Dropping the Ball:
EPA's Investigation and Regulation of Pharmaceuticals and Personal Care Products (PPCPs) and Endocrine Disrupting Compounds (EDCs)
March 19, 2008

Background. Pharmaceuticals and personal care products (PPCPs) include over-the-counter (OTC) medications, prescription medications, dietary supplements, hormones, cleaning agents (especially antibacterial cleaners), and the inert ingredients that are associated with these products. Some PPCPs are also endocrine disrupting compounds (EDCs). EDCs are synthetic compounds which either block or mimic natural hormones, which in turn disrupt normal functioning of organs.

Some pesticides can act as EDCs. Many of the components of OTC drugs, supplements, and prescription medications are not completely metabolized by the human body. Therefore, the unmetabolized portions of these compounds are excreted when people defecate or urinate. For example, when amoxicillin, a common antibiotic, is ingested, 60% of the drug comes out unchanged in the urine. Similarly, 40% to 50% of atenolol is excreted unchanged; and 90% of cephalexin (also known as the antibiotic Keflex).

Since wastewater treatment plants and septic systems are neither designed nor intended to remove PPCPs and EDCs from water, the compounds end up in our surface water and groundwater. When these waters are sources for drinking water, the PPCPs and EDCs end up in the drinking water. From 1999 to 2002, the United States Geological Survey (USGS) studied surface and groundwater samples from around the country to determine whether PPCPs were present. They found at least one compound in 80% of streams and 93% of groundwater. The most commonly found compounds were: steroids, OTC medications (like ibuprofen), and insect repellants.

Some argue that PPCPs and EDCs are found in our drinking water in such tiny amounts (parts per trillion, or ppt) that they cannot possibly cause human harm. However, the U.S. Environmental Protection Agency (EPA) regulates land disposal of dioxin at 300 ppt. Moreover, insulin, estrogen, and other hormones are exceptionally potent chemicals that operate at concentrations of ppt, and fetuses are sensitive to chemicals in the parts per *quadrillion* range.

The issue of PPCPs and EDCs in our water is not new – scientists have been aware of the problem for decades. Research on the issue began in the 1980s, and in 1996, EPA's Office of Research and Development (ORD) identified EDCs as one of its research priorities. EPA claims that it "established a leadership role" on this issue in 1999 by publishing of a critical review article on PPCPs.[1] In 2000, EPA devoted a website to the issue of PPCPs. This website was intended to be a repository for research, new information, and as a tool to educate the public about PPCPs and EDCs. Unfortunately, most of the research conducted until 2002 dealt only with assessing the

[1] http://www.epa.gov/ppcp/faq.html

presence of PPCPs and EDCs in wastewater and receiving surface waters such as streams, rivers and lakes. More recently, attention has been turned to treatment technologies, and the efficacy of particular removal techniques. Very little information exists on how these chemicals effect human health.

EPA's duties regarding PPCPs and EDCs. U.S. Congress directed EPA to screen pesticides for hormonal activity in humans through the enactment of the Food Quality Protection Act (FQPA) of 1996. Specifically, 21 U.S.C. Section 346a(p) states that under the estrogenic substances screening program, the Administrator shall:

- Develop a screening program "using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate" no later than August 3, 1998. This screening program must test all pesticide chemicals, and may test other substances, at the Administrator's discretion, unless the Administrator orders a substance exempt on the grounds that it is not anticipated to "produce any effect in humans similar to an effect produced by a naturally occurring estrogen";

- Implement the screening program after public comment and review, but no later than August 3, 1997;

- If a substance is found to have an endocrine effect on humans, the Administrator "shall, as appropriate, take action under such statutory authority as is available to the Administrator, including consideration under other sections of this chapter, as is necessary to ensure the protection of public health"; and

- Make a report to Congress no later than August 3, 2000, containing the findings of the screening program and recommendations for further testing needed to evaluate the impact on human health of the substances tested under the screening program, and recommendations for any further actions.[2]

The Safe Drinking Water Act Amendments of 1996 authorized EPA to screen drinking water contaminants for similar activities. Specifically, Section 136 of the SDWA Amendments states, "In addition to the substances referred to in (FQPA), the Administrator may provide for testing under the screening program authorized by (FQPA) for any other substance that may be found in sources of drinking water if the Administrator determines that a substantial population may be exposed to such substance."[3] EPA also has authority to test under the Toxic Substances Control Act

[2] http://frwebgate1.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=502248399920+0+0+0&WAISaction=retrieve

[3] 42 U.S.C.§ 300j-17

(TSCA). Specifically, it provides authority for EPA to require testing of TSCA chemicals, provided that certain hazard and/or exposure-based findings are made.[4]

Has EPA met its statutory duty to screen and test for PPCPs and EDCs? In order to fulfill its obligations under the SDWA and the FQPA, EPA developed an Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) in 1996. After meeting for two years, the EDSTAC presented its report to Congress in September of 1998. The EDSTAC was overwhelmed with the sheer numbers of chemicals that needed to be examined. In its report, EDSTAC stated:

> "The EDSTAC estimates the initial universe of chemicals that needs to be considered for prioritization for endocrine disruptor screening and testing numbers approximately 87,000 including: pesticides, commodity chemicals, naturally occurring non-steroidal estrogens, food additives, cosmetics, nutritional supplements, and representative mixtures. Simultaneous screening, testing, and evaluation of this universe is far beyond the capabilities of available facilities and resources….The EDSTAC recognized that biological effects data are incomplete or lacking for most chemicals, a condition which makes priority setting difficult."[5]

On August 11, 1998, EPA issued a Federal Register notice describing the screening program developed by EDSTAC.[6] Out of the approximately 50 vertebrate hormones, EDSTAC and EPA decided to focus only on three hormone effects - estrogenic, androgenic, and thyroid - as these systems were the most widely studied and had the most research available on them. On December 28, 1998, EPA issued a second Federal Register notice describing the screening program in more detail.[7] The EPA stated it would take a tiered approach to assessing the problem: the purpose of Tier 1 screening is to *identify* substances that have the potential to interact with the endocrine system, while Tier 2 is to determine whether the substance causes adverse effects.

On August 3, 1999, the Natural Resources Defense Council, The Breast Cancer Fund, CALPIRG Charitable Trust, Pesticide Watch Education Fund, Pesticide Action Network, San Francisco Bay Area Physicians for Social Responsibility, and United Farm Workers of America, AFL-CIO filed suit against EPA for failure to meet its statutory deadline its screening program. While the suit was underway, in August of 2000, EPA presented a second report to Congress, reporting its results thus far.[8] EPA had already missed

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[4] 15 U.S.C. § 2603

[5] http://www.epa.gov/endo/pubs/edspoverview/finalrpt.htm pages E-6 and E-8.
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[6] http://www.epa.gov/endo/pubs/081198frnotice.pdf

[7] http://www.epa.gov/endo/pubs/fr122898_1.pdf

[8] http://www.epa.gov/endo/pubs/reporttocongress0800.pdf

statutory deadlines, and it did not appear as if was making enough progress to comply with these deadlines.

EPA settled this lawsuit with the plaintiffs on January 19, 2001.[9] In it, EPA agreed to use its best efforts to make the Endocrine Disruptor Priority Setting Database (EDPSD) operational by May 31, 2002, and to publish a list of chemicals to be screened no later than December 31, 2002. Most importantly, EPA agreed to start requiring testing of certain chemicals by December 31, 2003, and for other chemicals by December 31, 2004.

On May 15, 2002, EPA submitted a status report to Congress.[10] The report described the formation of the Endocrine Disruptor Methods Validation Subcommittee (EDMVS) to provide independent advice on scientific and technical issues on the screening protocol. On December 30, 2002, EPA published a Federal Register notice seeking public comment on its approach for selecting the first group of chemicals for screening.[11]

Almost three years later, on September 27, 2005, EPA published a Federal Register notice stating that it had looked at the public comments from 2002, and proposing how it would approach the selection of chemicals.[12]

On June 18, 2007, EPA issued a draft list of chemical pesticides and pesticide inerts it would screen.[13] The agency listed only 73 chemicals out of the 87,000 that it intended to screen in Tier 1. In other words, it took eleven years for EPA to issue a draft list of 73 chemicals that it *intends* to screen. This list has not yet been finalized. Thus, it does not appear that EPA is actually requiring screening for any of these potential EDCs.

On its current website, EPA states:

> "While EPA has some data on endocrine-disrupting pesticides, currently insufficient scientific data are available on most of the estimated 87,000 chemicals produced today to allow for an evaluation of endocrine associated risks."[14]

[9] http://www.epa.gov/endo/pubs/settlement.pdf

[10] http://www.epa.gov/endo/pubs/edmvs/edmvsstatusreporttocongressfinal.pdf

[11] http://www.epa.gov/endo/pubs/12-02-frnotice.pdf

[12] http://www.epa.gov/fedrgstr/EPA-TOX/2005/September/Day-27/t19260.pdf

[13] http://www.epa.gov/endo/pubs/draft_list_frn_061807.pdf

[14] http://www.epa.gov/endo/pubs/edspoverview/primer.htm

Bland assertions of "no harm." EPA's webpage on PPCPs and EDCs contains a bland assertion that these chemicals do not harm humans. Specifically, the webpage states:

> "To date, scientists have found no evidence of adverse human health effects from PPCPs in the environment."[15]

Unfortunately, this misleading statement is quoted and repeated by developers looking to construct projects that would put even more PPCPs and EDCs into our drinking water supplies. Since EPA is the premiere governmental agency in charge of protecting the environment, people rely on its assertions. This assertion of no harm, however, is contradicted not only by scientists outside of EPA, but also from EPA's own scientists and publications.

The following statements are from EPA publications:

- "Endocrine disruptors … may cause a variety of problems with, for example, development, behavior, and reproduction. They have the potential to impact both human and wildlife populations."[16]

- "Although there is controversy on the subject, EPA … and the National Academy of Sciences … published recent reports based on reviews of the scientific literature on studies of declining human sperm counts over the last fifty years. Wildlife have been reported with malformed genitalia, aberrant mating behavior, sterility, and other physical and behavioral anomalies."[17]

- "…. there is little doubt that small disturbances in endocrine function, particularly during certain highly sensitive stages of the life cycle (e.g., development, pregnancy, lactation) can lead to profound and lasting effects …Taken collectively, the body of scientific research on human epidemiology, laboratory animals, and fish and wildlife provides a plausible scientific hypothesis that environmental contaminants can disrupt the endocrine system leading to adverse-health consequences."[18]

- "Adverse effects on wildlife and fish can serve as an early warning of potential health risks for humans. There is strong evidence for endocrine disruption observed in natural wildlife and fish populations. Moreover, wildlife and fish are inherently valuable components of ecosystems, and they act as sentinels for the relative health of the environment that they share with humans."[19]

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[15] http://www.epa.gov/ppcp/faq.html
[16] http://www.epa.gov/endo/pubs/reporttocongress0800.pdf, page 3.
[17] Id, at page 4.
[18] http://www.epa.gov/endo/pubs/fr122898_1.pdf at 71543
[19] http://www.epa.gov/endo/pubs/fr122898_1.pdf at 71545

Respected scientists outside the EPA have also cautioned that exposure to EDCs can result in adverse health impacts to non-humans, and therefore we must invoke the precautionary principal when considering the potential impacts on humans. In fact, the World Health Organization states:

> "…the biological plausibility of possible damage to human reproduction from exposure to EDCs seems strong when viewed against 1) the background of known influences of endogenous and exogenous hormones on many of the processes involved, and 2) the evidence of adverse reproductive outcomes in from wildlife and laboratory animals exposed to EDCs. The biological plausibility and the striking changes in human reproductive health trends in some areas, for some outcomes, are sufficient to warrant concern and make this area a research priority….there is biological plausibility and some experimental evidence that EDCs may contribute to hormonally influenced human cancer…"[20]

The Harvard School of Public Health states:

> "The effects of PPCPs once released into the natural environment and drinking water sources are largely unknown. Because many were designed to counteract chemical interactions or to target specific metabolic and biological pathways in humans, there is concern that some PPCPs may disrupt key processes in sensitive non-target organisms, including certain human populations."[21]

Finally, the Associated press story that was released on March 10, 2007 states:

> "… the presence of so many prescription drugs -- and over-the-counter medicines like acetaminophen and ibuprofen -- in so much of our drinking water is heightening worries among scientists of long-term consequences to human health. And while researchers do not yet understand the exact risks from decades of persistent exposure to random combinations of low levels of pharmaceuticals, recent studies -- which have gone virtually unnoticed by the general public -- have found alarming effects on human cells and wildlife. Mary Buzby -- director of environmental technology for drug maker Merck & Co. Inc. -- said: 'There's no doubt about it, pharmaceuticals are being detected in the environment and there is genuine concern that these compounds, in the small concentrations that they're at, could be causing impacts to human health or to aquatic organisms.' Recent laboratory research has found that small amounts of medication have affected human embryonic kidney cells, human blood cells and human breast cancer cells. The cancer cells proliferated too quickly; the kidney

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[20] Damstra, T., Barlow, S., Bergman, A., Kavlock, R., and Van der Kraak, G. (2002). "Global Assessment of the State-of-the-Science of Endocrine Disruptors," WHO publication No. WHO/PCS/EDC/02.2, pages 69 and 86.

[21] http://www.hsph.harvard.edu/shinelab/research/PPCP.htm

> cells grew too slowly; and the blood cells showed biological activity associated with inflammation. Many independent scientists are skeptical that trace concentrations will ultimately prove to be harmful to humans. There's growing concern in the scientific community, though, that certain drugs -- or combinations of drugs -- may harm humans over decades because water, unlike most specific foods, is consumed in sizable amounts every day. Pregnant women, the elderly and the very ill might be more sensitive."[22]

Drinking water criteria do not include PPCPs and EDCs. EPA has drinking water regulations for only 90 contaminants. The SDWA requires that EPA periodically publish a Contaminant Candidate List (CCL). The CCL is a list of priority contaminants which are known or anticipated to occur in public water systems. However, these contaminants on the CCL list are not regulated under existing federal drinking water regulations. Once a contaminant is placed on the CCL, it is not regulated. It merely advises people that it may be regulated in the future. The most recent addition to the CCL was in February of 2008.

However, because EPA has failed to even screen and test for PPCPs and EDCs, these chemicals are not only unregulated in drinking water, but they also have not made it onto the CCL. Moreover, as far as we know, no state regulates PPCPs or EDCs in drinking water.

The EPA is likely hesitant to regulate these chemicals for three reasons: 1) they are ubiquitous; 2) they are extremely expensive to test for; and 3) there is no known technology for removing them from the water.

We do not believe that these hurdles should result in ignoring the situation. It is crucial that EPA at the very least work to prevent additional PPCPs and EDCs from entering our water supply. Simple steps, such as prohibiting the construction of hospitals, nursing homes and assisted living facilities in our aquifer protection districts and near private drinking water wells, would prevent the problem from being exacerbated.

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[22] http://www.cnn.com/2008/HEALTH/03/10/pharma.water1.ap/index.html