entities (app. II provides federal guidelines on the proper disposal of pharmaceuticals). According to experts and program organizers we interviewed, the goals for implementing these programs include preventing drug abuse and accidental poisoning, as well as preventing unused pharmaceuticals from entering the environment. Pharmaceuticals collected through take-back programs are incinerated.

Through a survey of the literature and interviews with experts, we determined that take-back programs generally fall into one of three broad categories: (1) ongoing, (2) one-time, and (3) mail-back. To illustrate the three categories, we selected five take-back programs to review more closely. Figure 4 describes these five programs.

**Figure 4: Five Take-Back Programs GAO Identified**

Program type	State	Coverage	Program name	Collection
Ongoing	Utah 	Statewide	Proper Medication Disposal	5,625 lbs (June 2009 to June 2010)
	Washington 	6 counties	PH:ARM pilot - (Pharmaceuticals from Households: A Return Mechanism)	15,134 lbs (June 2009 to June 2010)
One-time	California 	San Francisco Bay Area	Bay Area Pollution Prevention Group Safe Medicine Disposal Days	3,634 lbs (May 13-21, 2006)
	Texas 	Amarillo, Canyon, and their surrounding communities	Medication Cleanout™	1,947 lbs (September 12, 2009; March 27, 2010; June 9, 2010)
Mail-back	Maine 	Statewide	Safe Medicine Disposal for ME	2,373 lbs (May 2008 to October 2009)

Sources: GAO; art (Art Explosion).

Note: Data on the volume of pharmaceuticals collected generally include packaging.

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As the figure shows, the following two programs are ongoing:

- *Utah's Proper Medication Disposal Program.* Consumers can leave unused pharmaceuticals in drop boxes at participating law enforcement agencies. The program collected over 5,600 pounds of pharmaceuticals, including packaging, from June 2009 to June 2010. It received \$70,000 in grants from EPA and the Utah Department of Environmental Quality. The program costs, not including in-kind donations, were \$40,000 from May 2007 to June 2010. According to program representatives, the program will seek additional grants to continue its efforts once it has spent the money from its current grants.
- *Washington State's PH:ARM Pilot (Pharmaceuticals from Households: A Return Mechanism).* PH:ARM began as a pilot project in 2006 with over 37 participating pharmacies in six counties. Consumers drop off their unused pharmaceuticals in secure drop boxes at pharmacies. From October 2006 to October 2008, the program collected over 15,000 pounds of pharmaceuticals, including packaging, at a cost of approximately \$170,000. According to program representatives, grant funding for the initial pilot project has ended, but the pharmacies have chosen to continue to collect unused pharmaceuticals on their own. Legislation proposed in the state legislature would have required pharmaceuticals manufacturers to pay for take-back programs in the state; however, the legislation failed a state senate vote in 2011.

We also identified one-time take-back events. These events are often organized by local communities and operate for a day, several days, or several weeks. For example:

- *Bay Area Pollution Prevention Group.* This group, a consortium of 43 wastewater agencies in the San Francisco Bay Area, piloted a week-long take-back program called "Safe Medicine Disposal Days" in May 2006. Consumers were invited to drop off pharmaceutical waste at 39 locations, including pharmacies, law enforcement offices, household hazardous waste facilities, and senior and civic centers. Over the course of the event, more than 1,500 residents disposed of over 3,600 pounds of pharmaceuticals. The event cost around \$180,000, including administrative costs, and was funded by local agencies, cities, counties, and wastewater treatment plants.
- *Amarillo and Canyon, Texas, "Medication Cleanout™" (MCO) program.* Three 1-day events were conducted between September



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2009 and July 2010. These events were organized and funded by the Texas Panhandle Poison Center of Texas Tech University Health Sciences Center School of Pharmacy, the Amarillo Independent School District's *Safe Schools Healthy Students* program, and the Amarillo Police Department. Medication Cleanout provided consumers with drive-through drop-off points in order to return their unused pharmaceuticals without leaving their cars. The cost for the September 2009 event—the only date for which cost data are available—was approximately \$44,000, and organizers reported that approximately 1,900 pounds of pharmaceuticals, including some packaging, were returned for all three events. Program organizers indicated that similar 1-day, drive-through events would be planned for the future.

Mail-back programs allow consumers to use the Postal Service to dispose of unused pharmaceuticals. For example, in 2008, Maine implemented a 2-year mail-back pilot program—called “Safe Medicine Disposal for ME.” The program distributed postage-paid return envelopes to pharmacies and health and social service agencies across the state to be given to consumers. The envelopes contained instructions for how to properly return the pharmaceuticals, including how to remove personally identifying information from prescription bottles before mailing the unused pharmaceuticals. The pharmaceuticals were sent to the Maine Drug Enforcement Agency for proper disposal. Between May 2008 and October 2009, the program collected more than 2,600 pounds of pharmaceuticals, including packaging. Organizers reported that some of the prescriptions returned were over 20 years old. The program was initially funded with a \$150,000 EPA grant and has since received \$150,000 from the Fund for Healthy Maine that will allow the program to operate into 2011. Program organizers stated that their main goals for implementing the program were to prevent poisonings and drug abuse, but that 77 percent of respondents to a survey included with the envelopes distributed by the program reported that they participated because they were concerned about the environment.

According to DEA, its two nationwide take-back events—in September 2010 and April 2011—collected more than 300 tons of pharmaceuticals at thousands of sites across the country.

Although the U.S. take-back programs differ in how they are implemented, organizers of the events have faced similar challenges. For example, according to experts and organizers of the take-back programs we spoke with, these programs have been hampered by legal restrictions

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and limited funding, although the legal restrictions are being addressed. These experts and organizers told us that collecting controlled substances was resource intensive because, until recently, according to DEA the Controlled Substances Act made it was unlawful for the recipient of a controlled substance to give that substance to anyone other than law enforcement, even for the purposes of disposal.<sup>57</sup> Thus, consumers were prohibited from returning unused controlled substances to their pharmacy or doctor. Any take-back program that intended to collect controlled substances had to arrange for law enforcement to receive the unused controlled substances and maintain custody of them until they were destroyed.

However, in October 2010 the Secure and Responsible Drug Disposal Act was enacted amending the Controlled Substances Act. The act gives DEA the authority to issue regulations allowing communities and others to establish secure disposal programs for unused controlled substances. It also authorizes DEA to permit long-term care facilities to dispose of controlled substances on behalf of consumers who no longer need them. According to the Deputy Assistant Director of DEA's Office of Diversion Control, DEA strongly supported this legislation and anticipates issuing a notice of proposed rulemaking in the fall of 2011.

According to experts and program organizers, take-back programs are also hampered by limited funding. Programs use a combination of in-kind contributions, volunteer time, grants, and local funding sources to pay for their programs. For example, between 2004 and 2008, EPA awarded 25 grants—totaling \$926,972—to support take-back programs; these grants ranged from approximately \$10,000 to \$150,000. In addition, at least one state has previously proposed legislation that would require pharmaceutical manufacturers to fund take-back programs. As of March 2011, no such state legislation had been enacted.

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<sup>57</sup>According to DEA regulations and the Controlled Substances Act, controlled substances include narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illicit production of controlled substances. This list includes pharmaceuticals that are considered to have a high potential for abuse, such as opium, morphine, and methadone. DEA officials we spoke with stated that about 10 percent to 12 percent of all pharmaceuticals dispensed in the United States are controlled substances.

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## Other Countries Also Support Take-Back Programs

In 2004, the European Union (EU) issued a directive to its member states to, among other things, ensure that appropriate collection systems are in place for medicinal products that are unused or have expired in light of the potential risks presented by these pharmaceuticals for the environment.<sup>58</sup> Three years later, in 2007, the European Federation of Pharmaceutical Industry Associations surveyed 27 EU member states on their implementation of programs to collect unused pharmaceuticals. Of the 22 national pharmaceutical associations responding to the survey, 19 reported they had a pharmaceutical waste collection program, and most of these 19 associations reported that the programs operate nationwide. In 6 of the 19 programs, the pharmaceutical industry funds all costs associated with collecting and destroying unused pharmaceuticals.

Sweden is an example of an EU country that has taken additional steps to reduce the occurrence of pharmaceuticals in drinking water. Sweden's efforts are supported by its government; pharmacies (most of which are publicly owned) are now obligated to take back all unused or expired pharmaceuticals and safely incinerate them. In 2009, 1,128 tons of pharmaceuticals, including packaging, were returned and destroyed. Sweden has also taken the following actions:

- *Classifying pharmaceuticals according to how toxic they would be if they were released into the environment.* According to a Swedish official, in 2004, officials from pharmaceutical producers and Sweden's health care system created an environmental classification system for pharmaceuticals to provide doctors and patients with information about the environmental effects of pharmaceuticals. Sweden developed this system by using risk and hazard data submitted by pharmaceutical manufacturers on their products. These data were then evaluated by an independent consulting firm, which provided an approval or disapproval for the proposed risk and hazard levels. The pharmaceuticals' risk and hazard determinations used the following criteria: biodegradability, potential to accumulate in the body, and toxicity to aquatic organisms. Individual jurisdictions throughout Sweden then used these results to compile lists of pharmaceuticals recommended for specific ailments, and doctors may consider these lists when prescribing pharmaceuticals. In addition, at least one pharmaceutical company has indicated that it is pursuing initiatives to

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<sup>58</sup>Article 1, paragraph 87 of the European Union Directive 2004/27/EC (2004).

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produce less toxic and more environmentally friendly pharmaceuticals.

- *Encouraging initial prescriptions in smaller amounts.* According to data from Sweden, in 2005 and 2006, nearly 40 percent of the pharmaceuticals collected were unopened, and the remaining packages were still nearly two-thirds full, suggesting that patients may be buying more pharmaceuticals than they need. As a result, the public providers of healthcare encourage doctors to prescribe smaller initial prescriptions so that patients and their physician can determine if the pharmaceutical will work for the patient. This practice may reduce the amount of pharmaceuticals that are disposed of when patients switch to different pharmaceuticals.

According to one knowledgeable Swedish official, Sweden adopted these policies—even though there is no scientific evidence that the occurrence of pharmaceuticals in the environment is affecting human health—as a result of its adherence to the “precautionary principle.” This principle states that action should be taken without waiting for the certainty of causation when an appropriate level of scientific evidence suggests an association between hazardous environmental exposures and ill health. According to the principle, action should be taken preventively because definitive knowledge about causation might take decades of further research.

Outside of the EU, Australia has a national take-back program—“Return Unwanted Medicines” (RUM). RUM is a national, government-financed program that allows consumers to return unwanted or expired pharmaceuticals to participating pharmacies. Educational materials from the RUM program instruct consumers that they should not dispose of pharmaceuticals in the trash, in the toilet, or in the sink. According to RUM data from July 2009 through June 2010, the RUM project collected 1,075,957 pounds of pharmaceutical waste, including packaging, that might otherwise have been disposed of through wastewater or in the trash and risk contaminating the environment. A program representative stated that RUM has been an integral component of Australia’s efforts to advise consumers on all aspects of pharmaceutical consumption and disposal.

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## Data Gaps Make It Difficult for EPA to Identify Pharmaceuticals for Regulation; Sustained Collaboration May Help EPA Address Such Difficulties

EPA faces challenges in obtaining sufficient occurrence and health effects data to support analyses and decisions about which pharmaceuticals to include on the Contaminant Candidate List as well as to make regulatory determination decisions. EPA is collaborating with other agencies on research to help obtain these data for use in developing future candidate lists, but these efforts are largely informal and EPA has not established a formal mechanism to sustain these collaborative efforts. We previously reported key practices for enhancing and sustaining collaboration among federal agencies that may be an option to help institutionalize an approach for conducting research that leverages resources among the agencies.<sup>59</sup> We recommended that the Director of the Office of Management and Budget continue to encourage interagency collaboration by among other things, promoting and collaboration practices identified in GAO's report; the Office of Management and Budget agreed with the recommendation.

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## EPA Faces Challenges Because of Gaps in Occurrence and Health Effects Data

EPA faces significant data gaps concerning both the occurrence and health effects of pharmaceuticals. Sufficient occurrence and health effects data are critical for EPA to assess pharmaceuticals for possible regulatory determinations under the criteria established by SDWA. The difficulties EPA experienced in evaluating pharmaceuticals to include on its most recent Contaminant Candidate List, in 2009, illustrate the challenges EPA faces in obtaining these data.

## Occurrence Data Were Limited for Pharmaceuticals Considered for the Most Recent Contaminant Candidate List

To evaluate pharmaceuticals for inclusion on its 2009 Contaminant Candidate List, EPA identified two general types of occurrence data: first, data on the actual detection of pharmaceuticals in source and treated drinking water, and second, data on environmental releases and production volumes of pharmaceuticals developed by industry and government.<sup>60</sup>

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<sup>59</sup>GAO, *Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, [GAO-06-15](#) (Washington, D.C.: Oct. 21, 2005).

<sup>60</sup>Production volumes include information on the volume of pharmaceuticals manufactured in or imported into the United States in amounts equal to or greater than 10,000 pounds per year.

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*Source and treated drinking water:* EPA occurrence data on pharmaceuticals detected in untreated source water came from USGS's national reconnaissance study on surface water and related efforts. These efforts provided data on 123 contaminants, including pharmaceuticals. The data contain measurements of contaminants in water but the data were from sample sites often chosen because they were predicted to be the most likely place that pharmaceuticals and other emerging contaminants would enter the environment (e.g., downstream from wastewater treatment plants). The sample sites are not statistically representative of average conditions across the nation. However, the sites were geographically distributed and included a mix of characteristics that were intended to provide a basic understanding of whether pharmaceuticals and other contaminants are in the nation's waterways. According to EPA, the most relevant occurrence data are for treated drinking water, but these data are often not available. EPA told us it evaluated the available studies from the scientific literature that included occurrence data for pharmaceuticals from treated drinking water, but there were only a limited number of studies available and the majority of these studies only sampled a limited number of drinking water systems. Thus, to identify pharmaceuticals for inclusion on the most recent candidate list, EPA instead relied on data on untreated source water. Most Americans consume treated drinking water.

*Environmental release and production volumes:* EPA also obtained occurrence data on pharmaceuticals from the Toxics Release Inventory and the High Production Volume Chemical List. The Toxics Release Inventory contains industry- and government-reported information on chemical releases into the environment—air, land, and water; the High Production Volume Chemical List contains production volume information for chemicals manufactured or imported into the United States in quantities greater than certain threshold amounts. However, EPA considered these data sources to provide less meaningful information on a chemical's potential to occur in drinking water than sources that actually detect the presence of chemicals in the environment, such as the USGS data that it did use.

For the 12 pharmaceuticals that it included on its 2009 Contaminant Candidate List, EPA reported it does not have comprehensive occurrence data for treated drinking water for any of them and does not have an

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Health Effects Data Were Limited for Pharmaceuticals Considered for the Most Recent Contaminant Candidate List

analytic method suitable for conducting national drinking water studies for 7 of them. For the remaining 5 pharmaceuticals, EPA reports that it has or is developing a suitable analytic method.<sup>61</sup>

According to the *Federal Register* notice for the draft 2009 Contaminant Candidate List,<sup>62</sup> the primary source of health effects information on pharmaceuticals in drinking water was the FDA database on maximum recommended daily doses. This FDA database includes the recommended doses for the “average adult patient” for over 1,200 pharmaceuticals and is based on human clinical trials of daily exposure, usually for 3 to 12 months. The maximum recommended daily dose is an estimated upper dose beyond which a pharmaceutical is not more effective and/or adverse effects begin to outweigh beneficial effects. However, according to EPA-sponsored research,<sup>63</sup> extrapolating health effects data from data on the therapeutic doses of individual pharmaceuticals does not address, among other issues, the following two areas of concern about pharmaceuticals in drinking water: the health effects of (1) long-term, low-dose exposure to pharmaceuticals and (2) exposure to mixtures of pharmaceuticals.

- *Effects of long-term, low-dose exposure to pharmaceuticals.* According to the EPA-sponsored research, the health effects of long-term, low-dose exposure to a pharmaceutical may not be predictable by extrapolating from an observed effect of shorter-term exposure to much higher concentration of that pharmaceutical. The research indicates that further complications arise when trying to predict the effects of exposure on sensitive sub-populations. For example, a child in the age group between birth and 1 month might be particularly sensitive to a contaminant during this life stage, during which the child

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<sup>61</sup>In March 2011, EPA proposed the list of contaminants to be monitored under the third Unregulated Contaminant Monitoring Rule. EPA uses this rule to gather occurrence data on unregulated contaminants in drinking water. The proposed list of contaminants for monitoring includes five of the pharmaceuticals on the 2009 Contaminant Candidate List. 76 *Fed. Reg.* 11713 (March 3, 2011)

<sup>62</sup>73 *Fed. Reg.* 9628 (Feb. 21, 2008)

<sup>63</sup>Daughton C.G., “Pharmaceutical Ingredients in Drinking Water: Overview of Occurrence and Significance of Human Exposure,” in ACS Symposium Series 1048, *Contaminants of Emerging Concern in the Environment: Ecological and Human Health Considerations*, ch. 2, Rolf Halden (ed.) (Washington, D.C.: American Chemical Society, November 2010).

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experiences rapid growth, weight gain, and immature immune system function, among other characteristics, which can influence a child's susceptibility to a particular chemical.<sup>64</sup>

- *Effects of exposure to mixtures of pharmaceuticals.* Also according to the EPA-sponsored research, the simultaneous exposure to multiple pharmaceuticals could result in an additive or interactive effect. In particular, studies on occurrence data have found more than one contaminant in a single water sample. For example, the USGS national reconnaissance study on surface water that EPA used to identify contaminants for the most recent candidate list found that there was a median of 7, and as many as 38, of the tested contaminants in a given sample.<sup>65</sup>

For the 12 pharmaceuticals that it included on the most recent candidate list, EPA reported that it has substantial data needs on health effects for 8 of them. For the remaining 4 pharmaceuticals, EPA reports that information exists or there is an ongoing assessment. Furthermore, as we recently reported, EPA has not identified the drinking water contaminants of greatest public health concern. In many cases, gathering sufficient data to make a regulatory determination has taken EPA more than 10 years, and obtaining data on other contaminants on the current list may well take decades.<sup>66</sup> We made recommendations regarding the need for EPA to develop criteria to identify contaminants that pose the greatest health concern and a process to obtain data to support regulatory determinations; EPA did not agree to adopt these recommendations and generally took the position that no further steps are needed.

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<sup>64</sup>EPA Risk Assessment Forum, *Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants* (Washington, D.C., 2005).

<sup>65</sup>Kolpin, D.W.; Furlong, E.T.; Meyer, M.T.; Thurman, E.M.; Zaugg, S.D.; Barber, L.B.; Buxton, H.T., "Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance," *Environ. Sci. Technol.*, 36(6) (2002): 1202-1211.

<sup>66</sup>[GAO-11-254](#).



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EPA Is Collaborating with Other Agencies to Obtain Needed Occurrence and Health Effect Data on Pharmaceuticals, but It Has not Established a Formal Mechanism to Sustain Future Collaboration

EPA is collaborating with other federal agencies to collect occurrence and health effects data on pharmaceuticals and other contaminants that could support decisions about which contaminants to include on future candidate lists as well as regulatory determinations. As the following examples demonstrate, collaboration is helping EPA leverage the resources and expertise of other agencies to obtain results that may have been more difficult for it to achieve on its own.

- EPA and USGS are jointly developing occurrence data for over 230 contaminants, more than half of which are pharmaceuticals, in a study designed to provide EPA with data for future candidate lists. The agencies' joint study will sample treated drinking water and source water in about 25 drinking water treatment plants across the nation. These plants were selected because they draw water from streams, lakes, reservoirs, or ground-water aquifers affected by a variety of waste sources (e.g., municipal waste, septic systems, livestock production). EPA is providing expertise to analyze micro-organisms, and has experience with drinking water treatment facilities and their design. USGS is providing its expertise in the logistics of operating a nationwide water sampling project. Both agencies have expertise in detecting low concentrations of pharmaceuticals and other contaminants of emerging concern. The study is expected to conclude in September 2012.
- EPA is working with FDA to develop a methodology to more efficiently assess the health effects of pharmaceuticals in drinking water by addressing groups of related pharmaceuticals, such as selective serotonin reuptake inhibitors, instead of individual pharmaceuticals. FDA is providing health effects data, and EPA plans to use the methodology to support decisions about which pharmaceuticals to include on future candidate lists. This effort is part of a larger EPA initiative to better implement SDWA by focusing on assessing risk from exposure to groups of contaminants instead of individual contaminants.

According to EPA officials, there is no formal mechanism, such as a long-term strategy or formal agreement, to manage and sustain these collaborative efforts. Agency officials and former members of the PiE workgroup told us that interagency efforts such as those described above are the result of informal collaborative relationships among agency personnel, particularly those fostered by the PiE workgroup. As one official from EPA's Office of Water noted, the current interagency collaboration is "ad hoc." In 2008 and 2010, we reported that by using informal coordination mechanisms, agencies may rely on relationships

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with individual officials to ensure effective collaboration, but these informal relationships could end if the responsible staff are not available to continue the efforts.<sup>67</sup> We recommended that those agencies develop clear guidance for interagency planning efforts in the 2008 report, and that roles and responsibilities be identified to support collaboration in the 2010 report; the agencies generally agreed with these recommendations.

The purpose of the PiE workgroup was to identify and prioritize research needed to better understand the risk from pharmaceuticals in the environment and to recommend areas for federal collaboration to address those priorities.<sup>68</sup> Its draft report was neither approved by NSTC nor publicly released.<sup>69</sup> According to OSTP officials, the draft report was not approved or released because the workgroup did not address OSTP's concerns, including that the report did not specifically outline how agencies would coordinate research and other long-term activities identified in the draft report once the workgroup expired. For example, OSTP officials stated that the draft report did not clarify collaborating agencies' roles and responsibilities by identifying which agencies are best positioned to address specific issues identified in the report and which existing or new programs would be most appropriate for addressing these issues. OSTP officials told us that providing this additional information was consistent with the purpose of the workgroup. The workgroup co-chairs told us that OSTP did not present the workgroup with its written concerns until June 2010, about a year after the draft report was approved by the Subcommittee on Toxics and Risk, and after the workgroup had expired. According to the co-chairs, addressing OSTP's concerns would have required the workgroup to update the scientific data included in the draft report and would have required the workgroup to

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<sup>67</sup>GAO, Homeland Defense: U.S. Northern Command Has Made Progress but Needs to Address Force Allocation, Readiness Tracking Gaps, and Other Issue, [GAO-08-251](#) (Washington, D.C.: Apr. 16, 2008); Live Animal Imports: Agencies Need Better Collaboration to Reduce the Risk of Animal-Related Diseases, [GAO-11-9](#) (Washington, D.C.: Nov. 8, 2010).

<sup>68</sup>*Charter of the Working Group on Pharmaceuticals in the Environment, Toxics and Risk Subcommittee, Committee on Environment and Natural Resources, National Science and Technology Council* (May 26, 2006).

<sup>69</sup>According to the NSTC 2008 Handbook, NSTC documents must be cleared by the White House Co-Chair of the Committee or by the OSTP Director, or, in the event that neither is available, by the OSTP General Counsel.

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provide additional information regarding agencies' roles and responsibilities that was beyond the purpose of the workgroup. Thus, the draft report was never finalized although, according to the co-chairs, the interagency activities begun by the workgroup continued.

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## Key Practices Can Enhance and Sustain Coordination

In an October 2005 report, we identified key practices for enhancing and sustaining collaboration among federal agencies. Three of these practices may help clarify how EPA and other agencies could coordinate their research efforts.<sup>70</sup>

- *Establish roles and responsibilities:* We reported that collaborating agencies should work together to define and agree on their respective roles and responsibilities, including how the collaborative effort will be led. In doing so, agencies can clarify who will do what, organize their joint and individual efforts, and facilitate decision making.
- *Leverage resources:* We reported that collaborating agencies should identify the human, information technology, physical, and financial resources needed to initiate or sustain their collaborative effort. Collaborating agencies bring different levels of resources and capacities to the effort. By assessing their relative strengths and limitations, collaborating agencies can look for opportunities to address resource needs by leveraging each other's resources, thus obtaining additional benefits that would not be available if they were working separately.
- *Establish mechanisms for monitoring, evaluating, and periodically reporting results of the collaborative research efforts:* We reported that federal agencies engaged in collaborative efforts need to create the means to monitor and evaluate their efforts to enable them to identify areas for improvement. Reporting on these activities can help key decision makers within the agencies to obtain feedback for improving both policy and operational effectiveness.

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<sup>70</sup>[GAO-06-15](#).

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## Conclusions

There are basic questions about the potential health risks from exposure to pharmaceuticals in the nation's drinking water. Other contaminants also have been detected in drinking water including personal care products, and chemicals used in industry and agriculture, including some that may act as EDCs. Some of these other contaminants may work in tandem with pharmaceuticals to affect human health through additive or interactive effects. Also of concern to government scientists are the health effects of long-term low-dose exposure to pharmaceuticals and exposure to mixtures of pharmaceuticals.

Since the 1996 amendments to SDWA, EPA has been required to publish a list of currently unregulated contaminants including pharmaceuticals that may require regulation in drinking water, and to make determinations on whether or not to regulate at least 5 of the contaminants on the list every 5 years. In 2009, EPA issued its third Contaminant Candidate List, which consists of 116 contaminants, 12 of which are pharmaceuticals. However, EPA continues to experience difficulty obtaining sufficient occurrence and health effects data for making determinations on (1) which contaminants present the greatest public health concern to include on the list and (2) whether or not to regulate any of the contaminants on the candidate list. It will continue to be difficult for EPA to prioritize contaminants on the candidate list without the necessary information on health effects and occurrence to determine the contaminants that present the greatest public health concern. In many cases, gathering sufficient data to address contaminants awaiting determinations has taken EPA more than 10 years, and obtaining data on other contaminants on the current list may well take decades. To collect occurrence and health effects data on pharmaceuticals and other contaminants that could support decisions about which contaminants to include on future candidate lists, EPA is collaborating informally with USGS and FDA, but does not have a formal mechanism for sustaining such collaboration in the future. Furthermore, the PiE workgroup, which pulled together the scientific expertise from eight federal agencies, has expired and its draft report was neither finalized nor released.

However, neither EPA's informal collaboration efforts nor the strategy proposed by the PiE workgroup details how agencies could coordinate their future interagency collaboration efforts. We have previously reported on key practices for enhancing and sustaining interagency collaboration efforts, such as (1) establishing roles and responsibilities, including how the collaborative effort will be led; (2) identifying the expertise and other resources that each agency can bring to bear on the issue, and (3)

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establishing a process for monitoring, evaluating, and reporting to the public the results of the collaborative research efforts.

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## Recommendation for Executive Action

To collect the pharmaceutical occurrence and health effects data necessary to better implement SDWA, and to address the broader issue of pharmaceuticals and their relationship to other contaminants in the nation's waterways, we are making the following recommendation to the Administrator of EPA:

- Establish a workgroup or other formal mechanism that includes the relevant federal agencies to collaborate and coordinate research on pharmaceuticals and, as appropriate, other contaminants in drinking water that present the greatest public health concern. In establishing this mechanism, EPA should: (1) define roles and responsibilities, including how the collaborative effort will be led; (2) identify the expertise and other resources that each agency can bring to bear on the issue; and (3) develop a process for monitoring, evaluating, and reporting to the public the results of the collaborative research efforts.

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## Agency Comments and Our Evaluation

We provided a draft of this report to EPA, the Department of the Interior (DOI), the Department of Health and Human Services (HHS), OSTP, and the Department of Justice (DOJ) for review and comment.

In written comments, EPA agreed with our findings and recommendation and noted that the extent of interagency collaboration may be dependent upon available resources. EPA also provided clarifying language regarding the responsibilities, accomplishments, and activities of the PiE workgroup which, according to EPA, reflects clarification provided by the PiE workgroup co-chairs. We modified our draft accordingly. EPA's comments are reprinted in appendix III. EPA also provided technical clarifications and comments, which we incorporated as appropriate.

DOI also provided written comments on a draft of this report and stated that it generally agrees with the findings and recommendation in the report. Additionally, DOI provided clarifying language regarding the PiE workgroup. DOI's comments are reprinted in appendix IV. Additionally, USGS, an agency within DOI, provided technical clarifications and comments, which we incorporated as appropriate.

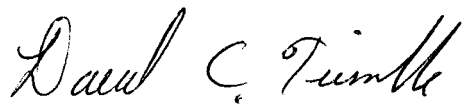
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DOJ, HHS, and OSTP did not provide written comments but provided technical clarifications and comments, which we incorporated as appropriate.

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As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution for 30 days from the report date. At that time, we will send copies to the appropriate congressional committees, the Administrator of EPA, and other interested parties. In addition, this report will be available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff members have any questions on this report, please contact me at (202) 512-3841 or [trimbled@gao.gov](mailto:trimbled@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix V.



David C. Trimble  
Director, Natural Resources and Environment

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# Appendix I: Objectives, Scope, and Methodology

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The objectives of this study were to (1) provide information on the extent to which pharmaceuticals occur in drinking water and the effects, if any, that their occurrence has on human health; (2) describe the approaches taken in the United States and in other countries to reduce the extent to which pharmaceuticals occur in drinking water; and (3) identify challenges, if any, that the Environmental Protection Agency (EPA) faces in determining whether any pharmaceuticals should be regulated under the Safe Drinking Water Act (SDWA), actions EPA is taking to address these challenges, and options for addressing such challenges in the future.

To identify the extent to which pharmaceuticals occur in drinking water, we reviewed federal and peer-reviewed reports, including (1) studies by the U.S. Geological Survey (USGS), (2) articles in peer-reviewed journals by federal scientists and others, and (3) the Pharmaceuticals in the Environment (PiE) workgroup's draft report. We also selected a nonprobability sample of scientific studies to review in our report. The data from these studies are not generalizable beyond the scope of these studies. We selected these studies on the basis of certain criteria, including the source of the study (e.g., a peer-reviewed journal); the geographic scope of the study; and whether the study focused on source water, treated drinking water, or wastewater. We also discussed the subject with scientists at USGS and other federal agencies as well as with representatives from academia, trade associations, the environmental community, and the pharmaceutical industry.

To identify the effects, if any, that the occurrence of pharmaceuticals in drinking water has on human health, we also reviewed federal and peer-reviewed reports, including articles in peer-reviewed journals by federal scientists and others; and the PiE workgroup's draft report. We discussed the subject with federal scientists and representatives from academia, the environmental community, and the pharmaceutical industry. We also attended an October 2009 academic conference on hormones and related compounds in the environment that was hosted by Tulane University.

To describe the approaches taken in the United States to reduce the extent to which pharmaceuticals occur in drinking water; we reviewed literature and spoke with officials from federal agencies including the Drug Enforcement Administration (DEA), EPA, and the Food and Drug Administration (FDA), as well as experts from academia, industry and nonprofit organizations that have ongoing work addressing pharmaceuticals in the environment; from these efforts, we identified consumer take-back programs as the primary approach to reducing occurrence. We also determined that take-back programs could be

grouped into three broad categories based on common characteristics—mail back, one-time, and ongoing. We selected a nonprobability sample of five programs to represent the three categories. The information from these programs is not generalizable to all take-back programs. We selected the programs because they provided geographic diversity and exemplified certain characteristics. For example, we selected one program, in part, because it was pharmacy-based. We did not attempt to evaluate the programs. We collected information on each program through a survey, follow-up interviews, and, where appropriate, additional documentation. To describe approaches taken by other countries to reduce the extent to which pharmaceuticals occur in drinking water, we chose to describe efforts in Sweden and Australia. We selected Sweden because it is undertaking a variety of stewardship activities. We selected Australia because it has a nationwide take-back program. We obtained information on each country's efforts through interviews with knowledgeable officials and, where appropriate, additional documentation.

To identify challenges, if any, that EPA faces in determining whether any pharmaceuticals should be regulated under SDWA, actions EPA is taking to address these challenges, and options for addressing such challenges in the future, we reviewed agency documents and interviewed relevant agency officials. Specifically, to identify challenges, we reviewed EPA's documentation on the process it used to develop the 2009 Contaminant Candidate List under the authority of SDWA. We also reviewed some of the sources of data that EPA relied upon to identify pharmaceuticals for inclusion on the candidate list. To identify actions that EPA is undertaking to address challenges we identified, we interviewed agency officials from EPA, FDA, and USGS and, where appropriate, obtained and reviewed additional documentation. To identify options to address these challenges in the future, we obtained and reviewed a 2009 draft report produced by the PiE workgroup. We also interviewed several of the workgroup members, including the three co-chairs. We also reviewed our own work on practices that can help enhance and sustain collaboration among federal agencies.

We conducted this performance audit from January 2010 through August 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.



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# Appendix II: Guidelines for Proper Disposal of Unused Pharmaceuticals

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According to FDA and the White House Office of National Drug Control Policy, consumers are encouraged to properly dispose of unused pharmaceuticals to avoid harm to others. In general, consumers should not flush prescription pharmaceuticals down the toilet or sink drain unless the label or accompanying patient information specifically instructs consumers to do so. However, in some instances, it may be necessary to dispose of unused pharmaceuticals by flushing. For a list of pharmaceuticals that are recommended to be flushed, consumers should visit FDA's Web site.<sup>1</sup>

Several disposal options are available to consumers for prescription pharmaceuticals that are not specifically labeled to be flushed. For example, other than the pharmaceutical take-back programs presented in this report, programs such as household hazardous waste collection events, which collect pharmaceuticals at a central location, can provide consumers with proper disposal of unused pharmaceuticals. Organizations such as the Product Stewardship Institute have information on such events across the nation.

In addition, FDA and the White House Office of National Drug Control Policy recommend that consumers consider the following steps to dispose of unused pharmaceuticals:

1. Take prescription pharmaceuticals out of their original containers.
2. Mix pharmaceuticals (do NOT crush tablets or capsules) with an undesirable substance, such as cat litter or used coffee grounds.
3. Place the mixture into a disposable container with a lid, such as an empty margarine tub, or into a sealable bag.
4. Conceal or remove any personal information, including Rx number, on the empty containers by covering it with black permanent marker or duct tape, or by scratching it off.
5. Place the sealed container with the mixture, and the empty pharmaceutical containers, in the trash.

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<sup>1</sup><http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/ensuringsafeuseofmedicine/safedisposalofmedicines/ucm186187.htm>

# Appendix III: Comments from the Environmental Protection Agency



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

JUL 22 2011

OFFICE OF  
WATER

Mr. David C. Trimble  
Acting Director  
Natural Resources and Environment  
U.S. Government Accountability Office  
Washington, D.C. 20548

Dear Mr. Trimble:

The U.S. Environmental Protection Agency (EPA) appreciates the opportunity to review and comment on the Government Accountability Office (GAO) draft report, "*Action Needed to Sustain Agencies' Collaboration on Pharmaceuticals in Drinking Water*" (Report Number GAO-11-346). EPA agrees with the recommendation in the draft report with the caveat that level of engagement is dependent upon available resources. Brief comments on the EPA's position regarding the recommendation are provided below. In addition, EPA is providing clarifying language for two specific places in the draft report regarding responsibilities, accomplishments, and activities of the Interagency Pharmaceuticals in the Environment (PiE) workgroup. This additional language reflects clarification provided by the PiE workgroup co-chairs. Other technical comments and clarifications on draft report language have been provided in a separate document.

#### GAO recommendation:

To collect the occurrence and health effects data necessary to better implement SDWA, and to address the broader issue of pharmaceuticals and their relationship to other contaminants in the nation's waterways, GAO made the following recommendation to the Administrator of EPA:

- Establish a workgroup or other formal mechanism that includes the relevant federal agencies to collaborate and coordinate research on pharmaceuticals and, as appropriate, other contaminants in drinking water that present the greatest public health concern. In establishing this mechanism, the EPA should:
  - Define roles and responsibilities, including how the collaborative effort will be led;
  - Identify the expertise and other resources that each agency can bring to bear on the issue; and
  - Develop a process for monitoring, evaluating, and reporting to the public the results of the collaborative research efforts.

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**EPA response to recommendation:**

The EPA supports the establishment of an interagency workgroup or other formal mechanism to collaborate and coordinate research on pharmaceuticals and, as appropriate, other contaminants in drinking water that present the greatest public health concern. The EPA anticipates that the extent to which collaborative efforts are conducted may be dependent upon available resources.

**Clarifying language:**

The PiE workgroup co-chairs recommend that the following language should replace the paragraph that starts at the bottom of page 12 and ends on page 13, significant additions to the draft report language are underlined:

The PiE workgroup was established in 2006 by the Committee on Environment, Natural Resources, and Sustainability (CENRS), Toxics and Risk Subcommittee, an executive branch entity under the National Science and Technology Council (NSTC).<sup>13</sup> NSTC is a council of cabinet-level officials chaired by the President and managed by the Director of Office of Science and Technology Policy (OSTP).<sup>14</sup> The purpose of the workgroup was to identify and prioritize research needed to better understand the risk from pharmaceuticals in the environment and to recommend areas for federal collaboration to address those priorities.<sup>15</sup> The workgroup, which was intended to be temporary, was staffed by scientists from eight federal agencies.<sup>16</sup> The EPA, FDA, and USGS scientists served as co-chairs. In May 2009, the PiE workgroup produced a draft report that was reviewed and approved by the Toxics and Risk Subcommittee and then conveyed to OSTP. OSTP officials told us they had several significant concerns with the draft report and indicated that it would not be approved or publicly released until the workgroup addressed these concerns. The workgroup co-chairs told us that the requested changes were shared with them after the workgroup had expired and, as a result, the document was not finalized. However, interagency collaborative efforts begun by the workgroup have continued.

<sup>13</sup> NSTC was established by Executive Order in 1993. NSTC has multiple committees to address its responsibilities regarding the scientific and technical work of the executive branch. For example, CENRS advises and assists NSTC on federal research and development related to environment, natural resources, and sustainability. The Toxic and Risks Subcommittee is one of several subcommittees of CENRS.

<sup>14</sup> Congress established OSTP in 1976 to advise the President and others within the Executive Office of the President on considerations of science and technology in federal policy, plans, and programs. OSTP is also charged with leading interagency efforts to develop and implement sound science and technology policies, among other things.

<sup>15</sup> Charter of the Working Group on Pharmaceuticals in the Environment, Toxics and Risk Subcommittee, Committee on Environment and Natural Resources, National Science and Technology Council (May 26, 2006).

<sup>16</sup> The eight agencies were the U.S. Department of Agriculture, the Department of Commerce's National Oceanographic and Atmospheric Administration, U.S. Environmental Protection Agency (EPA), the Department of Health and Human Services' Centers for Disease Control and Prevention, U.S. Food and Drug Administration (FDA), National Institute for Environmental and Health

Appendix III: Comments from the  
Environmental Protection Agency

*Sciences; and the Department of the Interior's Fish and Wildlife Service and U.S. Geological Survey (USGS).*

The PiE workgroup co-chairs recommend that the following language replace the paragraph that starts at the bottom of page 38 and ends on page 39; significant additions to the draft report language are underlined:

The purpose of the PiE workgroup was to identify and prioritize research needed to better understand the risk from pharmaceuticals in the environment and to recommend areas for federal collaboration to address those priorities.<sup>66</sup> The draft report was neither approved by NSTC, nor publicly released. According to the NSTC 2008 Handbook, NSTC documents must be cleared by the White House Co-Chair of the Committee (in this case, CENRS), or by the OSTP Director, or, in the event that neither is available, by the OSTP General Counsel. According to OSTP officials, the draft did not specifically outline how agencies would coordinate research and other long-term activities identified in the draft report once the workgroup disbanded. For example, OSTP officials stated that the draft report did not clarify collaborating agencies' roles and responsibilities by identifying which agencies are best positioned to address specific issues identified in the report and which existing or new programs would be most appropriate for addressing these issues. The workgroup co-chairs told us that OSTP did not provide the workgroup with its concerns until after the workgroup had expired. Nonetheless, the interagency activities begun by the workgroup were continued.

<sup>66</sup> *Charter of the Working Group on Pharmaceuticals in the Environment, Toxics and Risk Subcommittee, Committee on Environment and Natural Resources, National Science and Technology Council (May 26, 2006).*

Once again, thank you for the opportunity to respond to this draft report.

Sincerely,



Nancy K. Stoher  
Acting Assistant Administrator

Enclosure

# Appendix IV: Comments from the Department of the Interior



## United States Department of the Interior

OFFICE OF THE SECRETARY  
Washington, D.C. 20240

JUL 21 2011

Mr. David Trimble  
Acting Director, Natural Resources and Environment  
U.S. Government Accountability Office  
441 G Street, N.W.  
Washington, D.C. 20548

Dear Mr. Trimble:

The Department of the Interior has reviewed the draft GAO report entitled *ENVIRONMENTAL HEALTH: Action Needed to Sustain Agencies' Collaboration on Pharmaceuticals in Drinking Water* (GAO-11-346).

The Department of the Interior generally agrees with the findings and recommendation in the report. However, the description of the responsibilities, activities, and accomplishments of the Pharmaceuticals in the Environment (PiE) Working Group, established in 2006 by the Committee on Environment, Natural Resources, and Sustainability (CENRS), Toxics and Risk Subcommittee, an executive branch entity under the National Science and Technology Council (NSTC), should be clarified. Language is provided to make that clarification in two specific places in the draft report.

The following language should replace the paragraph that starts at the bottom of page 12 and ends on page 13; significant additions to the draft report language are underlined:

The PiE workgroup was established in 2006 by the Committee on Environment, Natural Resources, and Sustainability (CENRS), Toxics and Risk Subcommittee, an executive branch entity under the National Science and Technology Council (NSTC).<sup>13</sup> NSTC is a council of cabinet-level officials chaired by the President and managed by the Director of Office of Science and Technology Policy (OSTP).<sup>14</sup> The purpose of the workgroup was to identify and prioritize research needed to better understand the risk from pharmaceuticals in the environment and to recommend areas for federal collaboration to address those priorities.<sup>15</sup> The workgroup, which was intended to be temporary, was staffed by scientists from eight federal agencies.<sup>16</sup> EPA, FDA, and USGS scientists served as co-chairs. In May 2009, the PiE workgroup produced a draft report that was reviewed and approved by the Toxics and Risk Subcommittee and then conveyed to OSTP. OSTP officials told us they had several significant concerns with the draft report and indicated that it would not be approved or publicly released until the workgroup addressed these concerns. The workgroup co-chairs told us that the requested changes were beyond the charge of the workgroup and would reflect a markedly different document. The workgroup expired in 2009 and the report was never finalized. However, interagency collaborative efforts begun by the workgroup have continued.

<sup>13</sup> NSTC was established by Executive Order in 1993. NSTC has multiple committees to address its responsibilities regarding the scientific and technical work of the executive branch. For example, CENRS advises and assists NSTC on federal research and development related to environment, natural resources, and sustainability. The Toxic and Risks Subcommittee is one of several subcommittees of CENRS.

<sup>14</sup> Congress established OSTP in 1976 to advise the President and others within the Executive Office of the President on considerations of science and technology in federal policy, plans, and programs. OSTP is also charged with leading interagency efforts to develop and implement sound science and technology policies, among other things.

<sup>15</sup> Charter of the Working Group on Pharmaceuticals in the Environment, Toxics and Risk Subcommittee, Committee on Environment and Natural Resources, National Science and Technology Council (May 26, 2006).

<sup>16</sup> The eight agencies were the U.S. Department of Agriculture, the Department of Commerce's National Oceanographic and Atmospheric Administration, U.S. Environmental Protection Agency (EPA), the Department of Health and Human Services' Centers for Disease Control and Prevention, U.S. Food and Drug Administration (FDA), National Institute for Environmental and Health Sciences; and the Department of the Interior's Fish and Wildlife Service and U.S. Geological Survey (USGS).

We recommend that the following language replace the paragraph that starts at the bottom of page 38 and ends on page 39; significant additions to the draft report language are underlined:

The purpose of the PiE workgroup was to identify and prioritize research needed to better understand the risk from pharmaceuticals in the environment and to recommend areas for federal collaboration to address those priorities.<sup>66</sup> [The] draft report was neither approved by NSTC, nor publicly released. According to the NSTC 2008 Handbook, NSTC documents must be cleared by the White House Co-Chair of the Committee (in this case, CENRS), or by the OSTP Director, or, in the event that neither is available, by the OSTP General Counsel. According to OSTP officials, the draft did not specifically outline how agencies would coordinate research and other long-term activities identified in the draft report once the workgroup disbanded. For example, OSTP officials stated that the draft report did not clarify collaborating agencies' roles and responsibilities by identifying which agencies are best positioned to address specific issues identified in the report and which existing or new programs would be most appropriate for addressing these issues. The workgroup co-chairs told us that OSTP did not provide the workgroup with its concerns until June 2010, about a year after the draft report was approved by the Subcommittee on Toxics and Risk, and after the workgroup had expired. According to the co-chairs, addressing OSTP's concerns would have required the workgroup to update the draft report with significant additional information, including agencies' roles and responsibilities, which they felt would be beyond the purpose of the workgroup. Thus, the workgroup was not reactivated by the Toxics and Risk Subcommittee; however, the interagency activities begun by the workgroup were continued.

*<sup>66</sup> Charter of the Working Group on Pharmaceuticals in the Environment, Toxics and Risk Subcommittee, Committee on Environment and Natural Resources, National Science and Technology Council (May 26, 2006).*

We hope these comments will assist you in preparing the final report. If you have any questions, or need additional information, please contact Ione Taylor (703) 648-6403 or Herbert Buxton at (609) 771-3944.

Sincerely,



Anne J. Castle  
Assistant Secretary for  
Water and Science

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# Appendix V: GAO Contact and Staff Acknowledgments

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## GAO Contact

David C. Trimble, (202) 512-3841 or [trimbled@gao.gov](mailto:trimbled@gao.gov)

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## Staff Acknowledgments

In addition to the contact above, Diane B. Raynes, Assistant Director; Elizabeth R. Beardsley; Mark A. Braza; Tanya L. Doriss; Charles T. Egan; Brynne Keith-Jennings; Amanda M. Leissoo; Carol Herrnstadt Shulman; John B. Stephenson; and Kiki Theodoropoulos made key contributions to this report. Also contributing to this report were Sandra J.G. Kerr, Katherine M. Raheb, and Nicholas L. Weeks.



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