

FULL CIRCLE:

DRUGS, THE ENVIRONMENT AND OUR HEALTH

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INTRODUCTION

Since the mid-1990s, news headlines about “drugs in the water” have alerted the public to an unsettling public health risk.² 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 toiletries -- have also been detected, as have veterinary and agricultural chemicals. New biologics, genetic therapies and genetically modified foods are more recent-comers that could end up in this “chemical soup”. The health impacts on humans are not known, but deformities in the reproductive systems of marine life show that some chemicals contaminating the environment are not benign, despite the very low concentrations that have been detected³.

Such findings show that we need to rethink our relationship to pharmaceutical drugs and other personal care products. Taking a drug is not simply a personal decision that affects

¹ This paper was written for Women and Health Protection while I held the Elizabeth May Chair in Women’s Health and the Environment at the Atlantic Centre of Excellence for Women’s Health, Dalhousie University. I wish to thank the following members of Women and Health Protection and its affiliates for their helpful comments on an earlier draft of the paper: Wendy Armstrong, Warren Bell, MD, Anne Rochon Ford, Brewster Kneen, Joel Lexchin, MD, Abby Lippman, PhD, and Ellen Reynolds. All opinions expressed in the paper and any errors that remain are my responsibility.

² For example: Laghi, Brian, Pharmaceuticals found in Canada’s water system. *Globe and Mail*, Sept. 5, 2001, A1; Dennis Beuckert, Drugs in tap water health risk. *Chronicle Herald* (Halifax) Sept. 5, 2001, A1; Mittelstaedt, Martin, Drug traces found in cities’ water, *Globe and Mail*, Feb 10, 2003, A1.

³ For example, Bruce Pauli, “Impact of endocrine disrupting compounds on amphibian health in agricultural ecosystems”; and Chris Metcalfe, “Pharmaceutical Drugs in Canadian Surface Waters: Distribution and Effects on Fish”, presented at the Toxic Substances Research Initiative, Ottawa: March 5-8, 2002.

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 food we eat.

This discussion paper looks at this neglected form of environmental contamination from a public health perspective, with particular attention to women's health. The analysis evaluates the Environmental Assessments Regulations Project (EARP), a federal government project designed to protect the health of Canadians and the Canadian ecosystem from pharmaceutical and personal care products (PPCPs⁴). Women are the majority purchasers of many PPCPs, including drugs, foods, cosmetics and personal hygiene items. Within the family, women often buy these products, oversee their use and take responsibility for their disposal. To change patterns of purchase, use and disposal, women need to be fully engaged in policy discussions, decision-making and implementation.

This paper argues that **the most health-promoting, cost-effective strategy for everyone is prevention**: reducing inappropriate use, over-use and abuse are strategies that would improve health and mortality while also saving money. Similarly, **reducing the vast quantity of unused drugs and disposing of any unavoidable excess safely is more ecological and economical than trying to filter them from the water after the fact**. These “upstream” approaches also have the advantage that they can be implemented

almost immediately. Other approaches, such as improved filter systems and redesigned products, will take time and resources. Programs should be prioritized according to criteria such as product toxicity, importance and affordability.

In September 2001, Health Canada launched the Environmental Assessment Regulations Project (EARP), under the auspices of its Office of Regulatory and International Affairs⁵. Designed to address the health and environmental effects of PPCPs, the program has three parts: 1) regulations to protect the environment from PPCPs; 2) a scientific research program; and 3) best practices and public education programs.⁶

EAR Project documentation suggests a vision which meets many of the criteria for a model public health initiative. The project is to interpret health protection broadly, including harmful effects on the environment or its biological diversity, as well as direct human health impacts.⁷ The proposed decision-making strategy will incorporate the precautionary principle, which means protective action can be taken before harm has been demonstrated with scientific certainty.⁸ Prevention is to take precedence over mop-up, “avoiding the creation of pollutants rather than trying to manage them after they have

⁴ A more accurate term would be Pharmaceutical, Personal Care and Food Products (PPCFPs), to include food additives and genetically modified foods; however PPCPs has become the convention in the literature and is used here to avoid confusion when citing other texts.

⁵ Environmental Assessment Regulations, Notice of Intent, Canada Gazette, Part 1, Sept. 1, 2002. www.hc-sc.gc.ca/ear-ree/noi_e.html

⁶ Final Issue Identification Paper: Environmental Assessment Regulations, Ottawa: 2003, p 5 www.hc-sc.gc.ca/ear-ree/html.

⁷ Ibid, p 3

⁸ Ibid, p3 8

been created.”⁹A commitment to open discussion invites the public’s participation in solving the problem.¹⁰

To date, much of the government’s work falls short of these ideals. Smiling faces of Canadians adorn EARP documents, yet the program lacks a “big picture” vision that would engage the public and put the components in perspective. A key discussion paper closes non-specialists out of the dialogue with technical language and a legalistic emphasis on a regulatory framework¹¹. The proposed scientific program is narrowly toxicological, aimed at measuring substances and their effects, rather than preventing them from entering the environment.¹² The highly technical research agenda also limits opportunities for public participation. The public consultation process has been dominated by the pharmaceutical and biotech industries, a fact reflected in the concerns stakeholders most often expressed: that the regulations will slow down the introduction of new substances onto the Canadian market and affect international trade.¹³ The adequacy of the proposed regulations for health and environmental protection – ostensibly the purpose of the exercise -- were not even mentioned.

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.¹⁴ The

⁹ Ibid, p 36 .

¹⁰ Ibid, p35

¹¹ *Issue Identification Paper: Environmental Assessment Regulations*, Ottawa, 2003 and *Final Issue Identification Paper*, Ottawa: 2003.

¹² Ibid, p 3-4

¹³ EAR Newsletter, Vol. 1, No. 1, Spring, 2002, p 2.

¹⁴ PPCP FAQs, EPA, p 4

bellweather scientific study appeared in the literature in 1976, documenting pharmaceutical drugs in Kansas City sewage. Little notice was taken for 15 years when researchers studying aquatic contaminants accidentally discovered the cholesterol-reducing drug clofibrilic acid in Germany. More research in Europe detected clofibrilic acid in major waterways throughout Europe and in Berlin's tap water.¹⁵ Tests in Canada and the US have shown that North American waterways contain traces of antibiotics, painkillers, anti-inflammatories, hormones, tranquilizers, chemotherapy drugs and drugs used to treat epilepsy and blood cholesterol. Trace amounts of drugs have been found in tap water of some Canadian communities.

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 home stretch of our lives likely leach into cemeteries and groundwater¹⁶. Consumer use may account for the majority of trace pollutants in the environment although the available information is insufficient to prioritize sources.¹⁷ Other contributors are hospitals and long-term care facilities, veterinary drugs (including large amounts of antibiotics), drug-contaminated sewage sludge sold as farm fertilizer, and industrial waste disposal at plant sites.

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

¹⁵ Montague, Peter. Drugs in the Water. *Rachel's Environmental and Health Weekly*, #614, September 03, 1998. www.rachel.org/bulletin/bulletin.cfm?Issue_ID=501

quantities. Chronic exposure to low levels of multiple bioactive substances may well have a deleterious effect on some organisms.¹⁸ Some drugs (e.g., anti-epileptics) are persistent; others are “pseudo-persistent” -- they break down but are continually replaced by widespread use.¹⁹ Some drug compounds dissolve in water but about 30 per cent dissolve only in fat, which enables them to enter cells and move up food chains becoming more concentrated. The risks to both aquatic organisms and to humans are largely unknown but could include resistance to antibiotics and the disruption of endocrine systems.

A WOMEN’S PERSPECTIVE ON HEALTH PRODUCTS AND ENVIRONMENTAL POLLUTION

Ecosystem contamination with PPCPs has the potential to affect flora and fauna, fish and fowl, women and men. Women have a particular relationship to PPCPs, however. Effective policies designed to reverse this form of pollution need to consider differences between the sexes, both cultural (gender) and biological.

Gender Affects Purchase, Use and Disposal. 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., anti-depressants).

¹⁶ Daughton, CG. Cradle-to-cradle stewardship of drugs for minimizing their environmental disposition while promoting human health. II. Drug disposal, waste reduction, and future directions. *Environmental Health Perspectives*: 111 (5), May 15, 2003, 777

¹⁷ Ibid, 775-785.

Drug advertising, whether aimed at consumers or physicians, frequently plays on women's insecurities about weight, pimples, wrinkles, stress, bone loss and loss of cognitive powers in old age. Pharmaceutical companies also target women to expand the use of existing drugs and extend patent life, as in the promotion of anti-depressants for "mood disorders". Many of these prescribing patterns reflect the unnecessary medicalization of women's lives, that is, the prescribing of drugs to "treat" such healthy life stages as menstruation, pregnancy and menopause.²⁰

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.²¹ Some phthalates have been detected in drinking water, as have synthetic musk fragrances from perfumes and other toiletries.²²

A study commissioned by Health Canada found that women were more interested than men in learning about safe disposal of drugs and were more likely to state they would act on such information, even if it were inconvenient. Women were also more likely than men to state that they flushed unwanted drugs down the toilet or sink.²³ Strategies to

¹⁸ Final Issue Identification Paper, p 15.

¹⁹ PPCP FAQs, EPA, p 5

²⁰ See, for example, Kathryn Pauly Morgan, "Contested Bodies, Contested Knowledges: Women, Health and the Politics of Medicalization. In S. Sherwin (coordinator) *The Politics of Women's Health*, Philadelphia, Temple University Press, 1998, pp 83-121.

²¹ J. Houlihan, C. Brody, B. Schwan. Not Too Pretty: Phthalates, Beauty Products & the FDA, July 2002 www.nottoopretty.org

²² Daughton, 2002, p 38.

²³ F&DA Product Disposal Survey, COMPAS 2002. Appendix on Demographic Variations (Gender).

reduce use of particular drugs will only be effective if they recognize the gender dynamics underlying drug promotion and drug use.

Gender and Demographics. Women predominate in two demographic categories for which PPCP use may have a particular impact: the elderly and the poor. Elderly women comprise 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 geriatric drugs have been found in environmental monitoring studies.²⁴ Older women have had more years to absorb bio-accumulative drugs from the environment and reduced immunity could make them more sensitive to some effects of environmental chemicals in the water. For all these reasons, research, education and policies related to drugs in the environment must include elderly women.

At any age, women are more likely than men to be poor. The poor are less able to afford technical solutions, such as home filter systems or re-designed, environmentally “clean” drugs. Research and policies must recognize that corrective programs could widen class-based health disparities.

²⁴ Daughton, 2003, Op cit, p 781

Gender and Values. As a group, women are more willing to go out of their way to protect human health and the environment.²⁵ The women's health movement and the ecofeminist movement focus on health protection and environmental protection respectively. The survey conducted as part of EARP (and cited above) captures this gender gap in values. 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% versus 66%); and women were more likely to say they would dispose safely of household products "all the time, even if it's inconvenient" (70% versus 62%).²⁶ This commitment to health and the environment makes women 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 and government 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 (see below, p 21)?

Biological Differences between the Sexes. Biologically, women have different vulnerabilities to chemicals than men at certain points in the life cycle. Pregnancy is the most obvious example. The DES and thalidomide tragedies shattered the long-held rule

²⁵ Many health and environment analysts have noted and theorized about the reasons for this gender gap. See, for example, Miriam Wyman in *Sweeping the Earth: Women Taking Action for a Healthy Climate*, Miriam Wyman (Ed.), Charlottetown: Gynergy Books, 1999, pp 16-25 and Joni Seager, *Earth Folies: Coming to Feminist Terms with the Global Environmental Crisis*, NY: Routledge, 1993, pp 9-12. Consistent with these analyses, a poll undertaken by CRIC and the Globe and Mail in June 2003 showed that young women have a consistently higher awareness of social issues than do young men. www.theglobeandmail.com/servlet/story/RTGAM.20030611.nblow0611/BNStory/SpecialEvents3/-51k-24Jun2003/

²⁶ EAR Project Benchmark Survey, Op cit, Appendix.

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.²⁷

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.²⁸

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 than women of the same age and health status who have had children. Furthermore, women have more fatty tissue, on average, than men so store more endocrine disruptors in their bodies. Women have adverse reactions to drugs more often. This difference is only in part because women use

²⁷ Colburn, T, D Dumanoski and J P Meyers, *Our Stolen Future*. NY: Dutton, 1996, p 205; DES Action Canada. *Hormonal Pollution Alert*, 2001, p 2.

²⁸ See Steingraber, Sandra. Human Breast Milk Contamination Detection of Monocyclic Aromatic Amines, Possible Mammary Carcinogens, in Human Milk. Cornell University Program on Breast Cancer and Environmental Risk Factors in New York State (BCERF). *The Ribbon*, Vol. 4 No. 3, Early Fall, 1999. <http://envirocancer.cornell.edu/Newsletter/General/v4i3/rc.milk.cfm> ; and DeBruin, L.S., Pawliszyn, J.B.,

more drugs than men. A report by the US General Accounting Office concludes, “Greater health risks for women may be due to physiological differences that make women differentially more susceptible to some drug-related health risks.”²⁹

Health protection policies should be designed to protect the most vulnerable members of society. We can only be certain regulatory standards, and research designed to establish regulations, will adequately protect women if a gender analysis is built into research programs and policies.³⁰ 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. Research on male animal models, and on men, is easier to conduct precisely because researchers do not have to contend with the hormonal fluctuations of monthly cycles, pregnancy, and menopause – the very systems affected by endocrine disruptors.

Organizations working to promote access to clean water in the developing world have begun to analyse this issue from the perspective of gender equity.³¹ While poverty and health problems in the developing world differ in many respects from those in wealthy countries, similarities exist. In a report titled *Untapped Connections*, the Women's

and Josephy, P.D., Detection of monocyclic aromatic amines, possible mammary carcinogens, in human milk, *Chemical Research in Toxicology* 12: 78-82, 1999.

²⁹ GOA. Drug Safety: Most Drugs Withdrawn in Recent Years Had Greater Health Risks for Women. Washington, DC: General Accounting Office, GOA 01-286R; Fuller, Colleen. Women and Adverse Drug Reactions: Reporting in the Canadian Context. Background paper prepared for Women and Health Protection, March 2003.

³⁰ The Women’s Health Bureau of Health Canada has developed a training program for the inclusion of a gender-based analysis (GBA) in all Health Canada work and policies. www.hc-sc.gc.ca/english/women/gba.htm

³¹ See, for example, Prabha, Khosla and Rebecca Pearl, *Untapped Connections. Gender, Water and Poverty: Key Issues, Government Commitments and Actions for Sustainable Development*. NY: Women's Environmental & Development Organization (WEDO), 2003. Online at: <http://www.wedo.org>.

Environmental & Development Organization (WEDO) advocates for "a gender perspective in all water related policies" (p 2). WEDO also stresses that government commitments to health and gender equity rely on "a better understanding of the different roles and responsibilities women and men have in water access and use; health, sanitation and hygiene; environmental health and ecosystem stability; and public versus private services" (p. 3). These principles can form the basis of a global strategy to protect water resources while promoting human rights.

CONCERNS ABOUT "EARP"

As of this writing, the Canadian government's program has highlighted toxicological research, regulatory change and meetings with industry stakeholders about potential trade impacts. Discussions with public interest groups, including environmental, women's health and consumer groups, have been limited. EARP's narrow focus overlooks strategies for short-term action and offers little to promote a truly preventive strategy that puts health and environmental protection above trade and economic objectives.

A striking contrast to the government's approach is the Green Pharmacy Stewardship Program proposed by Christian Daughton, a scientist at the US Environmental Protection Agency. Daughton envisions a broad, holistic program jointly overseen by the healthcare industry and consumers. Three goals shape the Green Pharmacy concept: protect the environment, reduce medical expense for the consumer and improve patient and

consumer health.³² The analysis that follows uses selected highlights from Green Pharmacy documents to illuminate components of EARP.

Environmental Assessment Regulations

The government's environmental assessment regulations and industry consultations are intended to overcome a policy gap between the Health and Environment ministries. Drug safety assessments, which Health Canada carries out under Food and Drugs Act (F&DA) regulations, currently evaluate safety only for substances consumed directly. The assessments have not been concerned with protecting the environment or with human health problems arising from environmental contamination by PPCPs. The Canadian Environmental Protection Act (CEPA), the regulatory framework designed to protect Canada's environment, came into force in 1988 and was revised in 1999. When CEPA was enacted, according to a federal government Powerpoint presentation on EAR, both Health Canada and Environment Canada felt, incorrectly, that the substances regulated under Canada's Food and Drugs Act were exempt from CEPA.³³ Proposed new regulations will bring food and drug manufacturers, and Health Canada's review processes, in line with the requirements of CEPA.

When the regulations take effect, they will extend the information and reporting steps required for Health Canada's product approval process to include environmental

³² See documents posted at: <http://www.epa.gov/nerlesd1/chemistry/ppcp/greenpharmacy.htm>

³³ CEPA & the NSNR, see page beginning, "Why is Health Canada Developing new regulations?", available at: www.hc-sc-gc.ca/ear-ree

concerns.³⁴ As with current reviews, manufacturers will provide data for the government's assessment. Once the regulations are in place, products that came to market between 1987 and September 2001 will be assessed to see if they are deemed safe for the ecosystem and/or human health through environmental exposures. If they are not, EAR publicity states: "immediate and appropriate action will be taken."³⁵

In previous documents, Women and Health Protection expresses concerns about Health Canada's drug review processes, including government-industry conflicts-of-interest, the worrisome move towards 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.³⁶ As an extension of Health Canada's drug review process, EARP seems destined to inherit these systemic problems. EARP is guided by a regulatory approach designed to promote economic growth by increasing Canada's international trade competitiveness. This strategy includes the federal government's "smart regulations" which are intended to "contribute to innovation and economic growth and to reduce the administrative burden on business."³⁷ The smart regulations strategy involves international collaboration and harmonisation of regulations with those of Canada's trading partners. A paper published by Women and Health Protection critically evaluates

³⁴ Environmental Assessment Regulations, Notice of Intent, Canada Gazette, Part 1, Sept. 1, 2002. www.hc-sc.gc.ca/ear-ree/noi_e.html

³⁵ Frequently Asked Questions – Environmental Assessment Regulations, September 2002. Accessed February 2, 2003, at www.hc-sc.gc.ca/ear-ree/faq_e.html

³⁶ See, for example, *How Safe Are Our Medicines?, Preventing Disease: Are Pills the Answer?* and *Who Benefits? International Harmonization of the Regulation of New Pharmaceutical Drugs* on the Women and Health Protection Web site.

³⁷ *Final Issue Identification Paper*, pp 41-42.

the international harmonisation process from the perspective of women's health.³⁸ The Canadian Biotechnology Strategy, which promotes a favourable climate for investment, development and innovation, is also integral to EAR.³⁹ Feminist academics, health care activists and environmentalists have critiqued the market-driven, medicalized view of health inherent in the Canadian Biotechnology Strategy.⁴⁰

As stated in the EAR background documentation, "The F& DA was designed [in 1954] as a consumer protection statute dealing with health and safety and economic fraud in respect of food and drug products."⁴¹ The Act was not meant to promote industrial development: with commercial objectives embedded in the EAR framework, however, trade and economic development priorities could easily override concerns about human health, the environment and false product claims. Input of those free of industry conflicts-of-interest is of paramount importance.

The regulatory emphasis on toxicology in the government's initiative is also problematic. Daughton, in his Green Pharmacy proposal, questions how useful such regulations can be in controlling PPCPs in the environment. He notes the pitfalls of trying to track and regulate potential chemical stressors given that "The spectrum of pollutants typically identified in an environmental sample represent but an unknown portion of those actually

³⁸ Who Benefits? International Harmonisation of the Regulation of New Pharmaceutical Drugs. Women and Health Protection in Collaboration with DES Action Canada, 2002.

³⁹ Final Issue Identification Paper, p 46.

⁴⁰ See, for example, Workshop Proceedings for "The Gender of Genetic Futures: The Canadian Biotechnology Strategy, Women and Health", www.cwhn.ca and Anne Rochon Ford, *Biotechnology and the New Genetics: What it Means for Women's Health*, Prepared for the Working Group on Women, Health and the New Genetics, February 2001.

⁴¹ *Final Issue Identification Paper*, Op cit, p29.

present (possibly very small), and they are of unknown overall risk significance.”⁴²

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 mechanism of action” or a common physiological or behavioral endpoint.⁴³ He notes that any approach that uses “predicted” environmental concentrations fails to account for three major factors: geographic variability in drug usage, sources other than legal sales (e.g., physician samples, black market sales and “prescription drug patient assistance programs”), and interactions between chemical stressors.⁴⁴ EARP’s focus on regulating and testing specific drug and food products for toxicity could serve mainly to postpone action by deflecting attention and resources from more promising initiatives.

EARP materials do not mention other regulatory tools at the government’s disposal.

These tools include strengthening the drug approval system by only allowing new drugs on the market that show an advantage over existing treatments, tightening and enforcing the ban on direct-to-consumer advertising, directly regulating the promotion of drugs to physicians, opening the drug approval process to public scrutiny, improving post-marketing drug surveillance, and adopting a more stringent interpretation of the precautionary principle. Many of these approaches would help curtail the medicalization of women’s health. The government needs to revisit its initiative with a broader regulatory vision in mind.

⁴² Daughton, 2002, p 3

⁴³ Daughton, 2002, p 12

Science and Research

A second key component of EARP is its national science agenda. The government's research priorities are tied to its regulatory agenda; in other words, the research agenda is toxicological. This focus is reflected in the objectives of a workshop that Health Canada and Environment Canada sponsored in February 2002 to discuss Pharmaceuticals and Personal Care Products in the Canadian environment. The workshop's main objectives included, "identifying major scientific knowledge gaps and establishing risk assessment and risk management needs in Canada."⁴⁵ Predictably, research priorities identified by workshop participants reflected the pre-set 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).⁴⁶

At best, toxicological assessment research is long term. Making it the centerpiece of the science agenda for PPCPs in the environment excludes or marginalizes other, equally important scientific research that would support immediate and medium-term action. Daughton notes the well-documented fact that poverty and malnutrition contribute far more to ill health than lack of medication.⁴⁷ Curtailing some uses of medication can improve health outcomes. He proposes, instead of narrow technical objectives, a health promotion framework in which industries and the public would be encouraged to develop a consensus and cultural mindset toward "holistic environmental responsibility". A

⁴⁴ Daughton, 2002, pp 17-19

⁴⁵ "Assessment and Management of Pharmaceutical and Personal Care Products in the Canadian Environment: A National Science Agenda." Environmental Assessment Regulations newsletter, Vol. 1, No. 1, Spring 2002, page 3.

⁴⁶ "Workshop Conclusions" from the powerpoint presentation EAR: Science and Research, posted at www.hc-sc.gc.ca/ear-ree

⁴⁷ Daughton, Op cit, 2002, p 30.

multidisciplinary approach would expand the scientific agenda beyond analytic chemistry.⁴⁸ A cohesive, scientifically sound set of principles would guide changes to packaging, distribution, and purveyance of PPCPs, many of which could be implemented rapidly.⁴⁹ Examples include lowered dosing based on studies showing that effective doses of some drugs can be lower than previously realized. Cutting doses could reduce adverse drug reactions, including deaths, while minimizing the potential for environmental effects.⁵⁰ A survey of drug disposal in Ontario estimated the annual cost of wasted medication in the province at over Can\$40 million. Much of the waste was in the elderly population, which is predominantly female.⁵¹ Other 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.⁵² The same science-based principles would guide consumer actions. “Some of these actions would require little further research, some would demand attention to the patchwork of laws and regulations concerning drug recycling and disposal; others would require further research,” says Daughton. (It should be noted that Daughton emphasizes the advantage of voluntary initiatives, by both industry and consumers. While some voluntary programs may be effective, I believe many goals will only be achieved with regulations; but these regulations must go beyond toxicological risk assessment).

⁴⁸ Daughton, “Environmental Stewardship of Pharmaceuticals: the Green Pharmacy” Powerpoint presentation from the National Groundwater Association 3rd International Conference on Pharmaceuticals and Endocrine Disrupting Chemicals in Water, Minneapolis, MN, 19-21, March 2003, slide 5. Available: www.epa.gov/nerlesd1/chemistry/ppcp/conference-past.htm.

⁴⁹ Ibid, p 9

⁵⁰ Ibid, 41-42.

⁵¹ Boivin, M. 1997. The cost of medication waste. *Can Pharm J.* May 32-39. Available: [Http://www.napra.org/practice/toolkits/toolkit9/wastecost.pdf](http://www.napra.org/practice/toolkits/toolkit9/wastecost.pdf). Cited in Daughton, 2003, p 781.

⁵² Ibid, 54.

Substituting complementary and alternative medicine (CAM) approaches for conventional pharmaceutical interventions, and replacement of synthetic ingredients in personal care products with others made of naturally occurring substances, could have considerable impact, according to Dr. Warren Bell⁵³. “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. Awareness of the environmental impacts of synthetic PPCPs could be the impetus for investigating the therapeutic and environmental impacts of CAM remedies (and some, particularly herbal remedies and nutritional supplements, are highly bioactive⁵⁴).

This brief assessment only hints at the breadth of research that could be pursued under a refocused program within a broad, health promotion and ecological framework.⁵⁵

Public Education

The third prong of the EAR Program comprises public education and public participation initiatives.⁵⁶ The EAR Project Benchmark Survey, conducted for Health Canada in 2002,

⁵³ Personal communication, June 26, 2003.

⁵⁴ Daughton, Op cit, 2002, 39-40.

⁵⁵ For a complete overview of C.G. Daughton’s Green Pharmacy research ideas, see the articles in Environmental Health Perspectives, November 2002 and May 2003; and the Powerpoint presentation, “Environmental Stewardship of Pharmaceuticals: the Green Pharmacy” from the National Groundwater Association 3rd International Conference on Pharmaceuticals and Endocrine Disrupting Chemicals in Water, Minneapolis, MN, 19-21, March 2003. www.epa.gov/nerlesd1/chemistry/ppcp/conference-past.htm.

suggests that household disposal will be a focus of the Project's educational efforts. The survey assessed consumer attitudes to waste disposal, including the disposal of pharmaceuticals, and other PPCPs. Currently, British Columbia, Alberta and Saskatchewan have provincial take-back programs for unused drugs⁵⁷, but these are not well promoted and a patchwork of provincial waste-removal practices has stalled a national take-back program.

While household disposal practices are an obvious target for change, this is not primary prevention -- a stated goal of EARP. Educational programs to instill Best Practices need to actively promote reduced use of PPCPs.⁵⁸ A more visionary program, like the Green Pharmacy, could capture the public's imagination and encourage participation in a broad program of reduced use.

Post-Walkerton, the Canadian public cares deeply about water and understands that safe water is fundamental to good health. Media coverage has created a "teachable moment," in which the public is receptive to understanding the issues and eager to help find solutions.⁵⁹ The specter of contaminated water can be frightening, instilling a sense of helplessness over shrinking resources necessary to life. Much thought needs to be given to the framing of educational messages and programs so that risks are neither downplayed nor sensationalized.

⁵⁶ Final EAR Issue Identification Paper, p 5.

⁵⁷ NAPRA, Pharmacy Practice: Recycling and Disposal of Dispensed Drugs, Ottawa, Ontario: National Association of Pharmacy Regulatory Authorities, Canada, 2002. Available: <http://www.napra.org/practice/toolkits/pharm-toolkit9.html>.

A great deal can be done immediately and in the short term. Some drug use is necessary to good health, but much is inappropriate and causes harm. Corporate practices designed to promote drug use that is not scientifically based need to be curtailed. Examples are direct to consumer advertising⁶⁰, and commercially sponsored seminars to encourage off-label prescribing. Educational efforts to promote health maintenance through better nutrition could be stepped up⁶¹. Educational programs recognizing women's role as family educators and gatekeepers for PPCPs might be highly effective in reducing drug use. Women are familiar with medicalization issues, through experiences with drugs like HRT, and place a high value on health and the environment; a science-based program to improve their family's health while saving money and protecting the environment could have rapid results.

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.⁶² Public education about drugs in the water requires a similarly

⁵⁸ Daughton, Op cit, 2002, pp 48-49, 55-56.

⁵⁹ Ibid, p 15.

⁶⁰ See Mintzes, Barbara. Direct-to-consumer advertising for prescription drugs: when health protection is no longer a priority. Montreal: DES Action Canada and Women and Health Protection, 2001.

⁶¹ Daughton, Op cit, 2003, p 777.

⁶² Van Esterik, Penny. Risks, Rights and Regulations: Communicating about Environmental Risks and Infant Feeding, 2002. Available at: www.yorku.ca/nnewh

broad focus. Questions for public debate include: What is the full range of remedies?
What solutions will be emphasized? When parties disagree, who decides?

Public Participation and the EAR Consultation Process

Beginning with the Notice of Intent, Health Canada has stated its commitment to a process of consultations with stakeholders in the development of these new regulations. To date, this process has included meetings to explain EAR 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 include a website, newsletters and an information line to disseminate information and register reactions.

Despite the stated commitment to public participation in EARP, the consultations have been geared to industry players and have 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 have been narrowly focused on the proposed regulations.

The main vehicle to engage the public in the EAR process involved stakeholder groups. In May 2002, 16 NGOs from across the country accepted an invitation to attend a one-day Health Canada workshop on EAR. At an EARP multi-stakeholder meeting in February 2003, NGO participation had dwindled to four (plus three representatives from

the Public Advisory Committee, a government-appointed consumer panel that advises the Health Products and Food Branch). The government and industry representatives numbered about 70, from the federal departments of Environment and Health and from major pharmaceutical and biotech companies. The agenda at these meetings was pre-set, with Powerpoint presentations and guided discussion of the Issue Identification “workbook” on the regulatory proposals. At both meetings, the opaque language of risk assessment and regulation set up barriers to NGO participation by framing the problem and the process in terms meaningful to industry and government.

The issues inherent in EAR are challenging for NGOs. Historically, research, regulations and policies for health and the environment have evolved in separate silos; similarly, most NGOs have taken on either health or environmental issues, but not both. Some exceptions are WHEN (Women’s Healthy Environment Network), the Canadian Coalition for Green Health Care, and (in the US) Health Care Without Harm.⁶³ Most NGOs need additional resources if they are to extend their expertise to include the interaction between health and the environment.

If health and environmental protection are to take precedence over trade issues, the participation of health and environmental advocacy groups is vital. For NGOs working with tight budgets and staff cutbacks, EARP public consultations from 2002 through early-2003 were not a priority, however. For seasoned health and environment groups, EARP consultations fit a familiar pattern. NGOs were invited to only two meetings and

⁶³ See, for example, WHEN www.web.net/~when/; the Canadian Coalition for Green Health Care www.greenhealthcare.ca/index2.htm; and Health Care Without Harm www.noharm.org.

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 and engaged in discussions about EARP on an ongoing basis in their workplaces. A meeting to move the scientific agenda forward, planned for September 2003, will be restricted to invited scientists.⁶⁴

THE PRECAUTIONARY PRINCIPLE

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, the federal government affirms Canada's commitment to the precautionary principle.⁶⁵ 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

⁶⁴ This assessment is based on the author's observations at the May 2002 and February 2003 meetings, including discussions at the meetings and afterwards with NGO, government and industry participants.

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"; 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.

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. Application of the precautionary principle would require governments to curtail the use of potentially unsafe technologies, even if national economies could suffer some short-term losses as a result⁶⁶. EARP documents state that Canada promotes a precautionary approach, "distinctive within science-based risk management".⁶⁷ Subsuming the precautionary principle within risk management tempers the precautionary imperative in the interests of economic goals. An *alternatives assessment strategy*⁶⁸ would recognize that developing a "clean" technology industry is a way to realize direct and indirect economic gains. With vision, Canada could lead in 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.

⁶⁵ Final Issue Identification Paper, p 40-41

⁶⁶ See, for example, O'Brien, Mary. *Making Better Environmental Decisions: An Alternative to Risk Assessment*. Cambridge, MA: MIT Press, 2000.

⁶⁷ Final Issue Identification Paper, p 38.

⁶⁸ O'Brien, M. *op cit*, pp 3-15.

As the EAR Issue Identification Paper acknowledges, the precautionary principle is, “ultimately guided by judgment, based on values (acceptable levels of risks).”⁶⁹ 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.

Canadian values traditionally put the public welfare ahead of individual gain. Without adequate public consultations, it is impossible to say what level of risk the Canadian public is prepared to take with PPCPs. The government’s survey suggests a high level of commitment to health and environmental protection, among both men and women, but particularly among women. Before policy decisions are made, the public needs a plain language account of the full range of alternatives and an opportunity to engage in discussions. Public consultations should systematically seek the views of women and other vulnerable sub-populations.

CONCLUSIONS

The government’s Environmental Assessment Regulations Program (EARP) proposes narrow regulatory solutions to a broad ecosystem problem. Public consultation has been inadequate and priorities have been skewed to address the trade concerns of government and industry players. Public health concerns, especially prevention via reduced use of PPCPs, are oddly secondary or missing entirely from the program. A holistic, health promotion program, emphasizing primary prevention, is needed to respond to this emerging threat to health and the environment. An effective and just program for change

⁶⁹ Op cit, p 38.

will recognize the particular culture-based relationship of women to pharmaceuticals and personal care products, as well as women's biological vulnerability to certain chemicals in the environment. One existing model, the Green Pharmacy stewardship program, offers a global vision that could be adapted readily to Canadian needs.

RECOMMENDATIONS

- Make environmental and health protection the central objective of EARP; this requires a shift in priorities away from trade objectives;
- Emphasize primary prevention strategies (i.e., reduced product use) rather than focusing on regulating product approvals;
- Broaden and shift the research agenda from its current focus on toxicological assessment of products to a holistic, health promotion framework, encompassing a range of strategies to be used throughout a product's lifespan (see next point);
- Adopt a "product lifespan" approach to regulation, recognizing that production, purchase, use, and disposal of products are distinct stages requiring different precautionary policies;
- Reduce pharmaceutical drug use by promoting the rational use of drugs, eliminating over-use, inappropriate use, and the medicalization of healthy women's lives;
- Recognize the central role women play in purchasing, using and disposing of Pharmaceutical and Personal Care Products;

- Ensure that biologically-based differences between women's and men's sensitivity to pharmaceuticals, and other PPCP chemicals, are fully integrated into the scientific research agenda;
- Develop a framework for public consultation that will permit genuine participation, for example, by providing plain language documentation, encouraging members of the public to frame issues in ways meaningful to them, and providing funds so that NGOs can meet among themselves, consult with their members and analyze the public health and ecosystem dimensions of the issues;
- Tie the precautionary principle to Canadian values, in which health and environmental protection are central, rather than to a risk assessment framework emphasizing economic growth.

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