

## Chapter 9

# Full Circle Drugs, the Environment, and Our Health

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*Sharon Batt*

### Introduction

Previous chapters have detailed the serious public health concerns raised by the ubiquitous nature of pharmaceuticals in our society and how they are regulated. Since the mid-1990s, news headlines about “drugs in the water” have alerted the public to an even more unsettling public health risk. Trace amounts of pharmaceuticals have been detected in Canada’s lakes, rivers, streams, and tap water. Other chemicals from food and drug products—including food additives and the ingredients of personal care products, such as shampoos and perfumes—have also been detected, as have veterinary and agricultural chemicals. New biologics, genetic therapies, and genetically modified foods are more recent elements that could end up in this “chemical soup.” As analytic methods for detection are developed, the number of drugs identified worldwide has grown, rising from 20 in 1998 (Ternes, 1998) to more than 200 in 2008 (Donn, Mendoza & Pritchard, 2008a).

There is no certainty about the health impacts on humans, but effects on marine life show that some drugs contaminating the environment are not benign, despite the very low concentrations that have been detected. Male fish downstream from sewage-treatment plants whose effluent includes estrogenic compounds become “feminized”—they begin to develop eggs in their testes (e.g., Desbrow, Routledge, Brighty, Sumpter & Waldock, 1998; Jobling & Tyler, 2003; Kavanagh et al., 2004). These “she-male” or intersex fish lose interest in spawning and their biological capacity to reproduce may be impaired. Indeed, when a team of researchers added low concentrations of the synthetic estrogen contained in birth control pills to a lake in northern Ontario, they not only detected changes to the reproductive systems of male and female fathead minnows, the species became virtually extinct within a few years (Kidd et al., 2007). An Environment Canada study found that effluent from a sewage-treatment plant entering the St. Lawrence River was toxic to drug-metabolizing cells in rainbow trout (Gagné, Blaise & André, 2006). Other research has demonstrated that effects can travel up the food chain: starlings who fed off earthworms polluted with estrogenic sewage contaminants sang more complex songs than control birds, and the area of their brain that controls song complexity was significantly enlarged (Markham et al., 2008); vultures in Asia that feed on the carcasses of livestock treated with an anti-inflammatory drug died of kidney failure (Oaks et al., 2004; Prakash et al., 2003; Swan et al., 2006). Some effects may be caused by a specific drug; others may be the result of chronic exposure to low levels of multiple bioactive substances (Jørgensen & Halling-Sørensen, 2000).

Such findings add another dimension to the evidence throughout this book that we need to rethink our relationship to pharmaceutical drugs. Taking a drug is not simply a personal decision that affects one individual’s health. Drugs alter the ecosystem on which all living things depend. And, far from vanishing into the environment after use, these substances may travel full circle—into lakes and streams, and back into our bodies, via the water we drink and the foods we eat.

This chapter looks at this neglected form of environmental contamination from a public health perspective, with particular attention to its impact on women's health. The analysis evaluates federal government initiatives designed to protect the health of Canadians and the Canadian ecosystem from pharmaceutical and personal care products (PPCPs). We argue that reducing inappropriate pharmaceutical use is the most health-promoting, cost-effective strategy for reducing exposures to these substances. Similarly, reducing the vast quantities of unused drugs and disposing of any unavoidable excess safely is more ecological, economical, and socially just than trying to filter them from the water after the fact; improvements to water-treatment systems inevitably privilege wealthier communities and may bypass poor ones altogether. Reduced drug use remains oddly absent from most discussions of this issue, however.

### **The Problem in Context**

Although policy initiatives in this area are recent, pharmaceuticals have very likely been present in the environment as long as they have been commercially marketed (U.S. Environmental Protection Agency, 2008). The bellwether scientific study appeared in the literature in 1977, documenting pharmaceutical drugs in Kansas City sewage (Hignite & Azarnoff, 1977). Little notice was taken for 20 years when, using more sensitive detection methods, researchers monitoring aquatic pesticide contaminants in Germany accidentally discovered the cholesterol-reducing drug clofibric acid in the drinking water in Berlin (Heberer & Stan, 1997). Clofibric acid is a chemical cousin to the weed killer 2,4-D; its presence in the tap water spurred researchers in Germany, Denmark, and Sweden to look for clofibric acid throughout Europe. They documented measurable quantities in the North Sea, the Danube River, and the Po River (e.g., Buser, Müller & Theobald, 1998; for an overview, see Montague, 1998). In 1999, the U.S. Geological Survey began an extensive, ongoing testing program that discovered dozens of PPCPs throughout the United States, in groundwater, surface water, streambeds, and tap water (U.S. Geological Survey, 2008). Nine years later, a five-month investigation by Associated Press found drugs in the water supplies of 24 major American metropolitan areas (Donn et al., 2008a).

Tests in Canada have been more limited. We now know, however, that our waterways also contain traces of antibiotics, painkillers, anti-inflammatories, hormones, tranquilizers, chemotherapy drugs, and drugs used to treat epilepsy and blood cholesterol (Stevenson, 2002). Nor has our tap water escaped contamination. Tests conducted by a laboratory in Ottawa for the *Globe and Mail* and CTV News found trace amounts of drugs in the tap water of four out of 10 Canadian communities sampled (Mittelstaedt, 2003). Waste-treatment systems are not designed to remove PPCPs, nor do municipalities routinely test for them. Testing is expensive and so far is limited to research. The City of Ottawa announced plans to begin testing in 2008

Table 9.1A: Some Effects of Drugs on Wildlife (Selected Samples from Literature)

| Wild Fish Species     | Habitat   | Exposure   | Effects Observed   |
|-----------------------|---|--|--|
| Male rainbow trout    | Laboratory study with graded exposures  | Synthetic estrogen (EE2) used in oral contraceptives   | Decreased fertility (50% fewer eggs fertilized from harvested semen reached maturity)                        |
| Male fathead minnow   | Laboratory study  | Minnows exposed to a mixture of five estrogenic chemicals in environmentally relevant concentrations | Chemicals acted additively to induce vitellogenin (egg yolk proteins indicative of feminization)             |
| Male fathead minnow   | Chemicals added to a pristine lake in northern Ontario                                | Synthetic estrogen used in oral contraceptives   | Reproductive changes in males and females; virtual species extinction within a few years                     |
| Prawn                 | Natural waterway in Beijing, China, contaminated by water from a pharmaceutical plant | Pharmaceutical waste water from antibiotic production line   | Acute dose-dependent toxicity causing death  |
| Atlantic salmon       | Laboratory study  | Synthetic estrogen   | Effects on gene transcription in brain and head kidney*  |
| Adult male zebra fish | Laboratory study  | Synthetic androgen methyltestosterone  | Low concentrations significantly increased vitellogenin production and decreased endogenous ketotestosterone |

\* The head kidney is the definitive excretory organ of primitive fishes

Sources: Andersen, L., Goto-Kazeto, R., Trant, J.M., Nash, J.P., Korsgaard, B. & Bjerregaard, P. (2006, March 10). Short-term exposure to low concentrations of the synthetic androgen methyltestosterone affects vitellogenin and steroid levels in adult male zebrafish (*Danio rerio*); *Aquatic Toxicology*, 76(3-4), 343-352; Brian, J.V., Harris, C.A., Scholze, M., Backhaus, T., Booy, P., Lamoree, M. et al. (2005). Prediction of the response of freshwater fish to a mixture of estrogenic chemicals. *Environmental Health Perspectives*, 113(6), 721-728; Gerhardt, A., de Bisthoven, L.J., Mo, Z., Wang, C., Yang, M. & Wang, Z. (2002). Short-term responses of *Oryzias latipes* (*Pices adrianichthyidae*) *Macrobrachium nipponense* (*Crustacea: Palaemonidae*) to municipal and pharmaceutical waste water in Beijing, China: Survival, behaviour, biochemical biomarkers. *Chemosphere*, 47(1), 35-47; Kidd, K.A., Blanchfield, P.J., Mills, K.H., Palace, V.P., Evans, R.E., Lazorchak, J.M. et al. (2007). Collapse of a fish population after exposure to synthetic estrogen. *Proceedings of the National Academy of Sciences*, 104(21), 8897-8901; Lyssimachou, A. & Arukwe, A. (2007). Alteration of brain and interrenal StAR protein P450sc, and Cyp11 $\beta$  and mRNA levels in Atlantic salmon after nominal waterborne exposure to the synthetic pharmaceutical estrogen ethynylestradiol. *Journal of Toxicology and Environmental Health, Part A*, 70(7), 606-613; Schultz, I.R., Skillman, A., Nicolas, J.M., Cyr, D.G. & Nagler, J.J. (2003). Short-term exposure to 17-alpha ethynylestradiol decreases the fertility of sexually maturing male rainbow trout (*Oncorhynchus mykiss*). *Environmental Toxicology and Chemistry*, 22(6), 1272-1280.

**Table 9.1B: Some Effects of Drugs on Wildlife (Selected Samples from Literature)**

| Bird Species  | Habitat   | Exposure   | Effects Observed   |
|---|---|--|--|
| Three species of vultures found in Indian subcontinent                  | Vultures in their natural habitat ingest chemicals when they feed on livestock carcasses                      | Suspected cause: veterinary use of diclofenac (an anti-inflammatory) | Kidney failure causing death and near-extinction of all three bird species |
| Studies of non-threatened Eurasian and African species of Gyps vultures | Controlled laboratory studies confirm causal link between diclofenac and vulture deaths                       | Diclofenac (veterinary anti-inflammatory, also used in humans)       | Death from kidney failure  |
| Wild-caught European starlings  | Controlled laboratory studies matched exposures to those observed in birds foraging in sewage treatment sites | Estrogenic contaminants found in sewage                              | Birds sang more complex songs and brain changes were observed              |

*Sources:* Markman, S., Leitner, S., Catchpole, C., Barnsley, S., Müller, C.T., Pascoe, D. et al. (2008). Pollutants increase song complexity and the volume of the brain area HVC in a songbird. *PLoS ONE*, 3(2), e1074. Retrieved October 7, 2008, from: doi: 10.1371/journal.pone.0001674; Oaks, J.L., Gilbert, M., Virani, M.Z., Watson, R.T., Meteyer, C.U., Rideout, B.A. et al. (2004). Diclofenac residues as the cause of vulture population decline in Pakistan. *Nature*, 427, 630–633. Retrieved October 7, 2008, from: doi:10.1038/nature02317; Prakash V., Pain D.J., Cunningham, A.A., Donald, P.F., Prakash, N., Verma, A. et al. (2003). Catastrophic collapse of Indian white-backed *Gyps bengalensis* and long-billed Gyps indicus vulture populations. *Biological Conservation*, 109(3), 381–390; Swan, G.E., Cuthbert, R., Quevedo, M., Green, R., Pain, D.J., Bartels, P. et al. (2006). Toxicity of diclofenac to Gyps vultures. *Biology Letters*, 2(2), 279–282.

for PPCPs in the city's water supply, at a cost of \$20,000 for eight water samples (Vaidyanath, 2008).

As consumers, we excrete PPCPs into sewers; we flush unused medications down the toilet or sink; and we rinse soaps, shampoos, and cosmetics down the drain when we bathe. Even posthumously, the drugs administered in the last years of our lives likely leach into cemeteries and groundwater (Daughton, 2003c, p. 777). Consumer use may account for the majority of trace pollutants in the environment, although the available information is insufficient to prioritize sources (Daughton, 2003c, pp. 775–785). Other contributors are hospitals and long-term care facilities, veterinary drugs (including large amounts of antibiotics), fish farms, drug-contaminated sewage

sludge sold as farm fertilizer, and industrial waste disposal at plant sites (see Figure 9.1).

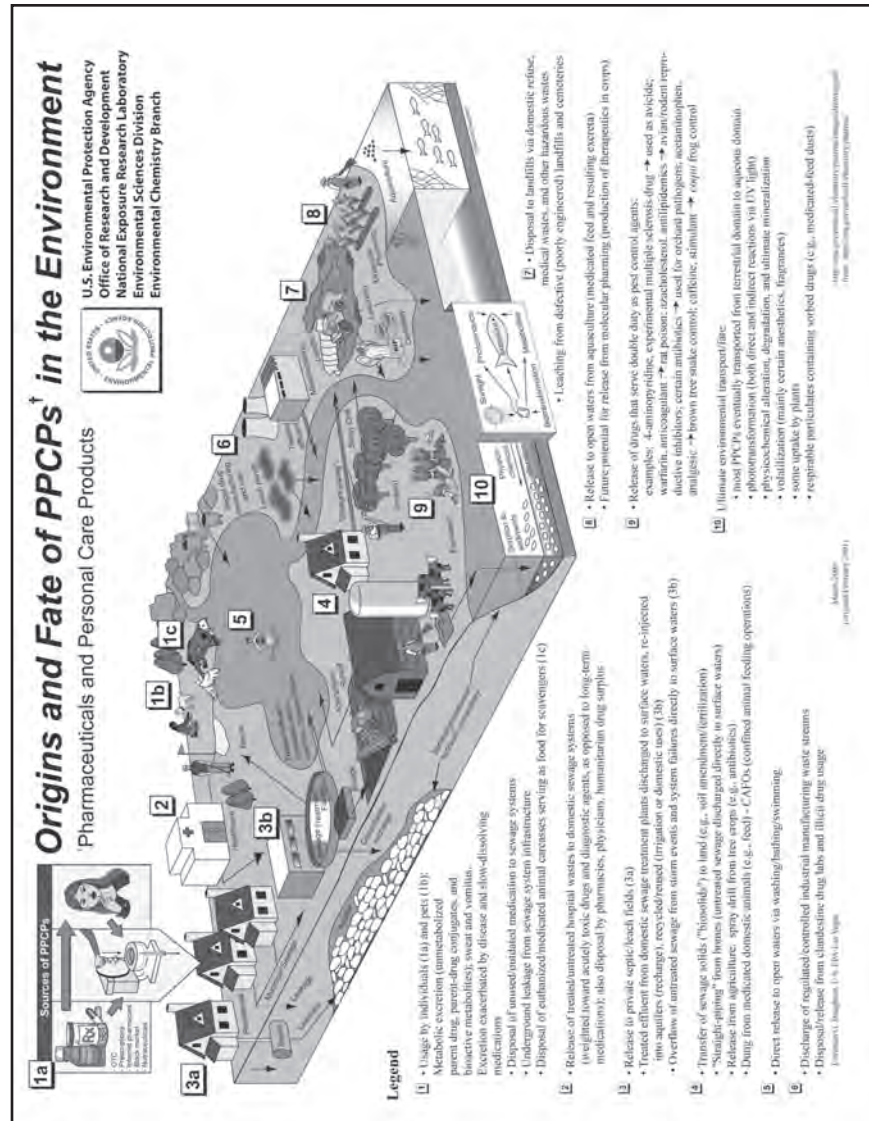


Figure 9.1

Source: Daughton C.G. (2006, March). *Origins and fate of PPCPs in the environment* [illustrated poster]. Las Vegas: U.S. Environmental Protection Agency. (Updated from an original work published in February 2001.) Retrieved September 14, 2008, from: [www.epa.gov/ppcp/pdf/drawing.pdf](http://www.epa.gov/ppcp/pdf/drawing.pdf)

The concentrations detected in water are typically between 20 parts per billion (ppb) and less than one part per trillion (ppt); however, drugs are designed to have an effect in small quantities. Furthermore, recognizing that drugs in environmental waterways are highly diluted does not mean that quantities are small. In their study of clofibric acid in the North Sea, Buser, Müller, and Theobald (1998) estimated that one or two parts per trillion of the chemical in the sea volume of 12.7 quadrillion gallons translated into 48–96 tons of colfibric acid. The evidence is now indisputable that biological effects occur at these very low levels.

Some drugs (e.g., anti-epileptics) are persistent—that is, they do not break down. Others are “pseudo-persistent”—they break down, but are continually replaced by widespread use. Some drug compounds dissolve in water, but others dissolve only in fat, which enables them to enter cells and move up food chains, becoming more concentrated. A study by the Royal Danish School of Pharmacy found that more than 30 percent of all medical substances developed from 1992–1995 were lipophilic (fat-soluble) (Halling-Sørensen et al., 1998). The risks to both aquatic organisms and humans are largely unknown, but could include resistance to antibiotics and the disruption of endocrine systems.

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**Box 9.1: PPCPs Ranked of Greatest Concern to Human and Ecosystem Health**

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- antibiotics
- antidepressants, tranquilizers
- anti-epileptic drugs
- anti-inflammatory agents
- antimicrobials (e.g., used for parasite control in animals)
- calcium channel blockers
- estrogenic steroids
- genotoxic drugs (e.g., cancer treatments)
- multi-drug transporters (efflux pumps)
- musk fragrances

*Sources:* Health Canada. (2003). *Issue identification paper: Environmental assessment regulations*. Ottawa: Health Canada. Retrieved October 31, 2008, from: [www.hc-sc.gc.ca/ewh-semt/alt\\_formats/hpfb-dgpsa/pdf/contaminants/iip-dde-eng.pdf](http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hpfb-dgpsa/pdf/contaminants/iip-dde-eng.pdf); U.S. Environmental Protection Agency. (2007, December). *Pharmaceuticals and personal care products: Frequent questions*. Retrieved March 11, 2008, from: [www.epa.gov/ppcp/faq.html](http://www.epa.gov/ppcp/faq.html); Collier, A.C. (2007). Pharmaceutical contaminants in potable water: Potential concerns for pregnant women and children. *EcoHealth*, 4(2), 164–171.

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### **Women, Health Products, and Environmental Pollution**

Ecosystem contamination with PPCPs has the potential to affect flora and fauna, fish and fowl, women and men. However, there are some ways in which women are particularly affected by PPCPs.

Biologically, women have different vulnerabilities to chemicals than men at certain points in the life cycle. Pregnancy is the most obvious example. The diethylstilbestrol (DES) and thalidomide tragedies shattered the long-held rule of toxicology that “the dose makes the poison.” Minute quantities of a drug taken by a pregnant woman at a particular stage in fetal development can cause deformities, cancer, and subtle cognitive effects. DES is now recognized as a member of a class of chemicals that disrupt the endocrine (hormonal) system. Some specialists believe no dose of synthetic hormones is safe for the developing embryo and fetus (Colburn, Dumanoski & Meyers, 1996; DES Action Canada, 2001). Emerging research on endocrine disruptors suggests that the male fetus may be more sensitive than the female fetus to many effects of these chemicals (Canadian Partnership for Children’s Health and the Environment, 2007). Indeed, epidemiological studies show a small but steady reduction in the proportion of boys born in Japan and the U.S. over the past four decades. Evidence that the “missing boys” phenomenon is the result, in part, of *in utero* exposure to endocrine-disrupting chemicals comes from communities where chemical exposures are exceptionally high. A 1976 explosion of dioxin from a chemical plant in Seveso, Italy, was followed by an immediate loss of males: 46 females and 28 males were born in the next seven years. The First Nations community of Aamjiwnaang, situated in Sarnia, Ontario, the heart of Canada’s petrochemical refining industry, has shown a startling 40 percent decline in the ratio of males to females over more than a decade (Van Larebeke et al., 2008).

Abby C. Collier, a pharmacologist at the University of Hawaii, used published dose-response data and clinical prescribing guidelines to estimate the risk that pharmaceuticals commonly identified in drinking water might pose to pregnant women and children (Collier, 2007). She analyzed 26 pharmaceuticals found in measurable quantities in various studies of drinking water systems and estimated cumulative drinking water exposures for these vulnerable populations. She concluded that five drugs were of greatest concern for pregnant women: ethinyl estradiol (a synthetic estrogen), norethindrone (a contraceptive), diazepam (a tranquilizer), ivermectin (widely used for parasite control in livestock), and the NSAIDs ibuprofen and diclofenac (anti-inflammatory agents). She ranked these same five drugs, plus the anti-cancer drug methotrexate, as the substances of greatest concern for the pediatric population, with the safety of an additional four not yet established (Collier, 2007, p. 169).

Based on her calculations, a pregnant woman drinking 2 litres (64 ounces) of water per day would ingest 13 percent of a minimum dose of ethinyl estradiol over

a nine-month pregnancy, approximately 1.5 percent of a minimum clinical dose of norethindrone, and almost 5 percent of a minimum clinical dose of diazepam. For ivermectin, ibuprofen, and diclofenac, the estimated percentages of a minimum clinical dose were 4 percent, 3 percent, and 2 percent respectively. Despite being lower than levels used in clinical treatments, Collier expressed concern about exposures to these drugs since they may not show linear dose-response relationships when causing birth defects (i.e., doubling the dose may mean more than twice the risk). “Because drinking water is considered healthy and positive in pregnancy, exposure of pregnant women to these five drugs through drinking water is a public health concern,” she concludes (2007, p. 169). As noted earlier, drugs in combination may interact so that estimated exposures to individual substances don’t tell the whole story.

To date, most research on the effects of chemical exposures to the developing fetus and to young children has focused on industrial toxins in the environment, such as pesticides, dioxins, lead, arsenic, and mercury. Evidence is mounting that these exposures affect both boys and girls, but the health effects manifest differently in the two sexes. Boys are at greater risk for cancer, asthma, learning disorders, certain birth defects, and testicular dysgenesis syndrome (Canadian Partnership for Children’s Health and the Environment, 2007). Girls are at greater risk for premature puberty, which is associated with a variety of psychopathologies in adolescence, including depression, eating disorders, drug abuse, cigarette smoking, and alcohol use. Early puberty in girls is also associated with a higher risk of breast cancer later in life (Steingraber, 2007). At present, there is a lack of research to specifically link these trends with pharmaceuticals in the environment. However, as Danish researchers Jørgensen and Halling-Sørensen (2000) argue, drugs are “in principle not different from other chemicals” so “to distinguish between drugs and other chemicals when they are discharged into the environment is preposterous” (p. 695).

Chemical contamination of breast milk is another women’s health issue linked to environmental contamination. Aromatic amines—used to make pharmaceuticals, dyes, plastic foams, and pesticides—have been detected in human milk and are known to cause cancer in mammary rat tissue (DeBruin, Pawliszyn & Josephy, 1999; Steingraber, 1999).

Pregnancy and lactation are not the only windows of vulnerability in a woman’s life cycle. Puberty, menstruation, and menopause are all the result of hormonal fluctuations. The cells in women’s breasts appear to reach full maturity only at a first full-term pregnancy, when they become more resistant to cancer-causing chemicals and radiation. Women of any age who have not had children may therefore have increased susceptibility to carcinogenic chemicals in the environment compared to women of the same age and health status who have had children (Steingraber, 1997). Furthermore, women have more fatty tissue, on average, than men so they store more endocrine disruptors in their bodies. Women also have adverse reactions to drugs

more often (see Chapter 7). This difference is only in part because women use more drugs than men and tend to weigh less. A report by the U.S. General Accounting Office (now called the Government Accountability Office) concludes that “Greater health risks for women may be due to physiological differences that make women differentially more susceptible to some drug-related health risks” (Heinrich, 2001).

Another consideration is that older women have had more years to absorb bioaccumulative drugs from the environment and reduced immunity could make them more sensitive to some effects of environmental chemicals in the water.

Health protection policies should be designed to protect all members of society, especially the most vulnerable. Despite the evidence of the particular damage chemicals can have on women’s health, safety standards for chemicals have often been based on healthy, White, adult males.

### **Canada’s Approach to PPCPs: The Environmental Assessment Regulations Project (EARP) and the Environmental Impact Initiative (EII)**

In September 2001, under the auspices of its Office of Regulatory and International Affairs, Health Canada launched a project to address the health and environmental effects of PPCPs. Called the Environmental Assessment Regulations Project (EARP), the program had three components: (1) regulations to protect the environment from PPCPs; (2) a scientific research program; and (3) best practices and public education programs (Health Canada, 2003).

The project did not meet its targeted completion date of 2003 and work continued for several more years. In 2006 it was relaunched with a new name (the Environmental Impact Initiative or EII), under a new director (Gordon Stringer), with a new target date, 2011. The EII will continue developing regulations, best management practices, and consumer education programs. A multi-stakeholder working group drawn from government, industry, and consumer and public interest groups oversees the EII process and meets several times a year. At the time of writing, insufficient information was available about the Environmental Impact Initiative to assess its import or progress. The analysis that follows is based on documentation produced under EARP and the author’s attendance at multi-stakeholder consultations held in 2002, 2003, and 2006.

EAR Project documentation suggests a vision that meets many of the criteria for a model public health initiative. The project was to interpret health protection broadly, including harmful effects on the environment or its biological diversity, as well as direct human health impacts (Health Canada, 2003, p. 4). The proposed decision-making strategy would incorporate the precautionary principle, which means protective action can be taken before harm has been demonstrated with scientific certainty (Health Canada, 2003, pp. 15, 40). Prevention would take precedence over

mop-up, “avoiding the creation of pollutants rather than trying to manage them after they have been created” (Health Canada, 2003, p. 38). A commitment to open discussion invited the public’s participation in solving the problem (Health Canada, 2003, p. 43).

Much of the work conducted under EARP fell short of these ideals. The project highlighted toxicological research on specific substances and meetings with industry stakeholders about potential trade impacts. Discussions with public interest groups, including environmental, women’s health, and consumer groups, which took place in the years 2002, 2003, and 2006, were limited.

### *The Regulations*

Central to EARP was a project to develop regulations that would limit the environmental impact of PPCPs. Drug safety data submitted by companies under the *Food and Drugs Act* (F&DA) regulations are designed to evaluate drug safety only for the individual consumer taking a drug. These data do not take the environment into consideration, nor are they concerned with health problems arising from environmental contamination by PPC products. A separate regulatory framework, the Canadian Environmental Protection Act (CEPA), is designed to protect Canada’s environment. CEPA, which came into force in 1988 and was revised in 1999, is administered by Environment Canada.

According to an EAR document, when CEPA was enacted both Health Canada and Environment Canada were under the mistaken belief that the substances regulated under Canada’s *Food and Drugs Act* were exempt from CEPA, so Health Canada did not require environmental safety data in the information packages manufacturers submitted for review (Health Canada, 2003). The purpose of developing new regulations is, therefore, to expand and define the data required of food and drug manufacturers. When the regulations are complete, manufacturers will have to include environmental safety assessments demonstrating that their products conform to CEPA. In addition to assessing safety and efficacy for the immediate user, Health Canada will review all new PPCP submissions for their environmental impact. In the meantime, new products that fall under the *Food and Drugs Act* are to be screened under existing CEPA regulations (the New Substances Notification Regulations), while the tens of thousands of PPCPs already on the market are to be included in a gradual review of existing products taking place under CEPA.

### *Science and Research*

A second key component of EARP was its national science agenda. While a science agenda is essential to an action program, the EARP’s research priorities were tied to its toxicological regulatory agenda. For example, a workshop that Health Canada and

Environment Canada sponsored in February 2002 to discuss PPCPs in the Canadian environment included as its main objectives “identifying major scientific knowledge gaps and establishing risk assessment and risk management needs in Canada” (Health Canada, 2002a, p. 11). Not surprisingly, research priorities identified by workshop participants reflected this agenda (e.g., obtain scientific data on exposure and effects of PPCPs in the Canadian environment; foster development of a Canadian regulatory framework in harmonization with international organizations).

Making toxicological assessment research the centrepiece of the science agenda excludes or marginalizes other, equally important, scientific research that would support immediate and medium-term action. For example, research to determine the best ways to reduce inappropriate drug use would explore ways to modify behaviours and would draw from the social sciences. Although EARP included behavioural change in its third prong (discussed in the next section), the framework for social science research could be greatly expanded, as the discussion of the Green Pharmacy approach (see p. 199) argues.

### *Public Education*

The third prong of EARP comprised public education and public participation initiatives (Health Canada, 2003, p. 5). A Benchmark Survey, conducted for Health Canada in 2002, assessed consumer attitudes to waste disposal, including the disposal of pharmaceuticals and other PPCPs (Health Canada, 2002b); however, a patchwork of provincial waste-removal practices has stalled a national take-back program. Increasingly, the public is encouraged to take unused drugs back to the pharmacy, rather than disposing of them in the toilet or sink. Unless pharmacists in a province or municipality have an organized system to dispose of the drugs safely, however, the pharmacist may simply make bulk deposits into the sewage, as one Ontario pharmacist was discovered doing in September 2003 (Environmental Commissioner of Ontario, 2005, p. 184). Canadian pharmacists recommend take-back programs as a model standard of practice (Campbell, 2007, p. 29) and such programs have been in effect in British Columbia since 1996; however, as of this writing, only British Columbia, Alberta, Nova Scotia, and Prince Edward Island have province-wide pharmacy-based programs for the return and safe disposal of unused drugs. A non-profit association funded by pharmaceutical industry groups, the Post-consumer Pharmaceutical Stewardship Association (PCPSA) provides information about programs across the country and supports these programs on a cost-sharing basis (Post-consumer Pharmaceutical Stewardship Association, 2008). A truly national take-back program would be a first step, but educational programs to instill best practices also need to actively promote reduced use of PPCPs (Daughton, 2003a, p. 762).

### **Assessing Environmental Assessment Regulations**

As we have seen throughout this book, the regulation of drugs always requires a delicate process of weighing potential health benefits against potential health risks, with economic drivers the unacknowledged elephant in the room. In other chapters, the authors express concerns about Health Canada's drug review processes, including government-industry conflicts of interest, the worrisome move toward fast-tracking of drugs, excessive secrecy in decision making, lack of public consultation, and evidence that Canada's trade objectives often override health protection concerns. One question underlying the critique that follows is whether trade and economic considerations are similarly impeding the environmental regulation of PPCPs. Already the years of inaction on this dossier suggest a process stalled by corporate lobbying.

The spectre of contaminated water can be frightening, instilling a sense of helplessness over shrinking resources necessary to life. We can, however, act responsibly, based on our present knowledge about inappropriate and excessive drug use. Some medication is necessary to good health, but there is growing evidence to show that some is not and causes harm. Corporate practices designed to promote drug use that is not scientifically based need to be curtailed. Examples are direct-to-consumer advertising (see Chapter 2) and commercially sponsored seminars to encourage off-label prescribing (Berenson, 2008).

Substituting non-toxic complementary and alternative medicine (CAM) approaches for conventional pharmaceutical interventions, and the replacement of synthetic ingredients in personal care products with others made of biodegradable substances, could have considerable impact, says Dr. Warren Bell of the Canadian Association of Physicians for the Environment. "Many CAM interventions have no effect on the ecosystem (e.g., manual therapies, body/mind therapies); others have minimal effects (e.g., homeopathy, lifestyle alterations). Many others probably have limited effects, or at least involve simple redistribution of known components of the biosphere (e.g., plant remedies, Epsom salts compresses, vitamin and mineral supplementation and therapy), often themselves considered to be broadly beneficial or at least neutral in effect," says Dr. Bell (personal communication, June 26, 2003).

Much thought needs to be given to the framing of educational messages and programs so that risks are neither downplayed nor sensationalized. Educating the public about PPCPs in the drinking water presents some of the same difficulties as educating nursing mothers about chemical contaminants in breast milk. Apprehension about drugs and other chemicals in the water could drive people to avoid their necessary intake of water, or to purchase expensive home filtering systems and bottled water, which may be no less contaminated. Penny Van Esterik, in an analysis of communicating risks about infant feeding, notes the importance of placing the issue in a broad environmental health context, so that the goal is reducing pollution rather than avoiding breastfeeding (Van Esterik, 2002). Public education about drugs in the

water requires a similarly broad focus. Questions for public debate include: What is the full range of remedies? What solutions will be emphasized? When parties disagree, who decides? Furthermore, as Sandra Steingraber points out in her discussion of chemical contaminants in breast milk, educating the public to make “safer” lifestyle choices avoids the central question, namely, what political action can be taken to eliminate these contaminants (Steingraber, 2001, pp. 274–280).

### **Public Participation and the EARP Consultation Process**

Beginning with the 2001 Notice of Intent (Health Canada, 2001), Health Canada stated its commitment to a process of consultations with stakeholders in the development of the new environmental assessment regulations. This process included meetings to explain EARP to government employees, industry stakeholders, and members of non-governmental organizations concerned about health and the environment. A benchmark survey of 1,512 Canadians was conducted to determine prevalent attitudes and product disposal habits. Passive methods of communication with the public included a website, newsletters, and an information line to disseminate information and register reactions.

However, despite the stated commitment to public participation in EARP, the consultations were geared to industry players and failed to engage the public or non-governmental organizations (NGOs). Rather than enlisting the public as full partners in debating the “big picture,” discussions with the public were narrowly focused on the proposed regulations for reviewing drugs. The agendas at these meetings were pre-set, with PowerPoint presentations and guided discussion of an Issue Identification “workbook” on the regulatory proposals. The opaque language of risk assessment and regulation set up barriers to NGO participation by framing the problem and the process in terms meaningful only to industry and government.

The industry groups’ domination of the consultation process is reflected in the concerns that stakeholders most often expressed: that the regulations would slow down the introduction of new substances onto the Canadian market, affect international trade (Health Canada, 2002c, p. 2), or prevent new drugs from entering the Canadian market “solely for environmental factors” (Health Canada, 2006, p. 20). The adequacy of the proposed regulations for health and environmental protection—ostensibly the purpose of the exercise—was not even mentioned in the account of stakeholder responses. As well, a key discussion paper issued in 2003 excluded non-specialists from the dialogue with technical language and a legalistic emphasis on a regulatory framework (Health Canada, 2003).

If health and environmental protection are to take precedence over trade issues, the participation of health and environmental advocacy groups in framing policy approaches is vital. However, for NGOs working with tight budgets and staff cutbacks, EARP public consultations from 2002 through 2006 were not a priority.

NGOs were invited to only three meetings and were expected to study, on their own, documents that appeared to have been written for industry lawyers by their government counterparts. No funds were provided to assist groups that wanted to brief themselves on the implications of EARP for public health, or to meet among themselves to develop a public health perspective on EARP issues. Industry representatives, by contrast, had more than 40 meetings with government as of May 2002. Not surprisingly, few non-profit groups in Canada have taken up the issue of PPCPs.

### **The Green Pharmacy: A Holistic Program for Change**

An interesting counterpoint to the Canadian government's strategy for addressing PPCPs is the Green Pharmacy Stewardship Program proposed by Christian Daughton, a scientist at the U.S. Environmental Protection Agency. Much like the goals of EARP on paper, Daughton envisions a broad, holistic program. His "blueprint" is more detailed and programmatic than EARP, however, proposing a broad spectrum of actions to be jointly overseen by the health care industry and consumers. Three goals shape the Green Pharmacy concept: protect the environment, reduce medical expenses for the consumer, and improve patient and consumer health (Daughton, 2003a, 2003b).

In contrast to EARP, Daughton questions how useful a risk assessment approach can be in controlling PPCPs in the environment given the pitfalls of trying to track and regulate potential chemical stressors. "The spectrum of pollutants typically identified in an environmental sample represents but an unknown portion of those actually present (possibly very small), and they are of unknown overall risk significance," he asserts (2003b, p. 758). Daughton also argues that the traditional chemical-by-chemical approach to pollutant tracking and regulation needs to give way to an approach based on probable cumulative exposure, "understanding the ramifications of entire classes [of chemicals] that share a common MOA [mechanism of action]" or a common physiological or behavioural end point (Daughton, 2003b, p. 759). He notes that any approach that uses "predicted" environmental concentrations fails to account for three major factors: (1) geographic variability in drug usage; (2) sources other than legal sales (e.g., physician samples and black market sales); and (3) interactions between chemical stressors (Daughton, 2003b, pp. 760–761).

Daughton notes that curtailing some uses of medication can improve health outcomes. He proposes a multidisciplinary approach based on a cohesive, scientifically sound set of principles that would guide changes to packaging, distribution, and purveyance of PPCPs, many of which could be implemented rapidly (Daughton, 2003a, p. 9). One example of such a change is lowering drug dosages. Some studies show that the effective doses of some drugs can be lower than previously realized. Cutting doses could reduce adverse drug reactions, including deaths, while lessening the potential for environmental effects (Daughton, 2003b, pp. 41–42).

Another area for change with a potential for immediate impact is reducing the amount of medication wasted. A survey of drug disposal in Ontario estimated the annual cost of wasted medication in the province at over Can\$40 million (Boivin, 1997). Drug shelf life is a third case in point. Research has shown that shelf lives for some drug formulations exceed the duration indicated by the expiry dates (under ideal storage conditions), providing the basis for substantial savings without compromising health (Daughton, 2003a, p. 54).

Despite this comprehensive plan developed by a government agency, the U.S. government's response to the PPCP issue as of early 2008 has been as disappointing as Canada's. An American media analysis (Donn, Mendoza & Pritchard, 2008b) observed that regulators in the U.S. had never rejected a drug on the basis of its environmental impact, and concluded that drugs in the environment were not a government priority.

### **Gender Affects Purchase and Use**

Effective policies designed to reverse this form of pollution need to consider cultural (gender) differences between the sexes. Because of cultural influences, women are the family members most often responsible for health, including purchase of drugs and food, food preparation, caring for sick family members and disposal of home-use products. Many drugs are gender-specific (e.g., birth control, menopausal hormone therapy) or are prescribed more often to women than to men (e.g., antidepressants). Women are also the main users of cosmetics, perfumes, and hair products, many of which have been found to contain phthalates, a family of industrial chemicals linked in animal studies to permanent birth defects in the male reproductive system (Houlihan, Brody & Schwan, 2002). Some phthalates have been detected in drinking water, as have synthetic musk fragrances from perfumes and other toiletries (Daughton, 2003b, p. 766).

Strategies to reduce use of particular drugs or ingredients in cosmetics and toiletries will be most effective if they recognize the gender dynamics underlying promotion and use of PPCPs.

Women predominate in two demographic categories for which PPCP use may have a particular impact: the elderly and the poor. Elderly women constitute a large and growing segment of the population. The elderly ingest more drugs than the young, and use them more often. Geriatric medicine has been shown to result in particularly high wastage, for a number of reasons, including frequent physician alterations in dosage and prescribing new drugs, patient improvement, "silent symptoms" that provide the patient with no incentive for continuing medication, and patient death. Many drugs for geriatric patients have been found in environmental monitoring studies (Daughton, 2003c, p. 781). These factors argue for a gender-based, age-sensitive approach to research, education, and policies related to drugs in the environment.

**Box 9.2: The Evra Patch: A Closer Look at One Product and Its Impact on the Environment**

Evra, a birth control patch that transfers hormones through the skin, was approved for use in Canada in 2002. It is promoted for its convenience. The patch is no more effective than birth control pills in preventing pregnancy and it has more side effects, including an increased risk of blood clots (see Chapter 2). Each patch contains 6 mg of norelgestromin and 0.6 mg of ethinyl estradiol. Users are instructed to replace the patch after seven days. At that point, the patch still contains over 80 percent of the norelgestromin and over 75 percent of the ethinyl estradiol. According to Janssen-Ortho, the manufacturer of the patch, this high level of waste is necessary to ensure that adequate amounts of the hormones are absorbed. The large amount of synthetic hormone remaining in the patch when it is discarded has been found to feminize male fish. The hormone is persistent—that is, it does not break down over time. But in a birth control market crowded with many different types of pills, a patch can be marketed as something new. This marketing advantage comes at the expense of greater environmental risks because of the amount of hormone remaining in the patch when it is discarded.

If the patch is folded in half and discarded with other household waste, as recommended by the manufacturer, the residual hormone may well find its way into the ecosystem and pollute our waterways. In Europe, the patch is distributed with its own disposal pouch. While this still doesn't guarantee that the hormones won't eventually leak out into the environment, it does illustrate an important point: disposal instructions are not based on what's good for the global ecosystem, but rather on what's required in each regulatory environment.

The impact that the disposal of drugs has on the environment is the responsibility of environment ministries, mostly at the provincial level. The actual disposal of hazardous drugs by individual households is the responsibility of municipal waste systems. Licensed medical/hazardous waste-disposal companies dispose of drugs from pharmacy take-back programs. This multi-level, multi-ministerial, public/private sector shared responsibility has created a jurisdictional gridlock. Unfortunately, most prescription drugs, including those containing synthetic hormones that are known to be endocrine disruptors,<sup>a</sup> are not classified as hazardous waste.

While the Canadian Environmental Protection Act (CEPA), passed in 1988 and revised in 1999 and administered by Environment Canada, does have a set of regulations intended to protect Canada's environment by preventing pollution, these regulations were designed with industrial chemicals in mind. A project to develop regulations under the *Food and Drugs Act*, which Health Canada administers, has been in bureaucratic limbo since September 2001. Until Health Canada's Environmental Impact Initiative is completed, CEPA regulations do apply to pharmaceutical products. The case of Evra suggests, however, that pharmaceutical products are not currently being restricted on the basis of environmental harm.

Every opportunity for a pharmaceutical chemical to leach into the water table allows a discharge into the natural environment. Although we are only beginning to understand the bioaccumulative<sup>b</sup> effect that these chemicals can have on the health of the ecosystem, the little we do know is enough to say that any discharge is unacceptable. We cannot control what happens once a chemical has been discharged into the ecosystem. Where we do have control is in reducing use.

### Notes

- a. *Endocrine disruptor*: Dr. Theo Colborn, a co-author of *Our Stolen Future*, defines an endocrine disruptor as “a compound that interferes with the production, release, transport, metabolism, binding action and/or elimination of hormones in the body.”
- b. *Bioaccumulative*: Toxic chemicals are isolated and stored in fatty tissue of living organisms. These toxins accumulate exponentially as they move up the food chain. Much like the greenhouse effect, this is known as a bioaccumulative effect—i.e., the end product of many chemicals interacting.

*Source*: Adapted from *Evra and the Environment*, written by Suzanne Elston for Women and Health Protection in 2004 and available on the WHP website.

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Women are overrepresented among Canadians living in poverty. The poor are less able to afford technical solutions, such as home filter systems. Corrective programs that require costly individual initiatives could widen class-based health disparities.

### *Gender and Values*

As a group, women are more willing to go out of their way to protect human health and the environment (Seager, 1993; Wyman, 1999). Women scientists, including Rachel Carson (1962), Sandra Steingraber (1997, 2001, 2007), Theo Colburn (Colburn, Dumanoski & Meyers, 1996), and Devra Lee Davis (2007) have been trailblazers in showing connections between chemical pollution of the environment and both human and ecosystem health. Feminist theorists have also challenged the assumption, embedded in much of Western philosophy, that humans have a right to dominate all other life forms (d'Eaubonne, 1974; Mies & Shiva, 1993; Warren, 2000). The women's health movement and the eco-feminist movement promote health protection and environmental protection respectively.

The survey conducted as part of the Environmental Assessment Regulations Project captures this gender gap in values.<sup>1</sup> Women were more likely than men to say they were interested in learning “all I can” about how to safely dispose of household products so they don't harm the environment (74 percent versus 66 percent); and women were more likely to say they would dispose safely of household products “all the time, even if it's inconvenient” (70 percent versus 62 percent). This commitment

to health and the environment suggests women could be key players in programs for change. The gender values gap must also be considered when framing value-laden policies, such as risk assessment and the precautionary principle. More men hold decision-making positions in industry, government, and elected office, while more women are poor and have little political power. Whose values will prevail in deciding what level of risk is acceptable to a community? Who decides when scientific evidence is sufficient to trigger the precautionary principle?

### **Planning with Foresight**

Clean water is so basic to human life that burbling brooks and waterfalls are enduring symbols of the life force. Fresh water is also an increasingly scarce and coveted resource. In the face of uncertainty about what effect PPCPs in the environment will have, the prudent course is to treat PPCPs in the water as an urgent issue for short-, medium-, and long-term action.

Under CEPA and, in turn, under EARP and the Environmental Impact Initiative, the federal government affirms Canada's commitment to the precautionary principle, a policy concept based on the German word meaning "foresight":

The precautionary principle emerged during the 1970s in the former West Germany at a time of social democratic planning. At the core of early conceptions of precaution (or *Vorsorge*) was the belief that the state should seek to avoid environmental damage by careful forward planning. The word *Vorsorge* means foresight or taking care.... (Jordan & O'Riordan, 1999, p. 19)

Science often lags behind the ideal that would permit fully informed decision making. The precautionary principle calls on governments, when faced with partial scientific evidence, to tilt policies in favour of protecting health and the environment. Rather than requiring the government to demonstrate certainty of harm before curtailing a product's use, the precautionary principle shifts the onus to industry to demonstrate a product's safety before bringing it to market. The Canadian government has an "international commitment to implement the precautionary principle" (Health Canada, 2003, p. 40), yet a close look at the details in EARP documents reveals a compromise that blunts the principle's edge for protecting health and the environment.

Usually it is much easier to calculate the short-term economic benefits from introducing a product compared to the long-term economic harm from its introduction. Advocates of environmental protection and health protection have advanced the precautionary principle as a challenge to the risk management practices that now guide government decision making. The precautionary principle exhorts

governments to curtail the use of potentially unsafe technologies, even if national economies could suffer some short-term losses as a result (Health Canada, 2003, pp. 40–41). EARP documents state that Canada promotes a precautionary approach, “distinctive within science-based risk management” (Health Canada, 2003, p. 38). Subsuming the precautionary principle within risk management tempers the precautionary imperative in the interests of economic goals. An alternative assessment strategy (O’Brien, 2000) would recognize that developing a “clean” technology industry is a way to realize direct and indirect economic gains. With vision, Canada could promote the development of ecologically sound PPCP policies and technologies, combining our well-established policy expertise in health promotion with a forward-looking “green science” agenda.

As the EARP “Issue Identification Paper” acknowledges, the precautionary principle is “ultimately guided by judgment, based on values (acceptable levels of risks)” (Health Canada, 2003, p. 41). Key questions then become: Whose judgments? Whose values? For a manufacturer eager to get a new product to market, zero contamination may seem too stringent; a pregnant woman may want no less.

### **Conclusion**

By early 2008, the evidence that pharmaceuticals in the environment are disrupting aquatic life and other wildlife was so unequivocal and disturbing that scientists were calling for action. A five-month study reported in the American media quoted Steven Goodbred, of the U.S. Geological Survey, as saying, “The onus has been on the scientific community to provide the research, but at this point the evidence is conclusive. Now it’s up to the public and policymakers to decide what they want to do about it” (Donn, Mendoza & Pritchard, 2008b, para 9).

As this chapter argues, we can begin by taking a hard look at the sheer quantity of drugs we use. The increase in pharmaceutical drugs, in humans, veterinary practices, agriculture, and aquaculture has been astonishing (Holtz, 2006, pp. 7–10). Materials prepared for EARP do not discuss policy tools that would reduce prescription drug use and therefore reduce environmental contamination. These could include tightening and enforcing the ban on direct-to-consumer advertising, taking drug-promotion regulation out of the hands of the pharmaceutical industry and voluntary bodies such as the Pharmaceutical Advertising Advisory Board, opening the drug approval process to public scrutiny, and adopting a more stringent interpretation of the precautionary principle. Many of these approaches would help curtail the medicalization of health.

The ubiquitous presence of chemicals from PPCPs in the environment extends the risks to the entire ecosystem, which we have a collective responsibility to protect. Our focus on testing individual drug and food products for toxicity could serve mainly to postpone action by deflecting attention and resources from initiatives that

would curtail our excessive dependence on drugs. Human health, particularly the health of children and developing fetuses, may be in danger; the health of aquatic life and other non-human species certainly is. Can there be any question that it's time to "treat" our unhealthy addiction to prescription drugs?

**Note**

1. A total of 1,512 people completed the survey; half were males and half females. All differences reported were statistically significant, although the report does not specify levels of significance. The authors describe gender differences as "relatively small"; however, the pattern of difference is consistent.