

# SYMBIOSIS

THE JOURNAL OF ECOLOGICALLY SUSTAINABLE MEDICINE



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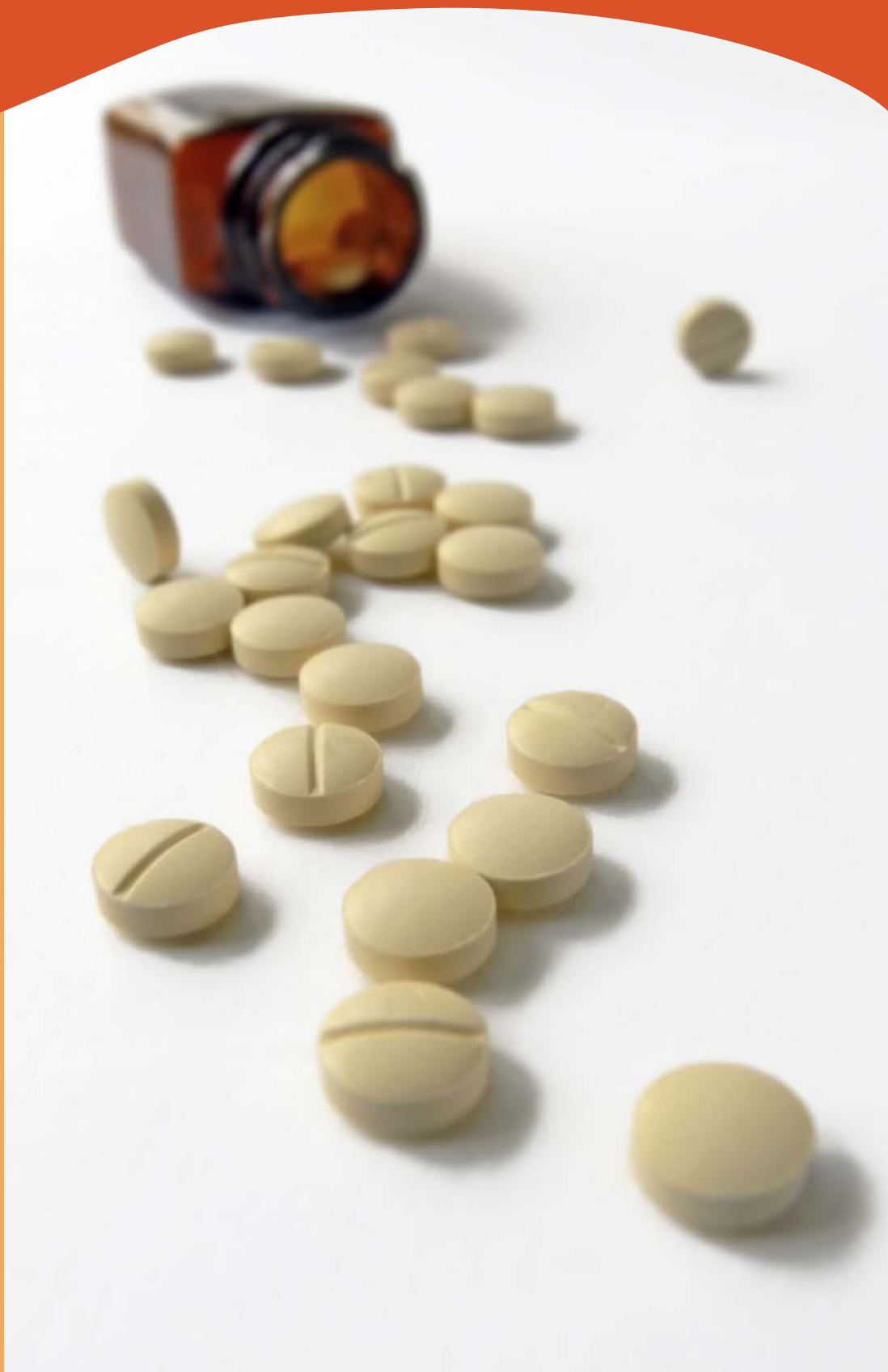
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## Letter from the Director

At last I can see clear water and blue sky! Perhaps just a vision, but it seems that our world is waking up to the inconvenient truth that our actions have ecological consequences and we must choose wisely to promote health. With so much talk about carbon footprints and greenhouse gas emissions, it may seem out of place to talk about green pharmacy practices, but it is equally important. Rather than waiting until researchers find more waterways contaminated with medicines, or sea life altered and deformed, we have an opportunity to exercise the precautionary principle—a choice to *prevent* health and environmental problems.

At Teleosis eight months ago, we initiated our investigation of pharmaceutical pollution prevention. To increase public awareness about this important topic, we compiled in this issue of *Symbiosis* a comprehensive, accessible series of articles dedicated to explaining this complex and often confusing subject.

We have condensed considerable research completed by Christian Daughton and many others, and we have connected with key players who are creating viable solutions today. Daughton, who has conducted much of the research in this field, encourages all of us to take responsibility: “A proactive, voluntary holistic stewardship program for pharmaceutical waste . . . offers thoughtful environmental responsibility rather than rote compliance to regulation.”

This issue of *Symbiosis* also marks the beginning of our real work: Teleosis Institute is launching the Green Pharmacy Campaign, with a goal of zero pharmaceutical waste in the environment. This can be accomplished by eliminating improper disposal and reducing over-consumption of medicines. Daughton reminds us, “All aspects of society can play an integral role.” I am enlisting all of us to help reach our goal. Each of us can begin by taking two initial steps toward pharmaceutical pollution prevention. First, go to your medicine cabinet and collect all expired and unneeded medicines and supplements and dispose of them in an environmentally safe manner; our website will show you how. Second, take care of your own health and promote personal, community, and environmental health, modeling to others that adopting diet and lifestyle commitments to wellness are essential for a sustainable future. The most effective way to prevent medical waste is by investing in better human and environmental health.

Paul Hawken recently inspired me with his words, “The promise of this unnamed movement is to offer solutions to what appear to be insoluble dilemmas . . . Inspiration is not garnered from litanies of what is flawed, it resides in humanity’s willingness to restore, redress, reform, recover, reimagine, and reconsider. Healing the wounds of the Earth and its people does not require saintliness or a political party. It is not a liberal or a conservative activity. It is a sacred act” (Orion Magazine, May/June 2007).

Our sacred act begins with claiming our own health. Be the change.

JOEL KREISBERG, DC, MA  
EXECUTIVE DIRECTOR

### SYMBIOSIS

Greek syn, ‘together’,  
+ bios, ‘life’ literally  
‘living together’

Symbiosis explores ecological principles of healing and medicine that support a healthy relationship with the living Earth. This educational forum offers relevant and timely information that promotes an ethic of sustainability for the Earth and its inhabitants.



**In 2004, 21 million pounds of antibiotics were administered to farm animals and pets in the U.S.**

## Health News

### Pharmaceutical Pollution

#### Wastewater Treatment Leaves Drugs in Water

In 1999-2000 the USGS analyzed pharmaceutical content in 139 streams throughout the U.S. to determine water contamination levels. Chemicals from various medications were found in 80% of samples: 24% of samples contained acetaminophen; 16% contained steroids and hormones (including 17-ethynyl estradiol, a birth-control hormone); 13% had Diltiazem (a blood pressure medication); 11% included codeine; 10% contained antibiotics and antimicrobials; and 10% contained Ibuprofen.

Sources of such pharmaceutical contamination are human excretion and waste disposal by healthcare providers and patients. Current wastewater treatment removes solids and other organic material, but organic micro-contaminants and low concentrations of synthetic pollutants such as pharmaceuticals remain. Two serious consequences of this pharmaceutical contamination are increased antibiotic resistance and disruption of human and animal endocrine systems.

Source: Kolpin D. et al. Pharmaceuticals, hormones and other organic wastewater contaminants in US streams, 1999-2000: A national reconnaissance. *Environmental Science and Technology* [online]. 2002;26:1201-1211. Available at: <http://pubs.acs.org/journals/esthag/36/i06/pdf/es011055j.pdf>. Accessed December 13, 2006.

#### Cow Manure: The Latest Weapon against Drug Contamination?

In 2004, 21 million pounds of antibiotics were administered to farm animals and pets in the U.S. Because antibiotics typically do not degrade on their own, they pose a significant environmental contamination problem. Cow manure may just be the solution. Agricultural Research Scientists (ARS), the U.S. Department of Agriculture's chief scientific research agency, ran a study on the effects that microbes, naturally found in cow manure, have on the traces of antibiotics that remain therein. In a scientific simulation of field conditions, manure laced with the common veterinary antibiotic *Sulfadiazine* was mixed with soil, and then measured. The results showed that microbes from the manure actually play a role in speeding the degradation of the remaining antibiotics, with some even digesting and inactivating them.

Based on this evidence, scientists suggest that farmers should create an environment that is hospitable to these microbes. Storing the manure in a warm, moist place for as long as possible before spreading it on the fields allows the microbes to thrive and do their work on the contaminants.

Source: Agricultural Research Services. Microbes in manure can minimize potential pharmaceutical pollution. January 26, 2006. Available at: <http://www.ars.usda.gov/is/pr/2006/060127.htm>. Accessed December 3, 2006.





**Green chemistry transforms benzene—a component of oil and oil products—into compounds that are useful in manufacturing drugs by introducing the bacteria *Pseudomonas putida* to benzene waste.**

## Study Finds Drugs in Coastal Waters

The National Center for Coastal Ocean Science (NCCOS) is conducting studies to determine the effects of pharmaceutical drugs in coastal environments. Drugs are brought to the coast primarily through municipal and industrial sewage effluents, as well as large-scale farms and golf courses that have been irrigated with treated sewage water. The pharmaceuticals commonly found include: antibiotics, hormones, blood lipid regulators, and chemotherapy drugs. In the past, monitoring the quantity and risk-level of contaminants has proven challenging due to the unpredictable levels of various components and highly complex interactions in a natural setting.

The project's goals are to evaluate the effects on and risks for humans of the pharmaceuticals found in estuaries, and to devise new methods for detecting these contaminants. The NCCOS studies of South Carolina waterways (including rivers) and the Atlantic coastline will continued through 2007.

*Source:* Key P. *National Centers for Coastal Ocean Science*. Determination of the effects of pharmaceutical drugs in the coastal environment. Available at: <http://www8.nos.noaa.gov/nccos/npe/projectdetail.aspx?id=58&fy=2007>. Accessed November 30, 2006.

## Green Chemistry to the Rescue

The Pollution Prevention Act of 1990 put our nation on notice that reducing and preventing pollution is a high priority. In tandem with this goal, those involved in “green chemistry” design chemical products and processes that reduce or eliminate the generation and use of hazardous substances. Among the 12 principles of green chemistry are efficient and economical use of resources in production and safe and complete degradation of harmful elements.

In medicine for example, green chemistry transforms benzene—a component of oil and oil products—into compounds that are useful in manufacturing drugs by introducing the bacteria *Pseudomonas putida* to benzene waste. This not only reduces the amount of hazardous material entering the waste stream and eliminates the costly process of removing it from the environment, but also creates a new and useful element that generates profit. If these benefits weren't incentive enough, the synthetic compounds this process produces are often preferable to natural versions, as many drugs extracted from plants are available only in small quantities. Further, because these synthetic versions produce more reliable results in patients, quality control is easier.

*Source:* Vecellio K. *University of Florida News*. ‘Green chemistry’ cleans up environment and renders synthetic drugs. Thursday, July 16, 1998. Available at: <http://news.ufl.edu/1998/07/16/grnchem/>. Accessed November 21, 2006.



**The primary contamination of fresh and ocean water today is from consumerism and personal human activities.**

## Green Pharmacy: Preventing Pharmaceutical Pollution

*This issue of Symbiosis features a series of articles on preventing pollution of the environment with pharmaceuticals and personal care products (PPCPs). A discussion of PPCP pollution is complex, involving many different aspects of chemistry, toxicology, ecology, science, medical science, public policy, and consumer behavior. Although public perception is based on a long-standing belief that our waterways are primarily polluted by agriculture and industry, the reality is that because of strong regulations put in place over the past 30 years, the primary contamination of fresh and ocean water today is from consumer wastes and personal human activities.*

*The ubiquity of PPCPs, and the fact that they are constantly reintroduced into the environment as contaminants, are serious and significant aspects of our pollution problems. Our first article in this issue gives an overview of PPCP ecology and ecotoxicology; this is followed by a spotlight on the work of Christian Daughton, PhD, a senior scientist at the EPA in Las Vegas, Nevada. The next piece, entitled “The 4 Ts” (toxicant, totality, tolerance, trajectory) discusses a model for evaluating long-term stresses on personal health presented by exposure to multiple chemicals over time. A companion piece is an excerpt from Daughton’s work that describes “cradle-to-cradle stewardship” of drugs as a way of minimizing any risks that might be posed to human health and the environment. In the final article, “Green Pharmacy: Preventing Pollution—A Cross Sector Approach”, outlines practical steps we can take to address complex ecological issues previously outlined.*

*This series of articles provides an overview of the complicated issues and potential solutions (some of which are already being utilized) for PPCP pollution. You can find more information on the topic at the EPA’s Web site on PPCPs (<http://www.teleosis.org/epa/ppcp>). Our review of this Web site is on page 47.*

## Pharmaceutical Pollution: Ecology and Toxicology

BY JOEL KREISBERG, DC, MA



**Joel Kreisberg, DC, MA**

Dr. Kreisberg holds a Doctor of Chiropractic degree from New York Chiropractic College and a Masters of Arts in Integral Ecology from Prescott College. He is adjunct faculty in JFK University's School of Holistic Studies. The author of several books on homeopathy, Dr. Kreisberg has been teaching for over 25 years and maintains a private practice in Berkeley, CA.

What happens to medicines after they are consumed? Are they utilized in their entirety by our bodies? Or are they partially excreted when we use the toilet? Where do unused and expired medicines end up? Do medicines have an effect on other organisms living in the environment? These are some of the questions the Office of Research and Development of the United States Environmental Protection Agency (EPA) is currently trying to answer. This first article in this series focuses on how pharmaceuticals and personal care products (PPCPs) enter our environment and what effects they trigger on organisms regularly exposed to them (ecotoxicology).

There are three main human activities that cause changes in ecosystems: habitat fragmentation, alteration of community structure, and chemical pollution.<sup>1</sup> During the past 3 decades, attention to the effects of chemical pollution has focused primarily on conventional "priority" pollutants, and rightfully so. These chemicals—referred to as persistent bioaccumulative toxicants (PBTs) or persistent organic pollutants (POPs)—include, for example, lead, mercury, and dioxin, and they continue to have highly detrimental effects over long periods of time (persistence). They are often bioaccumulative. *Bioaccumulation* refers to the tendency to increase concentration when a toxin is consumed in a successional food chain. Mercury, for example, is found in larger concentrations in fish than in shellfish, and is more concentrated in bigger fish, which feed on smaller fish. The good news is that through identification and regulation, the EPA and state and local municipal governments have curbed the most egregious of these chemicals to varying degrees. We continue to pay close attention to their ecological consequences.

Comparatively little attention, however, has been directed to a large class of chemicals comprising pharmaceuticals and personal care products (PPCPs). For the purposes of this discussion, pharmaceutical drugs include all the medicines used for the diagnosis, treatment, and prevention of disease; illicit or recreational drugs; veterinarian medicines (including those for agricultural livestock); over-the-counter medications; and nutritional supplements or nutraceuticals. Personal care products include fragrances, lotions and creams, cosmetics, sunscreen, and other consumer chemicals (including "inert" ingredients). The use of PPCPs continues to grow worldwide on par with many agrochemicals. Unlike agrochemicals, which are disposed of or discharged into the environment on a continual basis via domestic/industrial sewage and wet-weather runoff, PPCPs are in part subjected to the metabolism of the user; then, excreted metabolites plus some unaltered parent compounds are released



**Removal efficiencies vary widely, from 10% to 100%, averaging about 60% of total drugs in the waterway.**

into sewage water. Although U.S. manufacturers try to minimize the discharge of APIs, they are released by drug manufacturers and through disposal of unwanted and expired drugs directly into the domestic sewage system or via leachate from landfills. Through these processes, PPCPs enter the environment, where they are considered *pseudo-persistent* because the transformation/removal rate of PPCPs from the environment is compensated by the rate of replacement, a direct result of long-term use by consumers in higher quantities and subsequent improper disposal. A recent take-back event (where consumers return unused and expired medications) in the San Francisco Bay Area in California found that 45% of unused/expired medicines were flushed down the toilet, and 28% were disposed directly into the trash.<sup>2</sup> Persistence also results from medicines' natural resistance to degradation. One study in Germany showed that barbiturate concentrations were still found even though their use had been virtually eliminated 30 years ago.<sup>3</sup>

Since drugs in the environment have not captured as much attention as pesticides up until now, documentation of quantities and environmental impacts has been limited. Studies that quantify PPCPs in the environment are primarily European in origin. In sharp contrast, pesticide use is clearly documented and controlled. Unfortunately, pharmaceuticals are potentially released anywhere humans exist worldwide—for example, through human excretion in wilderness areas that have limited capacity for sewage treatment.<sup>4,5</sup> New drugs in development and clinical trials also are released directly into the environment, though in arguably low concentrations (see “*The True Cost of Drugs*” on page 31).

## PPCPs in the Waste Stream

Ideally, sewage treatment facilities would capture PPCPs entering the environment. These waste systems are only designed to handle human waste that is primarily biological in origin. The two primary mechanisms for removal of substances from the incoming waste stream are microbial degradation and sorption to filterable solids for later removal as sludge.<sup>1</sup> Most anthropogenic (human-made) substances suffer an unknown fate in this system. Further complicating matters, new drugs introduced into the marketplace are usually overlooked in monitoring studies. In the case of PPCPs, many compounds resist degradation, and others resist removal through sorption.<sup>1</sup> In a primary waste treatment plant in Frankfurt/Main, Germany, the daily load of active pharmaceutical ingredients ranged from the tens to hundreds of grams. Removal efficiencies vary widely, from 10% to 100%, averaging about 60% of total drugs in the waterway.<sup>6</sup> This particular sewage plant had a flow rate of 60,000 m<sup>3</sup>/day and serviced just over 330,000 people.

Other factors affecting removal of substances from the waste stream include weather-related incidents such as wet-weather overflow or the opposite, low inflow during drought conditions, which leads to higher concentrations due to a low volume of water. During seasonal flooding, this same treatment plant in Frankfurt suffered a removal efficiency decrease to less than 5%; it returned to normal levels only after a week. There is also evidence that PPCPs from household waste leach from landfills. Landfills accept sewage sludge and may produce leachates carrying concentrations of drugs higher than in wastes. Holm et al.<sup>7</sup> found high concentrations of antibiotics and barbiturates in a Danish landfill over a 45-year period.





**A recent study found over 100 kinds of PPCPs in significant concentrations in sampled waterways, the most common being aspirin, statins, hypertension medications, and hormones taken by women.**

Pharmaceuticals have been identified in domestic drinking water. A recent study found over 100 kinds of PPCPs in significant concentrations in sampled waterways, the most common being aspirin, statins, hypertension medications, and hormones produced or taken by women.<sup>8</sup> Drinking water regulations historically have been designed to protect consumers from threats of pathogens and industrial chemicals, but not from PPCPs. Little baseline information for concentrations of PPCPs in drinking water exists. Precaution is necessary to stave off future problems.

## Toxicity of PPCPs to Organisms and Environment

A significant problem in assessing ecotoxicological impacts of PPCPs at the ecosystem level occurs because of the orientation of traditional toxicological testing: individual chemicals are tested on a single species. This raises the question of whether these simplified tests of component parts of complex water systems can predict the impact of mixtures of pollutants on more highly organized communities.<sup>1</sup> Given the multitude of organisms potentially affected, it is doubtful that the spectrum of physiological effects of PPCPs can be effectively analyzed in this manner. The current system of quantifying toxicological effects of chemicals does not adequately assess PPCPs. (See *"The 4 Ts—Assessing Exposure to Multiple Chemicals"* on page 22.)

Due to biological diversity in aquatic environments, it is difficult to offer general conclusions about the mixtures of PPCPs found in surface waters today. Although limited data does exist for the potential of acute toxicity, this data may cloud our vision as to the subtle effects. There is plenty of evidence to suggest that this is a question of potential concern. Aquatic environments are a concern because aquatic organisms in this environment are subject to continual exposure.<sup>1</sup>

Interestingly, our regulatory system has not been designed to assess the potential risk. The Federal Drug Administration (FDA) requires Environmental Assessments (EA) under the National Environmental Policy Act of 1969 (NEPA), and the specifics for drug applications are set forth in "Guidance for Industry Environmental Assessment of Human Drug and Biologics Application."<sup>9</sup> The EA is only required if the expected concentration exceeds 1 part per billion (ppb). This does not take into account the cumulative effect of multiple drugs of similar type, each of which may be at a concentration less than 1 ppb, in the environment. In Europe, the European Commission-Pharmaceuticals and Cosmetics (EEC) responsible for regulating this process is somewhat more comprehensive. The concern is primarily acute and chronic effects as measured by traditional toxicity tests. Though provision is made for environmental effects other than toxicity, such as behavior or environmental impact, the effect must have significant intensity to be considered important. Again, this system is inadequate in assessing the effects of a variety of different PPCP compounds, many of which may act in the same or a different manner.

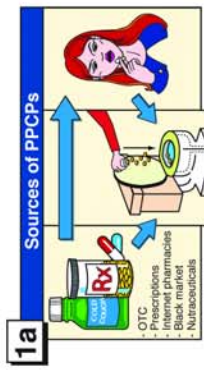
The next section of this article reviews evidence for the ecological effects of general categories of pharmacological agents. The list of medications that have not been evaluated is long. For more information, please refer to the EPA website dedicated to Pharmaceuticals in the Environment (<http://www.teleosis.org/epa/ppcp>).

*continued on page 9 . . .*

# Origins and Fate of PPCPs<sup>†</sup> in the Environment

Pharmaceuticals and Personal Care Products

U.S. Environmental Protection Agency  
Office of Research and Development  
National Exposure Research Laboratory  
Environmental Sciences Division  
Environmental Chemistry Branch



## Legend

- Usage by individuals (1a) and pets (1b):  
Metabolic excretion (unmetabolized parent drug, parent-drug conjugates, and bioactive metabolites), sweat and vomitus. Excretion exacerbated by disease and slow-dissolving medications
- Disposal of unused/outeddated medication to sewage systems
- Underground leakage from sewage system infrastructure
- Disposal of euthanized/medicated animal carcasses serving as food for scavengers (1c)
- Release of treated/untreated hospital wastes to domestic sewage systems (weighted toward acutely toxic drugs and diagnostic agents, as opposed to long-term medications); also disposal by pharmacies, physicians, humanitarian drug surplus
- Release to private septic/leach fields (3a)
  - Treated effluent from domestic sewage treatment plants discharged to surface waters, re-injected into aquifers (recharge), recycled/reused (irrigation or domestic uses) (3b)
  - Overflow of untreated sewage from storm events and system failures directly to surface waters (3b)
- Transfer of sewage solids ("biosolids") to land (e.g., soil amendment/fertilization)
  - "Straight-piping" from homes (untreated sewage discharged directly to surface waters)
  - Release from agriculture: spray drift from tree crops (e.g., antibiotics)
  - Dung from medicated domestic animals (e.g., feed) - CAFOs (confined animal feeding operations)
  - Direct release to open waters via washing/bathing/swimming
- Discharge of regulated/controlled industrial manufacturing waste streams
- Disposal/release from clandestine drug labs and illicit drug usage
- Release of drugs from aquaculture (medicated feed and resulting excreta)
  - Future potential for release from molecular pharming (production of therapeutics in crops)
  - Leaching from defective (poorly engineered) landfills and cemeteries
- Release of drugs that serve double duty as pest control agents:  
examples: 4-aminopyridine, experimental multiple sclerosis drug → used as avicide; warfarin, anticoagulant → rat poison; azacholesterol, antifipidemics → avian/rodent reproductive inhibitors; certain antibiotics → used for orchard pathogens; acetaminophen, analgesic → brown tree snake control; caffeine, stimulant → *coqui* frog control
- Ultimate environmental transport/fate:
  - most PPCPs eventually transported from terrestrial domain to aqueous domain
  - phototransformation (both direct and indirect reactions via UV light)
  - physicochemical alteration, degradation, and ultimate mineralization
  - volatilization (mainly certain anesthetics, fragrances)
  - some uptake by plants
  - respirable particulates containing sorbed drugs (e.g., medicated-feed dusts)

March 2006  
(original February 2001)

Christian G. Daughton, U.S. EPA-Las Vegas

<http://epa.gov/nreelad/chemistry/pharma/images/drawing.pdf>  
from: <http://epa.gov/nreelad/chemistry/pharma/>



## Ecotoxicological Effects of PPCPs

**Hormones:** Hormones—specifically estrogen compounds—are some of the earliest medicines reported in sewage, and they have been found in significant concentrations.<sup>10,11,12,13</sup> Synthetic oral contraceptive medication, combined with steroidal estrogens, cause feminization in male fish.<sup>14</sup> Screening for endocrine disruption is complex. Significant numbers of xenoestrogens—estrogen mimics—exist; certain PPCPs are often a subset of these mimics. Estrogen and their primary metabolites exacerbate the issue directly. (See *Symbiosis* Vol. 4, No. 1, July 2006 for more on the health effects of endocrine disruptors in the environment.)

**Antibiotics:** Due to the extensive use of antibiotics in aquaculture, veterinarian medicine, livestock, and human medicine, extensive literature exists on their environmental effects. Antibiotics enjoy widespread use, but studies show that up to 95% of antibiotic compounds can be released unaltered into the sewage system. This phenomenon may be a cause of the accelerated resistance of bacterial pathogens to antibiotics. High concentrations of antibiotics can lead to alterations in microbial community structure and affect food chains. Stream surveys document widespread prevalence of bacteria that are resistant to a wide array of antibiotics, including vancomycin.<sup>15</sup> Certain bacteria isolated from wild geese near Chicago, Illinois were reported be resistant to ampicillin, tetracycline, penicillin, and erythromycin.<sup>16</sup>

**Blood Lipid Regulators:** Perhaps the most frequently reported PPCP in Europe is clofibrac acid, the active metabolite in an array of widely used blood lipid regulators called fibrates. A report by Buser et al. found concentrations in remote lakes without any atmospheric contribution.<sup>17</sup> The research concluded that the route of introduction must be medicinal use and excretion. Of note, concentrations were similar to those of the conventional persistent organic pollutants (POPs), such as lindane.<sup>1</sup> Buser found concentrations of clofibrac acid in the North Sea (Northern Europe) to be up to 7.8 ng/L, higher concentrations than mecoprop, a pesticide structurally related to clofibrac acid. Buser's conclusion is that 50-100 tons of clofibrac acid enters the North Sea annually. Clofibrac acid is, in fact, the most widely reported drug found in open waters.

**Analgesics and Nonsteroidal Anti-inflammatory Drugs:** Diclofenac, ibuprofen, acetylsalicylic acid, ketoprofen, naproxen, indometacine, and phenazone have all been found in surface water. Heberer et al.<sup>18</sup> found that diclofenac, ibuprofen, and propyphenazone are the most commonly found drugs in the water systems after clofibrac acid. Diclofenac has been proven to be acutely toxic to vultures, decimating populations in the Indian subcontinent due to its ubiquitous use in cattle.<sup>19</sup>

**Beta-blockers/Sympathomimetics:** Metoprolol, propranolol, and nadolol<sup>20, 21</sup> have been found in surface waters.

**Antidepressants/Obsessive-Compulsive Regulators:** SSRIs or selective serotonin reuptake inhibitors, comprise a major class of antidepressants including Prozac, Zoloft, Luvox, and Paxil. A biogenic amine, serotonin is common in both vertebrate and invertebrate nervous systems. Fong found that Prozac and Luvox induced spawning in bivalves at low concentrations.<sup>22</sup> This is significant, as first noted by Daughton and Ternes, because it demonstrates the potential for dramatic physiological effects on nontarget species at low concentrations. Kulkarni et al. found that fluoxetine



Up to 95% of antibiotic compounds are released unaltered into the sewage system.

**A take-back event in the San Francisco Bay Area in California found that 45% of unused/expired medicines were flushed down the toilet and 28% were disposed directly into the trash.**

enhances the release of ovary-stimulating hormones in crayfish.<sup>23</sup> Evidence suggests that SSRIs elicit a subtle effect on aggressive behavior in lobsters, causing subordinates to engage in fighting against the dominant member, and reducing the propensity to retreat.<sup>24</sup>

**Antiepileptics:** Studies by Ternes and others have found that carbamazepine has very low removal efficiency from sewage treatment and therefore is ubiquitous.<sup>20</sup> It is the drug with the highest frequency and concentration found in his survey of German sewage treatment facilities.

**Antineoplastics:** Primarily used in hospitals, only small amounts are introduced into the environment due to their toxicity. Antineoplastics generally have longlived physiological effects and act as such in most organisms. Kümmerer et al. found ifosfamide in concentrations of up to 1.91 ug/L in the influent and effluent of treatment plants serving chemotherapy hospitals.<sup>2</sup> Kümmerer et al found this drug to be totally resistant to alteration during a 2-month bench scale simulation of sewage treatment, emerging essentially unchanged.<sup>26</sup> Kümmerer et al. also found that up to 30% of platinates including carboplatin and cisplatin reside in the body for years and are slowly excreted into residential sewage systems.<sup>26</sup> White provides an overview of the genotoxicity of wastewaters.<sup>27</sup> He found that municipal treatment plants have these compounds not just in the parts per trillion, but in parts per billion as well. Due to this data implicating antineoplastics for their ability to effect subtle genetic changes, antineoplastics are problematic.

**Impotence Drugs:** No data is available as to the toxicological effects on nontarget organisms; however, human usage has increased significantly. The physiological action of Viagra, for example, is to inhibit a phosphodiesterase. A logical concern is that this class of drugs will have the potential to disrupt phosphodiesterase metabolism in nontarget organisms.<sup>1</sup>







**Synthetic musk from perfumes, found in aquatic life including bivalves and fish, has also been identified in human breast milk!**

**Retinoids:** Retinoids have proven to have profound effects on the embryonic systems of amphibians. Though hydrophilic and photolabile, they are likely not to be persistent in the environment. However, high usage rates give cause for concern.<sup>28</sup>

**Diagnostic Contrast Media:** By design, contrast media have low physiologic activity and high persistence. The worldwide usage rate of diatrizoate and iopromide<sup>29</sup> exceeds 3000 tons, and the rate of contrast media in general is very high. The annual usage rate in Germany is 100 tons, with 95% of it unmetabolized. This leaves very high accumulations in the environment. As a class of pharmacological agents, they show no bioaccumulation potential and low toxicity.<sup>30</sup>

**Personal Care Products:** Personal care products—cosmetics, toiletries, fragrances, and the like—are marketed for use by the consumer, primarily on the human body. Many of these substances are used in extremely large quantities. Differing from drugs, personal care products are released directly into the environment, mostly through bathing, although excretion and disposal are routes of release as well.

**Fragrances:** Synthetic musks are somewhat persistent pollutants that can bioconcentrate to a limited extent; certain ones can be toxic. Musk xylol has been shown to be carcinogenic in rodents.<sup>31</sup> Significant research since 1981 shows that a variety of synthetic musks continue to be found in aquatic life including bivalves and fish. Some musks have been discovered in human breast milk, most likely due to applications in high concentrations directly to the skin. The worldwide production of synthetic musk in 1988 was 7000 tons!<sup>32</sup> Because synthetic musks are used in such large quantities and are released primarily through sewage effluent, they are prime candidates for monitoring the presence and impact of other PPCPs.<sup>1</sup>

**Preservatives:** Parabens are the most widely used preservatives in cosmetics, toiletries, pharmaceuticals, and foodstuffs. Although parabens have low toxicity levels, there is evidence for estrogenic activity.

**Disinfectants/Antiseptics:** Triclosan has been widely used for over 30 years. Commonly found in toothpaste, footwear, hand soap, and acne creams, it is registered with the EPA as an insecticide. Direct discharge into water systems is common.<sup>33</sup> McMurray et al. found it acting as a bactericide, potentially initiating resistance.<sup>34</sup>

**Sunscreens:** Concentrations of six sunscreen agents (SSA) have been found in fish on par with DDT and PCBs.<sup>35</sup> The detection of SSAs in human breast milk also suggests that they have bioconcentration tendencies.

**Nutraceuticals and Herbal Remedies:** The growth of nutritional supplements as well as herbal remedies in the past decade has been significant. Regardless of whether biological activity can be proven or not, these products still have not been classified as drugs. Herbal preparations are difficult to standardize because they rely on an array of compounds at different concentrations. Systematically, the potential effects of these products are unknown. The argument that they are natural and therefore safe is misleading, due to the fact that as supplements they are highly concentrated and thus might be found in effluent water at much higher concentrations. At the same time, these products, which are produced naturally only in certain parts of the world, end up in water systems in different parts of the world, causing exposure to organisms that have not adapted to these products naturally.

## Summary

Research to date points to the ubiquity of PPCPs in aquatic environments. Existing sewage treatment systems are not designed to remove them from the waste stream. Our current system of quantifying their toxicological effects is inadequate. Now is the time to prevent further harm to living organisms and the environment.

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**We live in a  
chemical sea.  
How we focus on a  
few of those with  
respect to hazard  
and risk is  
important.**

— Christian Daughton

## Christian Daughton and the Ecology of PPCPs: An Integral Vision

BY JOEL KREISBERG, DC, MA

“When I started giving presentations almost 10 years ago, just about everything I said was news to everyone. These days many people in the audience know a lot about pharmaceutical waste. There has been a tremendous transfer of knowledge. I hope by the end of the presentation you feel confused. This is far more complicated. It is not just this topic by itself, but pharmaceuticals as pollutants are forcing us to look at pollutants in general in a more comprehensive way” (Daughton, PhD, oral communication, April 2007).

If you want to understand the complexity behind pharmaceuticals and personal care products (PPCPs) in the environment, begin with the work of Christian Daughton (<http://epa.gov/nerlesd1/bios/daughton.htm>). Most authors who write about PPCPs are sure to have some of Daughton’s most prominent articles in their bibliography, including *Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?* (co-authored with Thomas Ternes), and *Cradle-to-Cradle Stewardship of Drugs for Minimizing their Environmental Disposition while Promoting Human Health: Part I and Part II*. Another option is *Environmental Chemistry of Pharmaceuticals and Personal Care Products (PPCPs)*, a virtual online symposium sponsored by the American Chemical Society, hosted by Christian Daughton. Daughton’s PowerPoint presentation in part of this symposium offers a clear and succinct summary of the various issues related to PPCPs.<sup>1</sup>

Much of the material in this issue of *Symbiosis* derives from the work of this accomplished scientist. Attempting to address the breadth of his work in so few pages is challenging. Among Daughton’s numerous accomplishments is the EPA’s *Scientific and Technological Achievement Award* for his seminal work on PPCPs in 1999.<sup>2</sup> His writing style is comprehensive and detailed, often integrating complex ideas from many different disciplines. He provides easily accessible and creative solutions through his elegant and often holistic perspective. On page 24 of this issue is a republished sample of Daughton’s literature. Sophisticated and well-crafted visual summaries or posters of complex concepts—such as the poster of the “4Ts: Toxicant, Totality, Tolerance and Trajectory” (see page 22)—supplement his writings. His works incorporate important philosophical principles that reveal his mastery of chemistry, biology, ecology, education, holistic thinking, environmental action, and systems analysis.

“This is a society based on chemicals. PPCPs are an example of pollutants that we haven’t look at before; they are only a fraction of the chemicals used in commerce.





**One action for a healthier future for people and the environment is simple, if not easy, stop throwing PPCPs into the waste stream.**

We live in a chemical sea. How we focus on a few of those with respect to hazard and risk is important. It's a hard thing to reconcile with our sense of risk" explains Daughton (Daughton, PhD, oral communication, April 2007). In "Green Pharmacy," a monograph in *Environmental Health Perspectives*,<sup>3,4</sup> Daughton discusses "the concepts of environmental surprise" and the "precautionary principle." He says, "Miniscule differences in initial conditions can lead to differences far out of proportion in the system's subsequent behavior...minor perturbations can essentially be slowly amplified to yield major effects."<sup>3(p762)</sup> Daughton makes the scientific case for how changes in individual behavior and changes in larger systems such as the environment are connected. He points out that in toxicology, the process of cause and effect is quite different for single organisms than it is at higher levels of organization (e.g., communities and ecosystems), "because of the myriad interactions and spatial relationships within the system—some imparting vulnerability to synergistic effects."<sup>3(p762)</sup> Irreversible change occurs when perturbations exceed a system's resilience. To summarize, accumulating evidence suggests that "although it may never be possible to gauge precisely humanity's contribution to adverse environmental or human health events or outcomes, it might behoove us to eliminate as many extraneous variables (impacts) in ecosystems as possible—regardless of their perceived immediate importance."<sup>3(pp762-763)</sup>

Daughton's argument that small decisions have the potential to create significant changes is logical, clear, historically relevant, and persuasive. Insisting that we must be cautious about what we dump into the environment, he advocates for the precautionary principle: "The principle of precautionary action redistributes the burden of proof because the science required for truly and fully assessing risks lags far behind what is needed."<sup>3(p763)</sup> The shift here is from science to action: "Science in the face of uncertainty, must be melded with policy and political judgment to arrive at a course for further study or action."<sup>3(p763)</sup> He notes that precautionary principles are emerging as environmental considerations are melding market imperatives. In simple terms, environmental stewardship yields economic benefits.

Daughton offers a visionary solution to the problems we are creating with PPCPs: "A proactive, voluntary holistic stewardship program for PPCPs would be preferable to a reactive, prescriptive regulatory program. By focusing on a mind set toward holistic, thoughtful environmental responsibility rather than rote compliance to regulations, all aspects of society can play integral roles."<sup>3(p763)</sup> Daughton's perspective is integral. "An integral worldview occurs when pluralism and relativism are transcended to include a more systemic whole. The beginning of an integral worldview allows for healthy value distinctions, acknowledging previous stages and integrating them without trying to change them."<sup>5</sup>

Daughton not only offers a pluralistic understanding of the many facets of the ecology of PPCPs, but also analyzes and evaluates potential opportunities. Expertly integrating many perspectives, he points out what each has to offer and enables readers to grasp the difficult and complex concepts surrounding the human use of PPCPs. His superb articulation of the issues offers the most helpful guide available to thinking through this thorny problem. Together, we can implement the clear and actionable solutions he outlines. "The ultimate question for physicians is, if we can get to the point where we have no leftover drugs, will that lead to improved therapeutic out-



**The ultimate question for physicians is, if we can get to the point where we have no leftover drugs, will that lead to improved therapeutic outcomes?**

comes? The right drug, at the right time, in the right amounts? Is the measure of unused drugs a way to determine the efficacy of the treatment?" (Daughton, PhD, oral communication, April 2007). Daughton reminds us that we do have a choice. A healthier future for people and the environment is simple, if not easy: stop the need for throwing PPCPs into the waste stream.

A significant part of the solution, Daughton explains, is *cradle-to-cradle stewardship*: "The fusion of ecology and marketplace imperatives has perhaps emerged most noticeably in the relatively recent product management philosophy termed 'cradle-to-cradle'...the incorporation of 'eco-effectiveness,' and 'ecologic intelligence' into life-cycle considerations for product development and use."<sup>3(p764)</sup> Cradle-to-cradle product stewardship is not only required for PPCPs, it is essential to all consumer goods and aspects of the built environment.

Daughton observes that while "The Institute of Medicine (IOM) Committee on Quality of Health Care in America...goals are far-reaching and urgently needed... [they] do not include the concept of ecology of health. Safety of the patient is pursued out of context of the safety of the ecology."<sup>3(p764)</sup> Daughton's critique is imperative for the future of the health of people and the environment. "With a little expansion of the IOM vision, an integration of human and ecological health could be formalized at a national level through their efforts. High-quality health care and environmental protection need not be competing goals—they are intimately linked."<sup>3(p764)</sup>

Christian Daughton is passionate in pursuing his goal of shedding light on the nature of a complex phenomenon—the effects of PPCPs in the environment. His integral and holistic vision identifies current efforts to solve these problems that are already under way and provides a unique forum for dialogue. In his words: "I hope these disparate professional communities will find compelling reasons to cross-communicate and, in doing so, expand their knowledge and effectiveness in their own fields."<sup>3(p765)</sup>

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## Water Quality: Key to Many Doors in the 21st Century

*The following is an excerpt from: Daughton C. Cradle-to-cradle stewardship of drugs for minimizing their environmental disposition while promoting human health. I. Rationale for and avenues toward a green pharmacy. Environmental Health Perspectives. 2003 May; 111(5): 763–765.*

The growing, cardinal importance of water for sustaining societies is becoming more widely recognized as recently evidenced by its central role in the Broadway musical *Urinetown* (2002). The story is set at a time when “water is worth its very weight in gold”: A depletion of the earth’s water supply has led to a government enforced ban on private toilets. The privilege to pee is regulated by a single, malevolent corporation, which profits by charging admission for one of mankind’s most basic needs.

A backdrop to the precautionary principle is the growing imperative for water reuse, which will prove to be the key, critical driving force for management of water quality in the 21st century. The NRC, as requested by the National Science Foundation (NRC 2001), synthesized the broad expertise from across the many disciplines embodied in environmental science to offer its judgment as to the most significant environmental research challenges of the next generation—based on their “potential to provide a scientific breakthrough of practical importance to humankind if given major new funding.” Of the eight “grand challenges” identified in the NRC’s report, two involve water quality issues, both relevant to PPCPs: a) hydrologic forecasting (for predicting changes in freshwater resources as a result in part of chemical contamination) and b) reinventing the use of materials. The impetus driving the second is that new compounds and other substances are constantly being incorporated into modern technology and hence into the environment, with insufficient thought being given to the implications of these actions. All of these issues assume added importance in urban areas, which concentrate flows of resources, generation of residues, and environmental impacts within spatially constrained areas. From a policy standpoint, reliable predictive models of material cycles could be invaluable in guiding decisions about . . . topics relating to human-environment interactions. . . . This grand challenge centrally encompasses questions about societal-level consumption patterns, since consumption is the primary force driving human perturbations of material cycles. (NRC 2001, p. 55)

Likewise, the World Health Organization’s (WHO) World Water Day Report draws international attention to the intimate connection between water and health:

**A healthier future  
for people and the  
environment is  
simple, if not easy:  
stop throwing  
PPCPs into the  
waste stream.**



**Ecologic stress is reflected by stress in humans—the two are intimately tied.**

Due to a mix of geographical, environmental and financial factors, as well as to increased pollution from municipal and industrial waste, the leaching of fertilizers and pesticides used in agriculture, only about one-third of the world's potential fresh water can be used for human needs. As pollution increases, the amount of usable water decreases. (WHO 2001, p. 7)

Links to numerous resources regarding freshwater can be found at the World's Water website (2002). The concept of the "ecological footprint" (Wackernagel and Rees 1995) also highlights the central importance of water. Residents of industrialized countries may need an average of 10-22 acres per capita to support an urban lifestyle. One of the major issues facing water resource managers in the 21st century will be to understand the overall impact of the urban ecologic footprint on water resources. Although there are numerous consequences of the footprint, a major concern may be the continued use of urban waterways as "waste receptacles"—merely for diluting and transporting downstream the by-products of urban consumption.

Although this background material emphasizes the aquatic environment, it is important not to lose sight of the other environmental compartments with which PPCPs can interact. The most significant of these secondary concerns is sewage sludge, to which certain PPCPs can sorb or partition. Subsequent application of sewage sludge ("biosolids") to land (e.g., as a soil amendment) holds the potential for exposure of terrestrial ecosystems. The NRC revisited the issue of biosolids (NRC 2002b; see especially chapters 5 and 6) with respect to reevaluating the approach used by the U.S. EPA in setting its chemical standards for the biosolids rule (U.S. EPA Office of Wastewater Management 2002b). The NRC recommended that "a research program be developed for pharmaceuticals and other chemicals likely to be present in biosolids that are not currently included in routine monitoring programs." The NRC also recommended that alternative (i.e., nontraditional) toxic end points be considered.

## Health of Ecology versus Ecology of Health

The intimate, inseparable connections between humans and the environment (actually, humans can be viewed as an integral part of the environment) have been discussed widely in many contexts. By applying principles of medicine and public health to the environment, David Rapport formalized the concepts of "ecologic health" and "ecosystem medicine" (Rapport 2002). The "health of ecology" refers to ecosystem health; the "ecology of health" refers to human health as determined partly by the condition of ecology (creation and transmission of antibiotic resistance is one example). Ecologic stress is reflected by stress in humans—the two are intimately tied. Adverse effects in one are eventually reflected in the other. The Institute of Medicine (IOM), a private, nonprofit institution that provides health policy advice under a congressional charter granted to the National Academy of Sciences, has called for a revolution and is reengineering all aspects of the health care system in the United States. A major objective of the IOM Committee on Quality of Health Care in America (formed in June 1998) was to develop a national strategy to radically improve the quality of U.S. health care within 10 years. To date, their recommendations (e.g., IOM, 2001; Kohn et al. 2000) address the many aspects of patient safety and how the concepts of quality systems can be applied.





**Due to a mix of factors, including pollution, only about one-third of the world's potential fresh water can be used for human needs.**

Although the IOM's goals are far-reaching and urgently needed, they do not include the concept of ecology of health. Safety of the patient is pursued out of context of the safety of the ecology. With a little expansion of the IOM vision, an integration of human and ecologic health could be formalized at a national level through their efforts. High-quality health care and environmental protection need not be competing goals—they are intimately linked.

## Connecting Health of Ecology and Human Health: Health Promotion and Social Entrepreneurs

The specific environmental issues and the example solutions posed in this mini-monograph are not as pertinent to those parts of the world where PPCPs are little used, such as economically disadvantaged regions [except in areas where large-scale drug disposal occurs, e.g., from humanitarian operations (WHO 1999)] or where illicit drug manufacturing or use is prevalent (Daughton 2001c). Nonetheless, the basic, universal concept of a “health state” (rather than an “absence of illness”)—one of a balanced and interconnected physical, mental, social, and spiritual well-being—is equally applicable to Western cultures and could have a profound impact on overall drug use (both licit and illicit). Treatment of physiologic and psychologic symptoms and even the curing of diseases are just one dimension of holistic health—and in many respects, preventive and curative approaches are but stop-gap measures in the absence of a sustainable environment. For example, one can argue that the single most important limitation in the continual quest to eliminate infectious diseases is not the lack of medication but rather the failure to address poverty and its attendant liabilities of hygiene and malnutrition.

Many people actively engaged in advancing the principles of “sustainability” (sometimes defined as meeting society's needs in ways not diminishing the capacity of future generations to meet theirs) have strongly felt that without empowering people to take charge of the basic aspects of their own lives, sustainable improvements in health are not possible. A model effort (Comprehensive Rural Health Project) begun in 1970 by the Indian medical doctors Raj Arole and Mabelle Arole has demonstrated how a holistic approach builds a foundation for sustainable living and only then is advancement in improving health possible. Health cannot be dissociated from all the other aspects of sustainable living (Arole 2001); the burgeoning field of sustainability is captured by the Initiative on Science and Technology for Sustainability (ISTS 2002), among others. Social entrepreneur projects in health promotion (vs. illness/disease prevention), such as those begun by the Aroles, abandon narrow technical objectives aimed at preventative and curative measures in pursuit of wider-ranging holistic goals that emphasize the interconnectedness of social systems.

## Cradle-to-Cradle Stewardship

Guided by the interrelationships among the precautionary principle, the ever-increasing and key worldwide importance of water, and the idea of “ecology of health,” the incorporation of “eco-effectiveness,” “ecologic intelligence,” or cradle-to-cradle design



**One of the tenets of this philosophy for a truly sustainable industry is that it benefits not just the environment but also consumer and corporation.**

concepts into life-cycle considerations for product development and use has gained momentum in the last decade. The idea of cradle-to-cradle stewardship has most recently been embraced by many international corporations. Some of the more visible and successful proponents of cradle-to-cradle concepts have been William McDonough and Michael Braungart (MBDC 2002; McDonough and Braungart 2002). They have been leaders in implementing the idea of full life-cycle product design, referring to this approach as the “next industrial revolution.” One of the tenets of this philosophy for a truly sustainable industry is that it benefits not just the environment but also consumer and corporation; this is one reason for the expression sometimes used for these programs: “waste to wealth.” Numerous similar efforts have been successfully under way; examples include those with such monikers as “Zero-Waste” and “Zero Emissions,” being implemented in Canada by the Recycling Council of British Columbia (RCBC 2002). Another effort toward directing organizations toward sustainability is being led by the international organization The Natural Step (TNS 2002). Of the “four system conditions” that The Natural Step framework is based on, the second states that “in a sustainable society, nature is not subject to systematically increasing concentrations of substances produced by society.” It is worth noting from an historical perspective, however, that the idea of sustainability was put forth decades ago, as early as 1966 (Blutstein 2003).

The United Nations Environment Programme (UNEP 2002) notes that although significant efforts in reducing environmental footprints have been made by a few companies across many industrial sectors, a gap continues to widen between these few and the vast majority that continue “doing business as usual.” Among the five major areas for advancement toward true sustainability identified in UNEP (2002), the fourth is the “integration of social, environmental and economic issues.” These efforts hint that a sustained future viability of this product life-cycle philosophy can be expected. A wide range of strategies that could foster a cradle-to-cradle approach for stewardship of PPCPs by the pharmaceutical/medical care industries could be adopted. Some could be implemented quickly (requiring only a collective will to implement them); others would require sustained research and development efforts (which in some cases are already under way, albeit for reasons unrelated to environmental benefits), and some would require major attention by the numerous agencies involved with a patchwork of laws and regulation of drug recycling and disposal. Several examples are outlined in various sections of this mini-monograph.

### **Viabile Options for Minimizing the Introduction of PPCPs to the Environment**

Numerous actions could be implemented in the near term for reducing what risks might exist from introducing PPCPs to the environment. In the longer term, a number of research avenues could be pursued regarding drug design, packaging, and delivery—all of which could provide environmental (as well as consumer) paybacks. Indeed, some of these are already being pursued. Many would yield direct benefits to human health for reasons unrelated to any environmental imperative, including reducing inappropriate drug use and lowering therapeutic dosages [thereby lessening adverse drug reactions (ADRs) and reducing consumer costs].



**Health cannot be dissociated from all the other aspects of sustainable living.**

Many pharmaceutical producers and organizations have “product stewardship” as an integral part of their business. These programs, however, although sometimes acknowledging the issues associated with consumer use of PPCPs, tend to focus on aspects of the manufacturing process (vs. distribution and use) as well as on hospital waste (Daughton/U.S. EPA 2002e). A potential mechanism for effecting change in the health care industry (starting with hospitals) is via an existing program established under a program agreed to in 1998 by the American Hospital Association and the U.S. EPA and administered by the Hospitals for a Healthy Environment (H2E 2002). This program’s overall goal is to reduce the impact of health care facilities on the environment. Although the program initially focused on eliminating mercury and reducing total waste volume, a future area to consider is development of model chemical waste minimization plans such as that developed for mercury by H2E (2002).

Some of the ideas presented below may prove controversial. I highlight them solely to generate an active dialog or debate across the many disciplines that must become involved to successfully address this topic. Many of these disciplines have never before had reason to interact or collaborate with each other. With the increasing visibility of PPCPs as pollutants, I hope these disparate professional communities will find compelling reasons to cross-communicate and, in doing so, expand their knowledge and effectiveness in their own fields.

### **Avenues for Progress toward a “Green Pharmacy”**

The last decade has seen tremendous progress in advancing the practice of “green chemistry” (e.g., minimizing the use of ecologically hazardous reagents and designing alternate synthesis pathways, some of which are based on aqueous chemistry) (U.S. EPA Office of Pollution Prevention and Toxics 2002). In fact, the pharmaceutical industry has a strong history of applying environmentally responsible chemistry (which also turns out to be economically advantageous) to drug synthesis and manufacturing. The same principles could be logically extended and applied to drug design, delivery, package design, dispensing, and disposal so that their benefits could accrue to the end user and not just the manufacturer. Some of these ideas for minimizing the release of PPCPs to the environment have already been put forth (Daughton and Ternes 1999) but are reiterated and expanded on here because all these ideas have never been brought together in one document. Unfortunately, despite the many avenues of advancement that could be—and sometimes are already being—made toward a green health care system, the transfer of new knowledge and technology to clinical practice is notoriously slow; as one example, new knowledge gained from clinical trials takes an average of 17 years to become incorporated into routine practice (IOM 2001).

*To view the full article, or references for this excerpt, visit [http://www.teleosis.org/public\\_html/pdf/CradletoCradlePt1.pdf](http://www.teleosis.org/public_html/pdf/CradletoCradlePt1.pdf)*

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**Assessing exposure to multiple chemicals requires an all-inclusive systems perspective.**

## The 4 Ts: Assessing Exposure to Multiple Chemicals

BY JOEL KREISBERG, DC, MA

*please see the chart on page 23*

Humans, like most life forms on Earth, are bombarded daily with multiple chemicals. Rarely are we exposed to a single, isolated chemical stressor. In analyzing the effects chemicals have on organisms, toxicologists traditionally have focused on a select number of pollutants regarded as “high volume” chemicals; but these represent only a small sample of the substances most organisms are exposed to on a regular basis. Although this type of research is valid and relevant, investigating the effects of one chemical on organisms or ecological systems may not be the best way to understand the toxic effects of multiple chemicals. Due to the large number of chemicals introduced into the environment in the 20th century, this approach does not account for many biologically transformed metabolites and other naturally occurring toxicants.

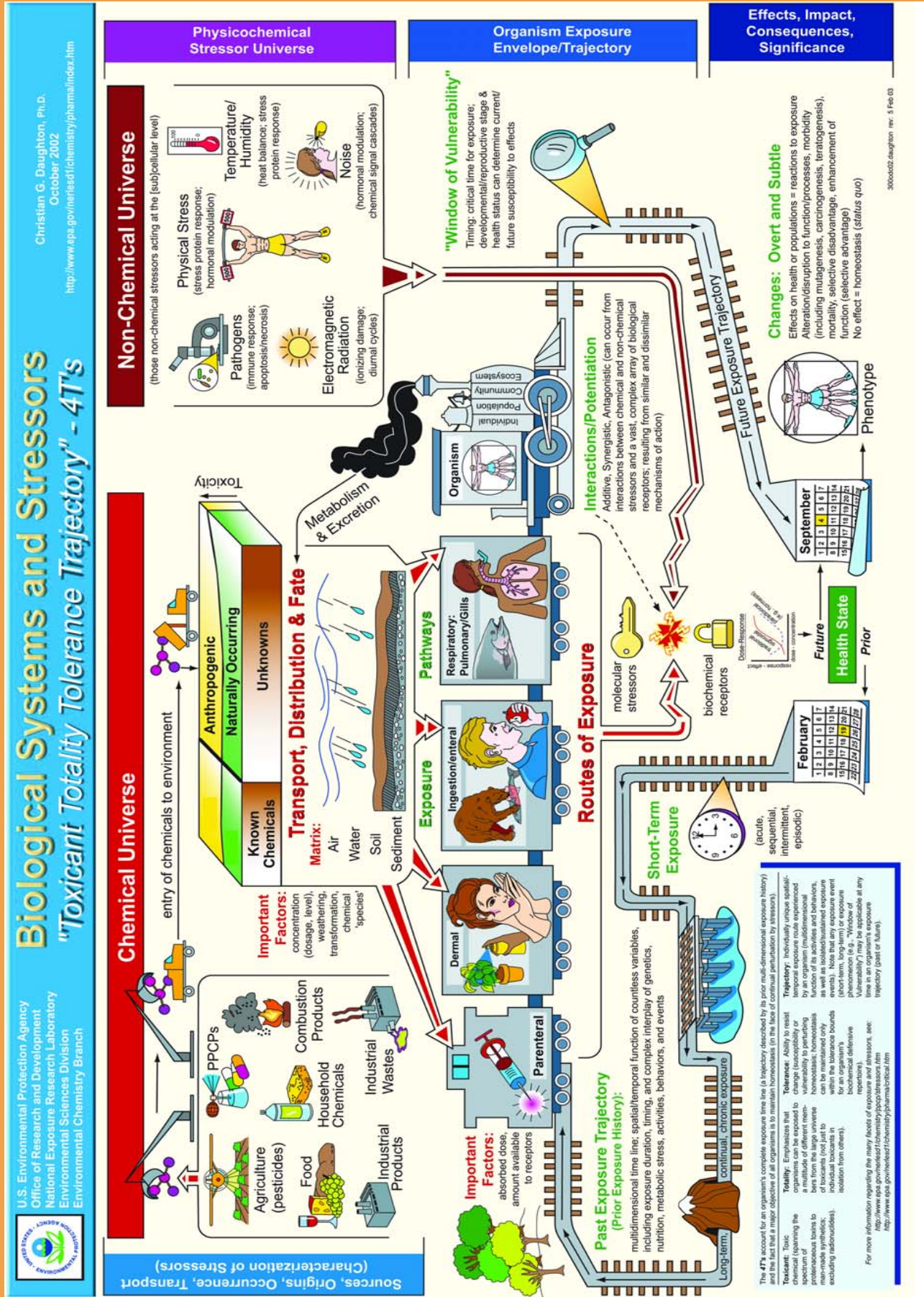
Assessing exposure to risk for multiple chemicals requires an all-inclusive systems perspective, and EPA senior scientist Christian Daughton has developed such a model: it outlines a way to conduct a holistic assessment of chemical exposure as it actually occurs in the real world. Dubbed “The 4Ts,” the model’s four primary categories are Toxicant, Totality, Tolerance, and Trajectory.<sup>1</sup> Daughton says, “The paradigm of the 4T’s sets the stage for the overall true risk as reflected by the sum total of exposure of all toxicants (anthropogenic [or created by humans] and naturally occurring) throughout the historical multidimensional space and trajectory of all other exposure variables.”<sup>2</sup>(p15) The categories encompass not only individual offending substances (toxicants), but the entire world of stressors (totality), the vulnerability of an organism (tolerance), and combined history of an organism’s exposure (trajectory) in assessing risk.

### Holistic Exposure Assessment: Toxicant, Totality, Tolerance, Trajectory

In addition to exposure to chemicals, multiple nonchemical stressors—physical, biological, and psychological—effect organisms and react in complex, often synergistic, ways. An individual organism’s vulnerability varies depending upon a variety of condi-

*continued on page 24 . . .*





## Holistic Exposure Assessment

### Toxicants

Naturally occurring and human-made toxicants that enter organisms through respiration, ingestion, dermal exposure, or parenteral (intravenously)

### Totality

All stressors including exposure to chemicals

### Tolerance

Ability to resist change at organismic level—determined by fitness and genetics

### Trajectory

Long term, intermittent, episodic, and acute—past and potential future cumulative exposures to toxins

tions; for humans, our developmental stages are one particularly important variable. For example, gestation and early childhood are more vulnerable stages of the human life cycle. Different toxicant dose concentrations and exposure duration—for example, lower doses for longer periods of exposure—may increase risk during these periods.

The macro-environment continues to accumulate “toxicants”—both naturally occurring and anthropogenic toxic chemicals. Chemicals may enter biological organisms in 4 ways: respiration, ingestion, dermal exposure, or parenteral (direct entry into the organism, e.g. through intravenous injection, such as a vaccine).

Rather than considering a one-time exposure to a single toxicant, it is important to take account for total number of past and present exposures, which occur in temporal patterns along a trajectory—long term, intermittent, episodic, and acute. This gives a more accurate picture of the organism’s exposure by looking at the duration and concentration of individual toxicants as well as all previous toxic exposures. This “totality” may be synergistically enhanced or resisted by nonchemical stressors—such as pathogens, electromagnetic radiation, physical stressors, temperature/humidity, emotional stress and noise—that affect the organism.

An organism’s “tolerance,” which accounts for its ability to resist change at the organismic level, is determined by its general fitness and genetic disposition. Various chemical and nonchemical stressors challenge the individual’s capacity for maintaining homeostasis, i.e., the tendency to return to a healthy physiological equilibrium.

The “trajectory” encompasses not only past cumulative exposures but also future exposure; this is a more accurate picture of overall exposure and resulting risk over time. Key to the 4Ts model is the critical state, which is defined as the “state at which an additional single exposure event can result in irreversible adverse effect, one that pushes the organism beyond its ability to maintain homeostasis.”<sup>2(p15)</sup> In humans, we call this state disease.

The 4Ts model offers a more sophisticated and systemic approach than previously available for addressing the complex distribution and effects of multiple chemical exposure on living organisms. The significance of this model will emerge as toxicologists and physicians begin to utilize this valuable resource.

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- 2 Daughton, CG. Emerging chemicals as pollutants in the environment: A 21st century perspective. *Renewable Resources Journal*. 2005; 23(4):6-23. [full text PDF also available at: [epa.gov/esd/chemistry/ppcp/images/iom-2003.pdf](http://epa.gov/esd/chemistry/ppcp/images/iom-2003.pdf)]. U.S. Environmental Protection Agency: National Exposure Research Laboratory
- 3 Environmental Sciences. Biological Systems and Stressors. Available at: <http://www.epa.gov/nerlesd1/chemistry/ppcp/stressors.htm>. Accessed April 16, 2007. [Pictorial representation of model available at: <http://www.epa.gov/esd/chemistry/ppcp/images/stressor.pdf>]

# Green Pharmacy: Preventing Pollution

## A Cross Sector Approach

BY JOEL KREISBERG, DC, MA

*The recent increase in awareness of environmental issues is creating an opportunity for all constituencies involved with PPCPs to take action and reduce potential harm. A “cross-sector” approach offers a systems perspective that includes all individuals and organizations involved with the production, distribution, consumption, and disposal of pharmaceutical medicine. For pharmaceutical pollution, the solution calls upon all sectors involved in health care—pharmaceutical developers and manufacturers, hospitals, individual physicians and all those involved in the health care system, law enforcement agencies, pharmacies, waste management agencies, consumers, environmental protection organizations, and governmental agencies—to participate in preventing pharmaceutical pollution. This powerful approach provides a comprehensive solution to an issue that has the potential to affect much of life on Earth.*

## The Manufacturing Sector

The manufacturing of medicine is ripe for leadership. In the past decade “green chemistry,” which minimizes the use of toxic chemicals in design and production, has emerged (see side bar on pg 37) as a technological advancement in the research and development of new pharmaceutical treatments. As manufacturers become more responsive to concerns about environmental hazards and sustainability, production techniques that lower the overall impact on the environment are becoming increasingly important. From a product standpoint, this sector is developing a new model of “product stewardship”—a “cradle-to-cradle” strategy for developing a new product. While all those involved in the production, distribution, sale, and use of any drug should be involved with product stewardship, the manufacturing sector is in the best position to reduce the environmental impact of medicines, because a product begins with development and manufacturing. If the process begins with cradle-to-cradle stewardship, it is more cost-effective and environmentally sensitive.

One way manufacturers can exercise healthy product stewardship is to design drugs that are more ecologically sensitive and medicines that biodegrade more

**Dispose Medicines  
Wisely**

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**Pharmaceutical developers and manufacturers, hospitals, individual physicians, law enforcement agencies, pharmacies, waste management agencies, consumers, environmental protection organizations, and governmental agencies—all can help prevent pharmaceutical pollution.**

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quickly and yield end products that are less harmful. Innovative drug design can improve delivery systems to require lower doses for efficacy; shifting from the current system of averaging, the practice of refining a medication's expiration date can bring shelf life into closer alignment with real time; recyclable materials can be used for packaging, or package size can be reduced to minimize the unused portion of prescriptions; and more complete and direct information about proper disposal techniques can be added to packaging.

The pharmaceutical industry is in an excellent position to provide more information directly to physicians. The European pharmaceutical industry is currently implementing a system in which medicines are graded for persistence, bioaccumulation, and toxicity (PBT). This information will be available to prescribing physicians, who will be in a position to make healthier environmental choices (see our Spotlight article on the Stockholm County Council on page 45). As is already happening in Canada, Australia, and New Zealand, our pharmaceutical industry could provide funding for the proper disposal of unused or expired medicines. Such initiatives might promote advanced recycling strategies, which would require changes in the current laws for drug handling in America. The pharmaceutical industry could also devote a portion of its huge advertising campaign to educate both physicians and consumers about the environmental and health issues associated with PPCPs.

## Health Care Systems

### Hospitals

Model solutions already exist for the medical industry. Those involved in hospital medicine are already developing methods for proper disposal. Hospitals for a Healthy Environment (H2E) (<http://www.h2e-online.org/>) is collaborating with many major hospitals in the United States, initiating proper disposal of hospital wastes. In May 2007, H2E's Environmental Excellence Summit focused on pharmaceutical waste management. Since much of medicinal waste is generated by hospital medicine itself, there is no reason why hospitals cannot be regional centers for "take-back" programs, where patients and consumers can easily return unwanted and expired medicines. With a high concentration of physicians and nurses, hospitals also offer an opportunity to expand the educational content required of the medical profession.

### Physicians, Veterinarians, and Dentists

Individual physicians must also participate in the solution. Any medical office can offer a take-back program. Physicians, as the first line in any health care strategy, can inform patients about healthy product stewardship. The time when a doctor is prescribing a medication is an ideal moment to educate patients about proper disposal habits. Imagine receiving a phone call from your medical office reminding you not only about your next appointment but also to bring your expired and unused medicines with you. Veterinarians and dentists can take these steps as well. Domestic animals are the object of increasing amounts of PPCPs in medicine. These offices, too, can participate in proper disposal programs.





**At least \$1 billion worth of unused drugs are flushed down the toilet each year.**

## Pharmacies and Law Enforcement Agencies

To date, many of the proposed solutions for proper disposal of PPCPs are focused on two sectors, pharmacies and law enforcement. Pharmacies seem a natural fit for proper disposal of medication, and in fact some pharmacies serve as take-back sites for proper pharmaceutical disposal. In British Columbia, 95% of all pharmacies have recycle bins, which allow consumers to bring their unused/expired medicines back whenever they shop. Because certain medications find their way into an illicit drug market, law enforcement agencies sometimes participate in take-back programs to ensure that these substances are handled only by a pharmacist, physician, or police officer. Take-back events and selected programs at police stations are helpful, but are less accessible.

## Hospice

One sector of the health care system that relies most heavily on medication is hospice. Researchers estimated in 2003 that at least \$1 billion worth of unused drugs are flushed down the toilet each year.<sup>1</sup> Senior centers and home hospice care should consider several types of disposal systems. Current hospice protocol is to have families dispose of medicine; unfortunately, it is often disposed of improperly. These medicines are typically good quality medicines that could easily be reused for others in need. While regulations prevent hospice workers from reverse handling of medicine, families could return unused medicines to proper disposal facilities, or investigate if long term care facilities in your area accept unused dispensed medications. Senior centers, too, can offer educational outreach and take-back services.

## Waste Management Agencies and Environmental Organizations

Waste management agencies have an interest in seeing that PPCPs are disposed of properly. Municipal water agencies in particular are developing policies that maintain proper water quality. Some agencies are proposing regulations that would prevent hospitals from disposing medicines directly into the municipal water system. Solid waste organizations too, have a similar interest, though unused medicines make up a relatively small percentage of solid waste. Most solid waste systems in the U.S. request that unwanted medicines be returned to hazardous waste facilities. However, only a very small percentage of household medicines are hazardous wastes (see page 39), and pound for pound, hazardous waste is much more expensive to handle. Since many medications are not hazardous, significant money can be saved by separating most drugs out of the hazardous waste stream.

Other approaches to drug recycling do exist. For manufacturers, “reverse-distribution,” which allows pharmacists to return unsold drugs back to the manufacturer, could be enlarged to include unused medication and expired medication.

While human health is very important, water quality needs to be preserved for nonhuman life as well. Many environmental organizations that support wildlife and aquatic ecosystems are supporting take-back programs. In Oakland, California, for example, Save the Bay is actively involved in preventing PPCP pollution.

**What you can do**

- Dispose of unused or unwanted medications at take-back sites or events only
- Do NOT dispose of any medication down the toilet or in the trash
- Purchase drugs in small amounts, limiting expired medications
- Ask for medications with low environmental impact
- Encourage your provider to take-back non-controlled unused/expired drugs.
- Commit to health prevention strategies to reduce your reliance on medications

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**Consumers**

Finally, consumers need to participate in keeping our environment clean. Each of us has a responsibility for healthy product stewardship of all consumer goods. Rather than throwing medicine down the toilet or in the garbage, bring non-controlled drugs to a take-back site or hazardous waste facility. Buy smaller containers of medicines. Buy products with recyclable packaging. Ask your doctor about environmental impacts of your medication and whether a more sustainable alternative exists. Always choose the smallest prescription amount or refill option unless the medication is for a chronic condition. Encourage your physician or primary care provider to take back unused/expired, non-controlled medicines. Most importantly, commit to health promotion strategies that reduce your need for medication in the first place. When given a choice, always choose sustainable medical treatments first, reserving more problematic choices for more difficult situations.

Unused medications may be donated to nonprofit organizations that redistribute medicines to charitable organizations in non-industrial countries that need basic medications. Green funeral practices are emerging as an alternative to traditional practices that release significant chemicals into the environment.





**Commit to health promotion strategies that reduce your need for medication in the first place—if there is a choice, always choose sustainable medical treatments first, reserving more problematic choices for more difficult situations.**

## Who Pays?

Perhaps the most contentious aspect of proper disposal of PPCPs is cost: Who should pay? No one wants to pay the additional cost for proper product disposal. In many sectors of durable goods or consumer goods, particularly electronics, the cost of disposal is beginning to be included in the cost of the product. For consumers, this is the preferred method, although a fee added at time of purchase, called an “advanced recycling fee” (such as the system for beverage bottles and cans), allows users to pay as they go. When this is mandatory, however, it feels like a tax. Many of us remember the struggle to get “bottle bills”—an added fee on bottles—passed in state legislatures. Perhaps medications can be handled that way, although experience shows that the public is not easily persuaded to mandate such fees.

The product stewardship model suggests that the cost be spread throughout the life cycle of the product and that the proportion of cost be distributed by the ability of the party to have a significant impact.<sup>2</sup> Applying this model, pharmaceutical companies would provide the largest proportion of investment. To date, this is how Europe and other industrialized countries are building capacity.

But healthy product stewardship requires everyone's participation. In addition to manufacturer involvement, we need to shift our focus to actions and processes that reduce the need for disposal, thereby reducing household accumulation of unwanted drugs. Currently our focus is on prudent disposal options, but we need to address this problem at the source rather than further downstream at the consumer/patient level. We need to aim for a healthcare-consumer system that results in fewer medications needing disposal. Each one of us can contribute to a healthier home for all of us on planet Earth—just by making the better choice.

## Everyone Participates

Green Pharmacy offers an opportunity for social action that will greatly benefit our environment at all levels of our society. With relatively simple yet firm commitments to change our habits, becoming stewards of medicine rather than consumers of medicine we effectively become part of the solution. Ideally, there would be no drugs to return. Until that time, all prescribed medicines would be brought back in subsequent visits to a physician, veterinarian and dentist. Manufacturers and pharmaceutical distributors would facilitate medical, dental and veterinarian offices in disposing of these medicines wisely. Consumers willingly participate by returning unused medication. Green Pharmacy is a commitment we undertake today. Our vision is zero waste. Our simple actions have a positive effect of the health and vitality of our world. It requires a commitment to restore that each of us carries in our hearts a vision of a sustainable healthy future.

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Learn What You  
Can Do To Prevent  
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Pollution

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## Facts on Pharmaceuticals and the Environment

- **80% of the 139 U. S. streams tested were contaminated with organic wastewater contaminants (OWCs), including pharmaceuticals (hormones, steroids, antibiotics, and other prescription drugs as well as nonprescription drugs).**

[USGS. Pharmaceuticals, hormones, and other organic wastewater contaminants in U. S. streams, 1999-2000: A national reconnaissance. *Environmental Science & Technology*. 2002; 3(6):1202-1211] and [toxics.usgs.gov/pubs/FS-027-02/pdf/FS-027-02.pdf. Accessed 11/1/06.]

- **Medications are discontinued by physicians 27% of the time because they are no longer needed or suitable for the patient.**

[Paone RP, Cogenberg FR, Caporello E, Ruthkowski J, Parent R, Fchetti F. Medication destruction and waste measurement and management in long-term care facilities. *Consultant Pharmacist*. 1996;11(1). Available from: <http://www.ascp.com/public/pubs/tcp/1996/jan/mdwm.html>. Accessed September 15, 2006.]

- **Costs associated with long-term care facilities' unused medications are between 4%-10% of the total dispensed costs.**

Congressman Tim Murphy Web site: RX: Healthcare FYI #10/Stop wasting prescription drugs. 2005. Available at <http://murphy.house.gov/News/DocumentSingle.aspx?DocumentID=26255>. Accessed 11/04/06

- **90% of medication waste results from "discontinuation or change in medication or death, transfer, or hospitalization of the resident."**

AMA. 2001. Report 2 of the Council on Scientific Affairs (I-97) Full Text: Recycling of Nursing Home Drugs. Chicago: American Medical Association. Available at <http://www.ama-assn.org/ama/pub/category/13655.html>. Accessed August 30, 2006.

- **In a survey on pharmaceutical waste pollution, only 1.4% of people returned medications to a pharmacy; 54% disposed of medications in the garbage; 35.4% flushed medications down the toilet or sink.**

Columbia University Web site. Pollution prevention measures for unwanted pharmaceuticals 2005. Available at [http://www.seas.columbia.edu/earth/wtert/sofos/Gualtero\\_IETerm.pdf](http://www.seas.columbia.edu/earth/wtert/sofos/Gualtero_IETerm.pdf). Accessed November 1, 2006.

- **For medications that are not returnable: 15% are incinerated; 17% are directed to hazardous waste handlers; 68% are disposed to solid waste or the toilet.**

Kuspis DA, Krenzelok EP. What happens to expired medications? *Veterinary and Human Toxicology*. 1996;38(1):48-49.

- **Reducing a prescription's supply to 28 days could reduce the need for discarding by as much as 30%.**

Blanchard B. 1998. Medication wasteland: Can we care for the environment as our patient? Toronto: Pharmacy Practice, Rogers Media. Available at: <http://www.pharmacygateway.ca/pastissue/content/phpractice/1998/11-98/php119804b.jsp>. Accessed September 3, 2006.





**Deteriorating human and environmental health is forcing us to change how we understand the life cycle of pharmaceuticals and personal care products.**

## Ecological Economics and the Drug Life Cycle: The True Cost of Medicine

BY NIYATI DESAI, MA

*Ecological economics recognizes that humans and their economies are parts of larger natural ecosystems and coevolve with those natural systems. . . Some concept of value is required for rational activities of human economies within their natural systems.<sup>1</sup>*

After 15 years, 10,000 compounds, and \$8 million, a new drug is born.<sup>2</sup> The life cycle of a drug is typically thought to encompass its journey from conception, design, and manufacture, to its introduction into the marketplace. Now, however, overwhelming evidence of deteriorating human and environmental health is forcing us to change how we understand the life cycle of pharmaceuticals and personal care products (PPCPs).

Forward-thinking individuals in the pharmaceutical industry—and those who use their products—realize that we must embrace “product stewardship,” which means becoming accountable for the *entire* life cycle of a medicine, from conception through drug recycling and disposal. A product-centered approach to environmental protection requires industry participants—manufacturers, retailers, users, and disposers—to share responsibility for reducing the environmental impacts of products.<sup>3</sup> In a stewardship model, pharmaceutical manufacturers, doctors, nurses, and consumers are all educated about ecological and social impacts of the life cycle of a drug.

True cost of pharmaceutical drug development is complex to evaluate. The path from understanding an illness to providing a treatment is lengthy, difficult, and expensive. Drug clinical trials involve complex processes of rigorous testing to determine efficacy and toxicity. To ensure the safety and well-being of future patients, such testing proceeds with the precaution and diligence necessary for offering effective medical care. However, this diligence comes at a high price, negatively affecting land, natural resources, and local communities on ecological, social, and spiritual levels. From initial idea conception to drug delivery, the medical industry can benefit by utilizing principles of ecological economics.



**Ecological Economics values a product or service according to its ability to enhance human wellbeing while supporting sustainable societies and ecosystems.**

The primary principles of ecological economics are social, human, built, and natural capital. This emerging economic perspective values a product or service according to its ability to enhance human well-being while supporting sustainable societies and ecosystems.<sup>4</sup>

**Social Capital** refers to the web of interpersonal connections, institutional arrangements, rules, and norms that facilitate individual human interactions.

**Human Capital** includes both the physical labor of humans and the know-how stored in their brains.

**Built Capital** encompasses machines and other infrastructure such as buildings, roads, and factories that compose the human economy.

**Natural Capital** refers to land and the many natural resources it contains, including ecological systems, mineral deposits, and other features of the natural world.

As we begin to apply the principles of ecological economics seriously, we are forced to question whether or not modern medicine as it is currently practiced can truly provide sustainable means for healing our communities.

## How Ecological Economics Changes our Understanding of the Drug Life Cycle

### Pre-discovery

In the first or pre-discovery phase of the drug life cycle, scientists fully understand the disease of interest and begin pharmaceutical design. The first step in the research is target identification<sup>1</sup>—choosing a disease to target with a drug—and the final step is target validation<sup>1</sup>—testing the target and confirming its mechanism in the body. Worldwide, more than \$70 billion is spent annually on health research and development (R & D) by the public and private sectors.<sup>5</sup> The great interest in drug R & D shows commitment to improving health conditions, but we must ask ourselves, who are these drugs being made for? Of the 1,393 new pharmaceuticals marketed between 1975 and 1999, only 13 were for “neglected” diseases.<sup>6</sup> Neglected diseases include illnesses such as Human African trypanosomiasis (HAT), V. Leishmaniasis, Malaria, and Chagas. Neglected diseases typically occur in developing countries whose patients are too deeply impoverished to constitute a market that can attract investment in drug R & D.<sup>7</sup> Only an estimated 10% of worldwide medical investments are used for research into 90% of the world’s health problems.<sup>8</sup> This is what is called “the 10/90 gap.”<sup>5</sup> The consequences of that profound imbalance are evident around the world.

In addition to this blatant disregard for social capital, pharmaceutical companies fail to consider the consequences of not valuing human relationships and interactions. For a moment, consider what an economic system would look like if it took the principle of valuing social capital seriously. Physicians might be more likely to accept uninsured, impoverished patients. Employers might be more inclined to provide better coverage to employees. Various sectors of the health care system, such as physicians and hospitals, might more efficiently coordinate care, and patients



**Only 10% of the world's medical investments are used for research into 90% of the world's health problems**

might be willing to absorb higher out-of-pocket costs because they trusted and valued the quality of their health care organizations.<sup>9</sup> Integrating the value of social capital into medical economics improves the health and economy of so-called “developing” nations. For example, the World Health Organization estimates Africa’s gross domestic product (GDP) would be up to \$100 billion greater annually if malaria had been the focus of pharmaceutical research years ago.<sup>10</sup> The complete integration of social capital into all stages of the pharmaceutical industry would undoubtedly serve to fulfill a vision of high quality health care for all.

### Drug Discovery

Drug discovery, the next phase of developing a drug, a candidate, or a “lead compound”<sup>2</sup> is identified. The sources for lead compounds vary and change considerably over the course of time. Nature is a primary source for drug discovery. Scientists and public health experts traditionally have paid little attention to either the relationship between human health and the health of other species, or the value of natural capital; neither have these topics been addressed in the education of health care professionals.<sup>11</sup> Take, for example, Taxol. During the 1960s, a potent anti-cancer compound, known as Taxol, was discovered on the bark of the Pacific Yew tree. Following considerable depletion of these valuable trees and additional research, scientists found that each patient would need 60 pounds of Yew bark to produce enough Taxol to sustain the course of their treatment. The problem was that one tree provided only 20 pounds, and over 40,000 women needed the remedy.<sup>12</sup> Due to the impact of this resource depletion on the local ecosystem and communities, scientists developed a synthetic and more powerful form of this groundbreaking cancer drug from the leaves of the Pacific Yew.

As pharmaceutical companies worldwide are becoming more aware of the need to conserve biodiversity and natural capital, some are developing local biodiversity action plans (BAPs) aimed at conserving natural resources, and where possible, increasing local diversity on and around the company’s land. For example, Glasko-Smith Kline is creating or maintaining refuges and “green corridors” for flora and fauna and reintroducing indigenous species. Some pharmaceutical manufacturing operations are now requiring sites to evaluate its impact on the environment:<sup>13</sup>

- identify and assess potential impacts of their activities on local habitats
- minimize adverse effects of their activities on important habitats
- enhance biodiversity where feasible
- monitor impacts to ensure action remains effective in protecting and enhancing local biodiversity

Prioritizing sustainability is a respectable step towards resource conservation, but it is only the beginning of actions the medical industry must take.

While the natural world is a primary source for drug discovery, scientists also develop medicine *de novo*, creating molecules from scratch using advanced computer modeling. A recent survey found that 30% of new drugs were completely synthetic in origin. The other 70% were derived from or were similar to chemicals found in nature.<sup>13</sup> But whether the compounds are synthetic or natural, the pharmaceutical industry’s efficiency rate relative to use of raw materials is abysmal. Typically, about 100 kg of material raw material is used for every 1 kg of active pharmaceutical

## Top 20 Prescriptions for 2006

- 1 Lipitor – Cholesterol lowering agent
- 2 Toprol XL – Antihypertensive
- 3 Norvasc – Antihypertensive
- 4 Synthroid – Thyroid hormone
- 5 Lexapro – Antidepressant
- 6 Nexium – Gastrointestinal
- 7 Singulair – asthma prophylaxis
- 8 Prevacid – Gastrintestinal
- 9 Ambien – Sedative
- 10 Zoloft - Antidepressant
- 11 Advair Diskus – Corticosteroid
- 12 Zyrtec – Antihistamine
- 13 Effexor XR – Antidepressant
- 14 Fosamax – Bisphosphonate
- 15 Plavix – Anticoagulant
- 16 Protonix – Proton pump inhibitor
- 17 Vytorin – Cholesterol lowering agent
- 18 Zocor – Cholesterol lowering agent
- 19 Diovan – Angiotensin blocker
- 20 Lotrel – Calcium channel blocker

Source: Drug Topics. Top 200 Brand-Name Drugs by Units in 2006. [www.drugtopics.com](http://www.drugtopics.com)

ingredient produced<sup>13</sup>—a miserable 1% material efficiency, compared to the production of fine chemicals (20%) and bulk chemicals (50%). This inefficient process, which wastes valuable resources and has negative environmental and financial consequences, demonstrates the industry's lack of regard for the worth of natural capital.

The brighter side is that the industry is initiating a variety of conservation methods to extend the life of raw materials and reduce the impact drug development on the environment. High throughput screening is currently the most common form of drug development.<sup>2</sup> Using robotics and computational power, researchers test hundreds of thousands of compounds in a relatively efficient manner. In addition, scientists are using biotechnology to genetically engineer living systems to produce the disease-fighting compounds in medicine.

## Pre-clinical and Clinical Phases, and Approval

Following discovery, drugs undergo extensive lab and animal testing in the pre-clinical phase to determine safety and efficacy for human testing.<sup>2</sup> In this stage, the pharmaceutical manufacturer submits an Investigational New Drug Application (IND) to obtain FDA approval to test on human subjects. This testing may reveal unanticipated weaknesses of the medicinal compound. The number of potential medicinal compounds is drastically reduced from 10,000 to 5 or fewer in this phase.<sup>2</sup> Problems can arise when the need to determine a potential drug's safety and efficacy overrides the welfare of living animals; because of concerns about abuse and maltreatment of animals, testing gets strong scrutiny from the public. Integrating the value of natural capital in the pharmaceutical industry would advance sophisticated technology development and replace harmful testing protocols.

In the next phase of drug development, which can last up to 6 or 7 years, researchers conduct clinical trials, or tests on humans, to determine if a drug is safe and effective. A clinical trials starts with Phase I tests on a small group of healthy volunteers and concludes with Phase 3 tests on a large group of patients. Some treatments may have unpleasant or even serious side effects. Often these are temporary and end when the treatment is stopped. Others, however, can be permanent. Side effects may appear during treatment, or not show up until after the study is over.<sup>14</sup>

Drug companies that are not committed to human capital fail to consider individual and community knowledge and may contribute to already deteriorating health conditions. In the previous decade or two, investigations by both public and private sectors have uncovered the fact that some researchers conduct unethical testing of impoverished peoples in the developing world. Without internal ethical review committees, such as research institutes or scientific panels, drugs continue to be tested without consent, on men, women, and children of developing nations. In 1996, Pfizer treated 100 Nigerian children with the antibiotic Trovan in order to determine the drug's effectiveness.<sup>15</sup> Eleven children in the trial died, and others suffered brain damage, were partly paralyzed, or became deaf.<sup>16</sup> Pharmaceutical industry researchers failed to acknowledge the inherent value of human life and became witnesses, and in some cases perpetrators of, unnecessary and unjustifiable deaths. It is imperative that the pharmaceutical industry reclaim its stance on human and social capital and insist on providing humane and effective care to all people, regardless of social or economic status.



Once clinical tests prove a drug to be effective, it goes through the approval phase. Once approved by the FDA, the drug goes into the manufacturing process. This phase is responsible for the majority of damage to natural capital within the drug development process.

## Drug Production and Natural Capital

In order to scale up production, pharmaceutical manufacturers rely on excessive use of the natural capital of energy, water, and toxic chemicals can be excessive, resulting in significant air, water, and land pollution.

### Energy

Perhaps the hottest topic right now among those concerned with sustainability is energy. Evidence that shows an increase in greenhouse gases, such as carbon dioxide, in the atmosphere is causing a rise in the Earth's temperature—global warming<sup>13</sup>—is spurring the search for alternative forms of energy production. The U.S. pharmaceutical industry consumes almost \$1 billion in energy annually.<sup>17</sup> In 2002, the industry generated over \$140 billion in output, up from \$108 billion in output in 1999.<sup>17</sup> In an attempt to curb energy usage, pharmaceutical companies have implemented a number of conservation methods, including solar-powered streetlights, wind turbines, and solar-heated water canteen and temperature control.

### Water

Water is the most abundant liquid on our planet, covering 70% of the Earth's surface and making up 60% of the human body. Of this, only 1% is freshwater. Freshwater is used in the drug development in manufacturing (for processes, products, cooling, and cleaning) and for general uses such as drinking, food services, and sanitation.<sup>2</sup> In 2005, the average pharmaceutical company used 22 million cubic meters of freshwater,<sup>17</sup> which is sourced mainly from municipal water supplies (59%) or wells or boreholes (40%),<sup>13</sup> with a small amount from other sources.

Many pharmaceutical manufacturing facilities are located in countries where water resources are classified as “highly stressed.”<sup>18</sup> Beyond excessive resource consumption, threats to water include the unknown effects associated with active ingredients in the drugs being produced on nontarget species.<sup>2</sup> In addition, environmental pressures on water negatively impact the surrounding society's access to food and drinking water and lessen the opportunities for those in the affected areas to build sustainable communities.

Conservation measures the pharmaceutical industry has taken to date include rainwater collection for sanitary purposes and recycling up to 90% effluent process water for landscaping, with an eventual goal of zero-wastewater (no discharge to water bodies or municipal sewers).

**Ecological economics poses the question, Is modern medicine as it is currently practiced a truly just and sustainable way to truly heal our communities?**



**Typically, about 100 kg of material raw material is used for every 1 kg of active pharmaceutical ingredient produced.**

## Air

Clean air is essential for overall well-being and good health. The heavy use of solvents in drug research, development, and manufacturing results in the emission of Hazardous Air Pollutants (HAPs), such as volatile organic compounds (VOCs). The emissions of VOCs can give rise to ground level ozone in the presence of UV light, which has adverse effects on human and plant life. Some VOCs are also greenhouse gases and may contribute to climate change.<sup>19</sup> In order to curb air pollution, pharmaceutical industries are increasing the reuse and recycling of solvents during drug manufacturing and installing VOC abatement equipment. A reduction in the manufacture and prescription of CFC-driven inhalers could further decrease the release of ozone-depleting substances.<sup>20</sup>

## Solid Waste

More than 80% of the hazardous waste in drug development consists of solvents that are used in production processes,<sup>13</sup> and a daunting number of regulations guide and restrict the way hazardous waste is handled. Regulations vary widely around the world, and the primary disposal option is incineration. In 2005, GlaxoSmithKline disposed of 68 million kg of hazardous waste (excluding demolition and construction waste): 44% of this was incinerated with energy recovery, and 54% was incinerated without energy recovery. During that year, the company recycled 72% of the total waste it generated, an increase of 2% since 2004. This is far from reaching its seemingly simple goal of 10% increase in the proportion of waste recycled since 2001.<sup>13</sup> In 2003, Roche incinerated 23% of its general waste, and the rest (77%) was sent to landfill.<sup>17</sup>

Packaging is a significant source of solid waste in the drug life cycle. Conservation initiatives include increasing the amount of recycled and renewable material used in packaging, and eliminating the presence of harmful products such as PVCs associated with plastics. For example, companies in Japan are replacing PVC packaging material with polypropylene (PP) blister packaging and optimizing blister packaging, which will eliminate approximately 20 tons of cardboard and 5 tons of aluminum bags.<sup>13</sup>

The latest research on the life cycle of pharmaceuticals and personal care products exposes the serious environmental consequences associated with pharmaceutical use and improper disposal (See Pharmaceutical Pollution on p.5). Solid waste conservation efforts include waste minimization and recycling initiatives. Ecological economics would prioritize and require recycling of solvents.

## Land

Land is an increasingly scarce resource due to population increase, urban sprawl, and the impact of modern society on land productivity. In order to sustain future generations, every industry's use of land should be analyzed. For many pharmaceutical manufacturers, operations at processing sites have taken place for nearly 100 years.<sup>19</sup> Often manufacturers need to build a new facility or reconstruct old ones, since every drug has different and varying needs.<sup>2</sup> Inefficient building construction and poor management of solid waste, water, and energy at these facilities harm the land on which operations take place.

## 12 Principles of Green Chemistry

1. Prevent waste
2. Design safer chemicals and products
3. Design less hazardous chemical syntheses
4. Use renewable feedstock
5. Use catalysts, not stoichiometric reagents to minimize waste
6. Avoid chemical derivatives
7. Maximize atom economy
8. Use safer solvents and reaction conditions
9. Increase energy efficiency
10. Design chemicals and products to degrade after use
11. Analyze in real time to prevent pollution
12. Minimize the potential for accidents

Increasing concern about environmental sustainability is prompting some manufacturers to minimize environmental impact and promote sound land management policies as they construct or select new facilities. During project planning, soil surveys inform decisions about facility construction and appropriate disposal methods for surplus soil resulting from construction.

### Transportation

Once developed, a drug must reach appropriate dispensaries. In 2005, Glasko-Smith Kline products were transported a total of 195 million kilometers, the majority (82%) by air freight. Business-related travel accounts for a great majority of CO<sub>2</sub> emissions and include plane (232 million kg), employee plane travel (112 million kg of CO<sub>2</sub>), and global sales fleet by car (102 million kg of CO<sub>2</sub>).<sup>13</sup> In addition to business travel, manufacturers also transport products from manufacturing plants to distributors.

Efforts to advance sustainability in regards to transportation include “green travel plans”, encouraging employees to carpool, drive fuel efficient vehicles, and provide showers for cyclists.<sup>13</sup> In addition, teleconferencing is made available to employees to reduce travel.

### Summary

If the pharmaceutical industry integrates and addresses the true cost of drug development, a healthier world and more sustainable way of living can and will emerge. The four principles of value of the ecological economics model—social, human, built, and natural capital—offer an integral perspective for drug development and administration. If we inform our economic analyses, strategies, and policies with an understanding of the interdependency of these four types of capital, we can better meet our goals of sustainable human health and contentment.<sup>4</sup>

The emerging field of green chemistry and environmentally sound improvements in hazardous waste management suggest that the gate to environmental sustainability is open wider than ever before. Two important steps the pharmaceutical industry can take are committing to environmental protection and advocacy, and implementing a cradle-to-cradle approach to the life cycle of drugs. To reach true sustainability, however, the industry—and all of us—will need to expand our understanding of product stewardship to value the social, human, built, and natural capital outlined in ecological economics model. We have a great opportunity.

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Campaign**

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## What Pharmacists and Providers Can Do

- Do not prescribe more medications than can be used
- Prescribe starter packs and refill packs
- Review and regularly reassess the patient's total consumption of medication
- Consider environmental impact when prescribing medications
- Learn more about which drugs have large environmental impacts
- Educate consumers about the importance of proper disposal of pharmaceutical waste

Pollution Prevention  
Partner

## PharmEcology, LLC.

*"Healthcare should be leading the country by providing a pollution prevention example of best management practices."*

— Charlotte Smith, President of PharmEcology, LLC

Since the RCRA was enacted in 1976, the EPA has not updated the categories of hazardous waste management in health care. This obsolete classification system is inadequate for the many new drugs released every year since the bill was passed, including over 100 highly toxic chemotherapy agents. The widespread need for hospitals to manage pharmaceutical waste in a cost-effective, compliant, and environmentally friendly manner inspired pharmacist Charlotte Smith to develop PharmEcology Associates LLC, an environmental consulting firm headquartered in Brookfield, Wisconsin.

"Most healthcare professionals have no training in environmental law, and I had the feeling hospitals and other healthcare providers would begin facing greater scrutiny from the regulatory community in coming years," explains Smith.

PharmEcology is committed to providing the healthcare and pharmaceutical industry with the information and technology to minimize the destructive impact of pharmaceutical waste on the environment and to insure compliance with state and federal regulations in a cost-effective manner. PharmEcology improved current listings by developing the criteria necessary for identifying additional drugs that pose a serious threat to human health and/or the environment. Their database currently includes over 150,000 drug products and is updated weekly with about 200 new items.

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### Resource Conservation and Recovery Act (RCRA)

A 1976 cradle-to-grave regulatory program that will infringe penalties and statutes on health care industry for improper disposal of hazardous waste.

#### Hazardous Waste:

Chemicals or formulations deemed to be so detrimental to the environment that they must be segregated for special waste management and cannot be sewered or land filled.

Four characteristics of hazardous waste:

- Ignitability
- Toxicity
- Corrosivity
- Reactivity

#### The primary goals of RCRA are:

- To protect human health and the environment from the potential hazards of waste disposal
- To conserve energy and natural resources
- To reduce the amount of waste generated
- To ensure that wastes are managed in an environmentally sound manner

# Unused and Expired Medicines: A National Pandemic

BY MATTHEW C. MIRELES, PH.D., M.P.H.

*President and CEO, Community Medical Foundation for Patient Safety*

## Mission

The mission of the Community Medical Foundation for Patient Safety is to promote patient safety and healthcare quality through education, research, and the demonstrated practice of patient-centered healthcare within a supportive culture of safety. We aim to educate and empower patients and their families to enable them to be more actively involved in making decisions to improve the quality, equity, timeliness, and safety of their own healthcare

What you find in your medicine cabinet may shock you. If you are like most people, you have a store of unused and expired prescription and over-the-counter (OTC) medicines. Do you recall why you no longer use a particular medicine? Do you know which medicines have expired or may be toxic? Throughout the U.S., the unused and expired medicines (UEM) stockpiled in our homes are rapidly becoming a major source of danger to our communities. Unfortunately, there is no systematic program for legally and safely dealing with these medicines.

Each month, more than 135 million Americans use prescribed medicines;<sup>1</sup> when people stop taking them or keep them beyond their expiration date, staggering quantities of unused medicines accumulate. To promote personal and community safety, some communities have begun to organize collection events to take back unwanted medicines. However, there are wide variations in how the collected medicines are classified and destroyed. What one group labels “medical waste” another might call “household waste.” Programs involving retail pharmacies typically involve reverse distributors, programs allowing return of unused pharmaceuticals to the manufacturer, and others simply transport the medicines to a landfill. Studies on the best classification system, as well as which method of destruction is most efficacious for various products, are urgently needed, but prudent individuals would do well to follow the “precautionary principle” to protect the environment.







**The Community Medical Foundation for Patient Safety has established the only national database on UEM—the Unused and Expired Medicines Registry.**

The Community Medical Foundation for Patient Safety strongly recommends and supports collection programs that directly involve law enforcement, which has the authority to collect and destroy unwanted controlled substances. For example, the *TRIAD Program* in Indiana and the *Maine Benzodiazepine Study Group (MBSG)* are collection events in which medicines are returned to law enforcement officers for processing and incineration. A planned pilot study, *Get Rid of Unused Medicines (GROUP)* in Houston, Texas, also will involve law enforcement officers.

Further, the Community Medical Foundation for Patient Safety has established the only national database on UEM—the Unused and Expired Medicines Registry. To date, we have entered and analyzed data from collection organizers on more than 3,000 UEM. A recent study in Maine reported that 40% of medicines that had been prescribed and purchased had never been used.<sup>2</sup> In that study, antidepressants (12%) were the most common UEM and the usual reason they had not been used was that the “doctor discontinued the medicine.” Another sample from Maine showed that analgesics (13%) were the most common UEM because of “expiration.”<sup>2</sup> Of the analyzed UEM (n=400), 15% was categorized as potentially hazardous to the environment (PBT Index: 4-9). Most of these were antibiotics.

While our ambitious effort to learn about UEM addresses the problem of this pandemic after the fact, our ultimate goal is to address the root causes of the problem by learning more about the reasons for the excessive prescription, production, and demand for medicines in our society. With our partners and collaborators, we are committed to solving this problem through awareness, education, research, and cost-effective interventions and preventive measures. However, as more medicines are manufactured, marketed, and consumed faster than at any time in our history, stemming the tide of a pandemic in the making is a formidable challenge.

*Matthew Mireles is an injury and occupational epidemiologist, and is applying his training and expertise to the study of medical errors and patient safety through Community of Competence. He has an adjunct faculty appointment at the University of St. Thomas, Houston, Texas, and at the Center for International Studies.*

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## Dispose of Unused Medicines Safely

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## Statistics about Unused and Expired Medicines

- Of the 4 billion prescriptions to be filled in the U.S. in 2007, the elderly population will waste more than \$1 billion of drugs.<sup>3,4</sup>
- Approximately 15 million people misused pharmaceuticals in 2005.<sup>5</sup>
- One of the most common sources of illicit pharmaceuticals is the home medicine cabinet.<sup>5</sup>
- Medication errors result in 700,000 emergency room visits each year.<sup>6</sup>
- Of non-institutionalized seniors, 90% used at least one medicine and 40% used 5 or more medicines weekly.<sup>7</sup>
- The average person over 65 takes between 2 to 7 prescription medicines daily and consumes more than 30% of all medicines prescribed nationally.<sup>8</sup>
- Medicines at home are a major source of accidental poisoning of children—36% occurs in grandparents' homes.<sup>8</sup>
- 19% (4.5 million) U.S. teenagers abuse prescription medicines—such as Vicodin and OxyContin—by engaging in “pharming,” which involves combining cocaine and other narcotics with painkillers. Ingesting these sometimes results in an overdose or death.<sup>9</sup>
- Illegal possession, theft, and diversion of prescription medicines and narcotics from homes to the streets contribute to crime.<sup>1</sup>
- Four out of five patients leave their doctor's office with at least one prescription.<sup>11</sup>

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## Mission

Guided by the values and expertise of medicine and public health, Physicians for Social Responsibility works to protect human life from the gravest threats to health and survival.

# Physicians for Social Responsibility

## Pediatric Environmental Health Toolkit

Students in medical school must master a dizzying array of facts and figures, possess prodigious stamina, and learn about seemingly innumerable diseases and treatments. Yet despite these demands, very few schools address a serious and growing health problem: the negative effects of toxicants in the environment on human health.

Physicians for Social Responsibility (PSR), an organization that shared the Nobel Peace Prize with International Physicians for the Prevention of Nuclear War in 1985, is concerned about the lack of an environmental health component in the training of future doctors. PSR—which is committed to creating a world free of nuclear weapons, global environmental pollution, and gun violence—aims to “educate and activate the medical and broader health community, and the public, through research, analysis, collaboration, and targeted communications and to advocate for government and societal change at the local, state, national, and international levels.”

PSR notes that only one in five pediatricians in the United States report that their training included how to take an environmental history as it may affect health. To address concerns of practitioners and parents about issues such as pesticide residues on foods, mercury in fish, and arsenic in drinking water and on play structures, the San Francisco Bay Area and Greater Boston PSR chapters are hosting a series of workshops in 2006-2007 to introduce practitioners to a new clinical tool which they developed called the Pediatric Environmental Health Toolkit. The first workshop in this series took place in Oakland, California in October, and subsequent workshops were held in Minnesota, Oregon, Washington and Massachusetts this spring.

The Pediatric Environmental Health Toolkit provides health care professionals with information that helps them to identify various routes of exposure to common toxic chemicals and substances including metals (mercury, lead, arsenic), solvents, pesticides, and other persistent organic compounds such as PCBs. It also addresses the health effects associated with these environmental exposures, with particular attention to the unique vulnerabilities of children. Practitioners learn specific practical and effective communication skills relative to environmental health issues, including the risks and precautions associated with the “built” and “food” environments.



**Only one in five pediatricians in the United States report that their training included how to take an environmental history as it may affect health.**

The Pediatric Environmental Health Toolkit is a useful tool for preventing or reducing a child's exposure to toxic chemicals. By addressing the connection between human and environmental health, PSR is training health care professionals to become environmental health advocates. Integrating environmental health guidelines into everyday practice enhances practitioners' ability to educate parents to reduce children's exposure to toxins in the environment.

The Toolkit addresses key concepts and principles in pediatric environmental health. It provides a summary of children's unique susceptibilities to toxic substances, a brief Environmental History Intake form, summaries of major toxicants and their potential health effects, and a pocket reference card outlining "priority anticipatory guidance" relative to specific developmental stages. Resources for parents explain how to prevent toxic threats to their child(ren)'s development and create a healthy environment for their child(ren).

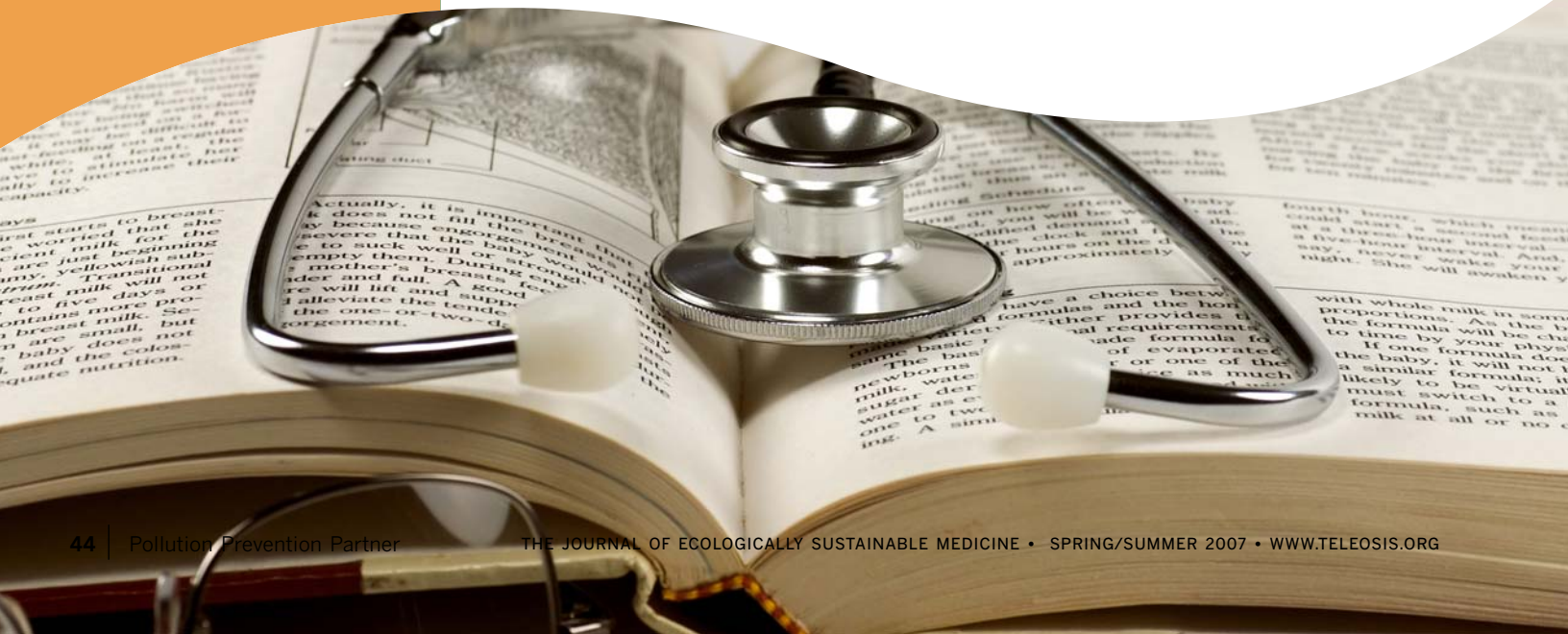
Physicians for Social Responsibility believes that social justice and public health depend on a safe and healthy environment. This principle is the foundation for a range of programs and projects that inspire physicians to engage with patients in a way that enriches and supports a healthy relationship with the environment.

**To learn more about Physicians for Social Responsibility and PSR's Pediatric Environmental Health Toolkit, contact:**

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Spotlight on  
Green Pharmacy

## Stockholm County Council

**Assessing and Classifying Drug Ecotoxicity**

Have you ever wondered what happens to medicine after you ingest it? Since pharmaceutical medicines are often only partially metabolized in the body, many residues and metabolites enter unchanged into wastewater facilities or directly into open waterways. Pharmaceutical drugs are often adapted to resist biodegradation, allowing medicines to remain in the environment for a significant length of time. Current research suggests that a variety of medicines are found in drinking water samples—a warning sign that existing pharmaceutical management and disposal practices may lead to future health and environmental problems.

Because we still know very little about the effects on humans and the environment of continuous, long-term exposure to trace quantities of pharmaceuticals and other chemicals, precaution is advisable. In Sweden, the Stockholm County Council (SCC) is pressuring the pharmaceutical industry to address environmental issues in the manufacturing process itself. An important aspect of this work is assessing and classifying pharmaceutical medicines according to their impact on the environment.

**Assessing and Classifying Drugs**

In 2005, the Swedish Association of the Pharmaceutical Industry conducted a preliminary environmental risk assessment on marketed pharmaceutical drugs. During the 5-year course of study (ending in 2009), this pollution prevention project will conduct a comprehensive assessment of all medications on the Swedish market. Then researchers will classify the medications according to the drugs ability to harm environment and human health. The SCC's ultimate goal is to eliminate the county's input of persistent residues of medicinal products to the soil, water, and air.

The SCC's novel classification system assesses pharmaceutical substances with respect to *environmental hazard* and environmental risk. An environmental hazard assessment is based on the three characteristics: *persistence*—the capacity for resisting degradation in the aquatic environment; *bioaccumulation*—the degree of accumulation in adipose tissue in aquatic organisms; and toxicity for aquatic organisms. The term *environmental risk* refers to the level of possible threat to the aquatic environment; categories are *insignificant, low, moderate or high*.

**The SCC's ultimate goal is to eliminate the county's input of persistent residues of medicinal products to the soil, water, and air.**



## Environmental Hazard Assessment

- (P) Persistence: ability to resist degradation in aquatic environment
- (B) Bioaccumulation: accumulation in adipose tissue of aquatic organisms
- (T) Toxicity: potential to poison aquatic organisms

When comparing the environmental impact of two substances, both risk and hazard—the PBT value—must be considered, because bioaccumulation and persistence are not included in the initial risk assessment. The classification system includes information for patients, those who prescribe medicine, and health care specialists about the least harmful choices for care.

As European leaders in the movement toward a more sustainable health care system, the SCC provides a model of pharmaceutical pollution prevention that benefits human and environmental health. By engaging participants along the broad spectrum of health care, the assessment and classification program educates practitioners, consumers, and communities about pollution reduction and prevention.

To learn more, visit [www.janusinfo.se/environment](http://www.janusinfo.se/environment)

## What Physicians Can Do

*from the Stockholm County Council*

- Consider cost-effectiveness and environmental impact when choosing from comparable medications.
- Prescribe starter packs.
- Prescribe refill packs if available.
- Encourage patients to return unused medications to local take-back events or programs, and controlled substances to local police.
- Urge patients to also return used estrogen patches to pharmacy and avoid flushing them down the toilet, since most of the estrogen remains in patch after use.
- Do not prescribe more medications than can be used; if in doubt, repeating the prescription is preferable.
- Review and regularly reassess patient's total consumption of medication to reduce waste.
- Visit [www.janusinfo.se/environment](http://www.janusinfo.se/environment) and ask pharmaceutical company representatives to learn which drugs have the worst environmental impacts.

# Pharmaceuticals and Personal Care Products (PPCPs) as Environmental Pollutants

from U.S. Environmental Protection Agency

REVIEWED BY NIYATI DESAI, MA



Visit the EPA Web site at  
[www.teleosis.org/epa/ppcp](http://www.teleosis.org/epa/ppcp)

Whether you are someone who is concerned about the environmental and health impacts of your daily beauty products, or a health care provider who wishes to dispose of prescription drugs without causing harm to people or nature, the U.S. Environmental Protection Agency (EPA) Web site offers “news you can use” through its comprehensive section on pharmaceuticals and personal care products—PPCPs—which include prescription and over-the-counter therapeutic drugs, fragrances, cosmetics, sunscreen agents, diagnostic agents, nutraceuticals, biopharmaceuticals, and more.

In 2000, the American Chemical Society sponsored the first ever full-day conference in North America on the subject of PPCPs as environmental pollutants. Interest in the ACS conference was conceived by Daughton and Ternes as a result of their 1999 review article, spurred the creation also in 2000 of the world's first website devoted to the environmental issues surrounding PPCPs. Work on this site (developed by EPA's Office of Research and Development in Las Vegas) stopped in March of 2005, in anticipation of creating a EPA-wide website which will be released in 2007. The new site focuses primarily on research sponsored by the EPA. The general public, researchers, and health professionals now have access to a dense





**Acknowledged gaps in research include incomplete information on PPCP sources and origins, occurrence, fate and transport, hydrology, exposure, toxicology, and environmental stewardship.**

amount of information that, in addition to research, covers general questions and suggests ways to actively engage with the issues.

The site offers easy access to published data on the health effects of PPCPs in the environment. As one of the primary resources on the subject, users must exercise diligence to comb through the vast amount of data, but the materials density reveals the importance of the topic and is sparking much needed scientific dialog and debate. It also enhances the public's understanding of the origins of chemical pollution, as well as how individuals can help to decrease the proliferation of PPCPs.

The EPA Web site defines the full scope of the complex scientific issues related to PPCPs in the environment, including the need for better coordination among researchers to fill in gaps in the research. Acknowledged gaps include incomplete information on PPCP sources and origins, occurrence, fate and transport, hydrology, exposure, toxicology, and environmental stewardship.

The primary criticism of the site is that since 2005, the site has been inactive and does not reflect any research conducted since that time. However, due to its comprehensive coverage of topics, it maintains its position as the primary resource for research on pharmaceuticals and personal care products. The most positive aspect of the site is that it offers solutions to the problems associated with the proliferation of PPCPs, not only defining the issues, but also outlining out how the medical, scientific, and public communities can work together to reduce the impact of PPCPs in the environment.

## Office of National Drug Control Policy Federal Guidelines:

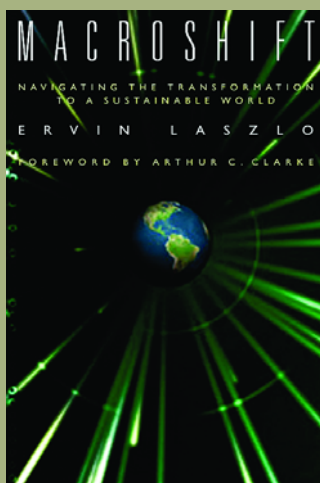
- Take unused, unneeded, or expired prescription drugs out of their original containers and throw them in the trash.
- Mixing prescription drugs with an undesirable substance, such as used coffee grounds or kitty litter, and putting them in impermeable, non-descript containers, such as empty cans or sealable bags, will further ensure the drugs are not diverted.
- Flush prescription drugs down the toilet only if the label or accompanying patient information specifically instructs doing so.
- Take advantage of community pharmaceutical take-back programs that allow the public to bring unused drugs to a central location for proper disposal. Some communities have pharmaceutical take-back programs or community solid-waste programs that allow the public to bring unused drugs to a central location for proper disposal. Where these exist, they are a good way to dispose of unused pharmaceuticals.

## Book Review

## Macroshift: Navigating the Transformation to a Sustainable World

BY ERVIN LASZLO, PHD

REVIEWED BY JOEL KREISBERG, DC, MA



*Macroshift: Navigating the Transformation to a Sustainable World*

by Ervin Laszlo, PhD

Berrett-Koehler,

San Francisco

2001

218 pages

ISBN-10: 1576751635

ISBN-13: 978-1576751633

Why bother reviewing a book that is 6 years old? What is a *macroshift* anyway? Reading *Macroshift: Navigating the Transformation to a Sustainable World* reminds us that some cultural changes occur more slowly than cell phone technology or the latest in renewable energy. And author Ervin Laszlo is one of the most qualified and articulate individuals to teach us about a shift in social consciousness—one that will decide the future of our children and grandchildren—that is happening at this very moment. An expert in systems theory and evolutionary theory and author of 69 books, Laszlo is also the editor of *World Futures: The Journal of General Evolution*. His book *Macroshift* offers a compelling analysis of the process of social evolution of the human species on planet Earth.

Laszlo begins by describing what a macroshift is, outlining macroshifts that have occurred in the past, and examining the macroshift that is happening now. The author explains, “A Macroshift is a process of societal evolution in which encounters with the system’s limits of stability initiates a bifurcation—a process of rapid and fundamental change in complex systems.”<sup>(p9)</sup> Macroshifts have 4 phases: the trigger phase, the transformation phase, the critical or chaos phase, and the breakdown/breakthrough phase (see Sidebar on page 50). The decisive factors in our current macroshift echo the familiar call of progressive political, environmental, and social justice communities for ecological and social sustainability.

Beyond analyzing our current macroshift, Laszlo offers compelling solutions to current beliefs and practices that lead to an unsustainable future. He urges us to eliminate obsolete beliefs—e.g., nature is inexhaustible, nature is a giant mechanism, life is purely a struggle for survival, the market distributes benefits, the more you consume the better you are. Other fundamental solutions include learning to live with diversity, embracing a planetary ethic, and meeting our responsibilities. Laszlo sees the current macroshift as an evolution from Logos consciousness to Holos consciousness: “Logos-inspired evolution was materialistic and conquest- and consumption-oriented. The

## Four Phases of Current Macroshift

### 1. Trigger Phase (1860-1960)

Innovations in hard technologies (tools, machines, operations systems) result in greater efficiency in manipulating nature for human ends

### 2. Transformation Phase (1960 to present)

Hard technology innovations irreversibly change social/environmental relations, resulting in:

- higher level of resource production
- faster growth of population
- greater societal complexity
- growing impact on social and natural environments

### 3. Critical or Chaotic Phase (The Decisive Epoch 2001-2010)

Changes in social and environmental relations result in:

- pressure on established culture
- questioning of time-honored values and worldviews
- challenge to “given” ethics and ambitions
- society that is extremely sensitive to fluctuations—“chaotic” in the chaos theory sense
- changes in dominant culture/mode of consciousness determine new developmental trajectory

### 4. Breakdown/Breakthrough Phase (2010 and beyond)

**[evidence of both breakdown and breakthrough exist concurrently]**

Elements of breakdown:

- values, worldviews, and ethics of a critical mass resists change
- established, rigidified institutions resist timely transformation
- social complexity and degenerating environment create unmanageable stresses
- social order undergoes series of crises that degenerate into conflict and violence

co-exist with

Breakdown events:

- consciousness of a critical mass evolves in time
- culture shifts towards more sustainable worldviews, practices, ethics
- improved social order establishes itself
- social system stabilizes in changed conditions—the human species chooses a positive future!

September 2007

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alternative to it is evolution centered on human development and development of human communities.”(p110) Holos is globally whole but locally diverse. People live more simply, striving for a healthy lifestyle rich in contact with others and with nature, rather than living an ostentatious lifestyle. Laszlo declares, “At the levels of the vast and complex system in which people participate, self-reliance is the goal and voluntary cooperation the means to achieve it. People recognize their unity within their social and cultural diversity and become conscious architects of their destiny.”(p119)

Laszlo continues with details about what you and I can do to make a difference. The simplest principle and my favorite is “Live in a way that allows others to live as well.” If this seems too lofty and abstract, Laszlo offers simply ways of doing this: eat less meat, don’t smoke, and drive less. *Macroshift* begins with lofty theory that fulfills our need for a theoretical intellectual construct, continuing with an excellent summary of the inadequacies and damaging effects of modern American and European lifestyles. Laszlo goes on to articulate actions we can take to reach a genuinely higher quality of life—in our personal lives, business, art, science, and government.

Read the “Ten Benchmarks of Holos Consciousness” (See list below)—you may discover you are already playing a significant role in the current macroshift towards the next level of human social evolution. And perhaps you will be inspired to find additional ways to contribute to a more sustainable world!

### Ten Benchmarks of Holos Consciousness

You have Whole-brain Holos Consciousness when you:

1. Live simply, satisfying your own needs while taking into account others’ needs.
2. Live in a way that respects the lives and socio-economic development of all peoples.
3. Safeguard the intrinsic right to life and life-supportive environment for all living things.
4. Pursue happiness, freedom, and personal fulfillment in harmony with the integrity of nature other people.
5. Require government to relate to other nations peacefully and cooperatively; recognize that all peoples have the right to strive for a better life and healthy environment.
6. Require businesses to adopt sustainable practices that do not detract from local enterprises and developing economies.
7. Require media to provide reliable information that enables citizens and consumers to reach informed decisions.
8. Help those less privileged than yourself to move out of poverty and live with dignity.
9. Work with like-minded people to preserve/restore environmental balance.
10. Encourage others to empower themselves to make ethical decisions on issues that will decide their own and their children’s future.



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## Join Today!

# Green Pharmacy Campaign

## Participate in the solution

The Teleosis Institute is launching our Green Pharmacy Pollution Prevention Campaign. Our goal is zero pharmaceutical waste in the environment! You are invited to bring your unwanted and expired medicine for proper disposal.

The Teleosis Institute campaign works to create partnerships with the health care community to build a movement for positive social and environmental change. Through collaboration with local pharmacies, health providers, and consumers, we will reduce pharmaceutical pollution and the “footprint” of pharmaceutical medicine. Our Green Pharmacy Program provides the education and the opportunity for everyone who produces, sells, prescribes, or consumes medicines to participate in the solution. We are providing an environmentally positive alternative to throwing unwanted drug waste down the drain, toilet, or the trash.

Partner with the Teleosis Institute in creating a cleaner, healthier environment. By supporting our campaign and our growing health care community, you can build a positive future with us. Seemingly small actions by many individuals will help us realize our goal of zero waste.

## Support Green Pharmacy

### Yes, I want to support the Teleosis Green Pharmacy Campaign

I will:

- Return unwanted medicine and supplements to take-back sites
- Make a donation to support Green Pharmacy
- Help expand a take-back program to a pharmacy near me
- Encourage my provider to take back unused drugs
- Spread the word through forwarding this journal to colleagues and friends
- Ask my provider to prescribe drugs with the least environmental impacts
- Practice healthy product stewardship

### Donate Today!

Visit [www.teleosis.org](http://www.teleosis.org) to donate to the Green Pharmacy Campaign. We depend on community members and organizations to support the development of our programs and environmentally sound solutions. Your tax deductible gift supports the operation of our pilot take-back sites, educational materials, and advocates for prevention of pharmaceutical pollution.

A not-for-profit organization, the Teleosis Institute was founded by Dr. Joel Kreisberg, DC, CCH, a health care practitioner and environmental educator. The Institute is based in Berkeley, California.

The word *Teleosis* is derived from the Greek and may be translated as “greater self-realization.”

## Our Mission

### TELEOSIS INSTITUTE

The Teleosis Institute is devoted to effective, sustainable health care provided by professionals who serve as environmental stewards.

The Institute has three major goals:

To educate health professionals about the principles and practices of Ecologically Sustainable Medicine (ESM)



To build a community-based network for professionals providing Green Health Care



To provide access to high quality, cost-effective, sustainable medical services benefiting underserved populations and the environment in which we live



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The Teleosis Institute

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