

Pharmaceuticals, Personal Care Products and Chemicals of Concern: A Briefing on an Emerging Issue

Florida Department of Environmental Protection
Hazardous Waste Management Section
November 13, 2006

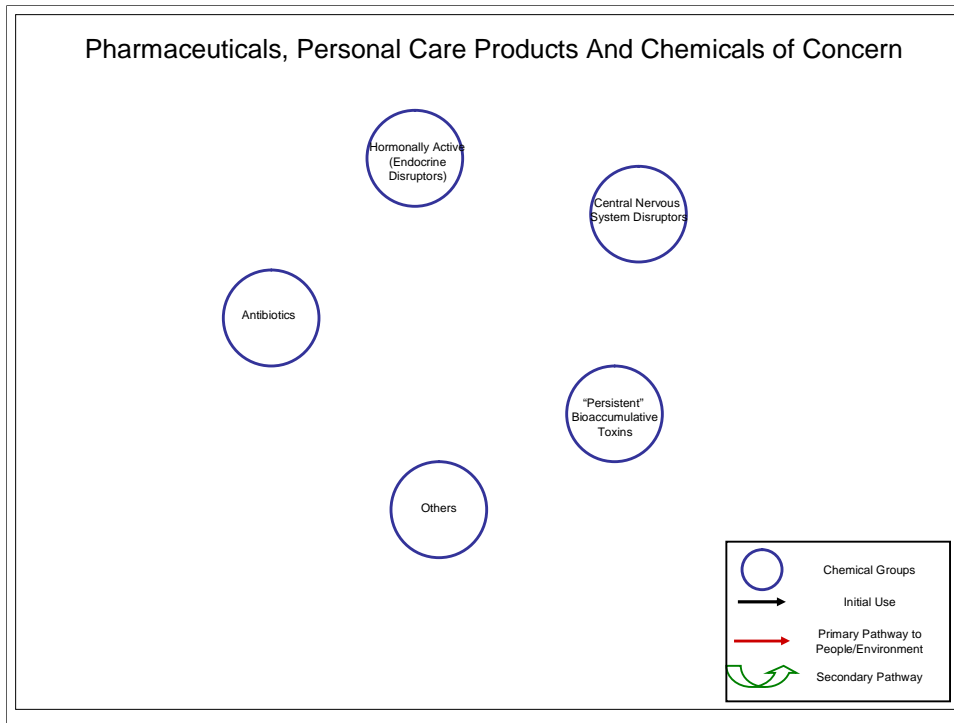
The intent of this briefing is to lay out the complexity, scientific uncertainty and risk scenarios surrounding selected groupings of these emerging chemicals of concern. The objective is to ensure that Floridians are aware of the growing concern with this issue among the scientific, regulatory, and environmental advocacy communities and among the general public.

Why are there so many chemicals in the environment?

- EVERY DAY the U.S. produces or imports 42 billion pounds of chemicals
- About 2,000 pharmaceuticals have been approved for human use with hundreds more approved for veterinary use
- Disposal down the drain or in the garbage
- Not removed using conventional treatment and passed into receiving waters

Drug Portal to the World





There are thousands of chemicals so we need some sort of framework or grouping to get our arms around them. The diagram we have developed is complicated and "busy" . . . just like this issue is. It is not necessary to completely understand all the diagram's details: It is meant to be a framework by which we can refer to and by which we can begin to look at a complex issue.

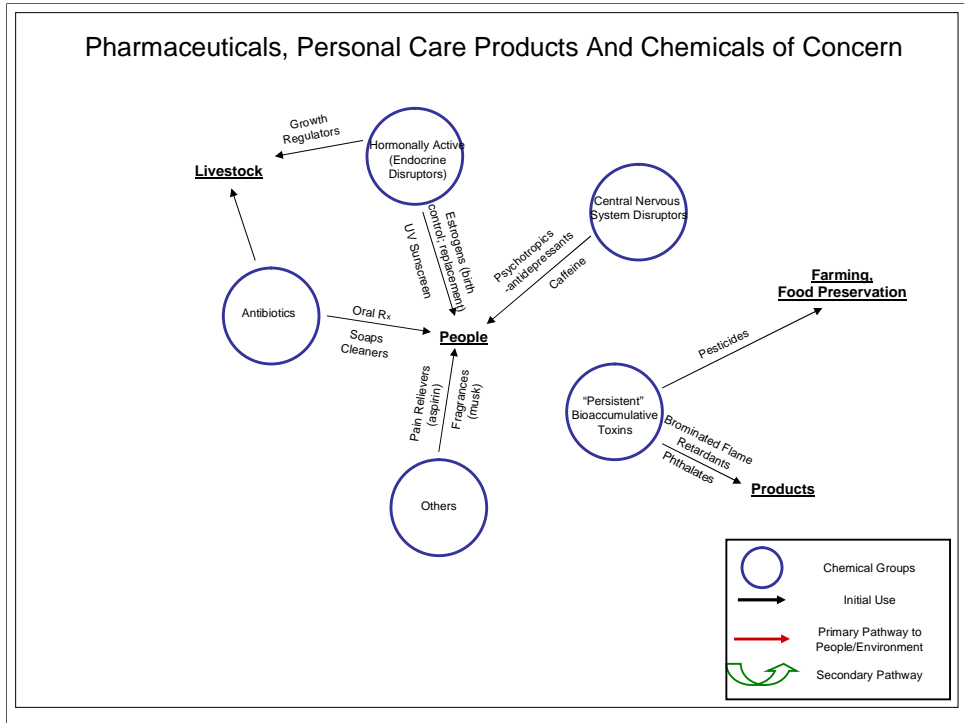
These chemical groups are commonly used in research, risk analysis and discussions.

-Antibiotics, Hormonally Active (Endocrine Disruptors) and Central Nervous System Disruptors group the chemicals by their effect on organisms.

-"Persistent" Bioaccumulative Toxins group the chemicals based upon their environmental characteristics.

"Persistent" is in quotes because many of these substances that do not persist in the environment may act as if they do because the supply is constantly being replenished (pseudo-persistence).

-Other is a catch-all for some other chemicals that do not fit any of the other groups.

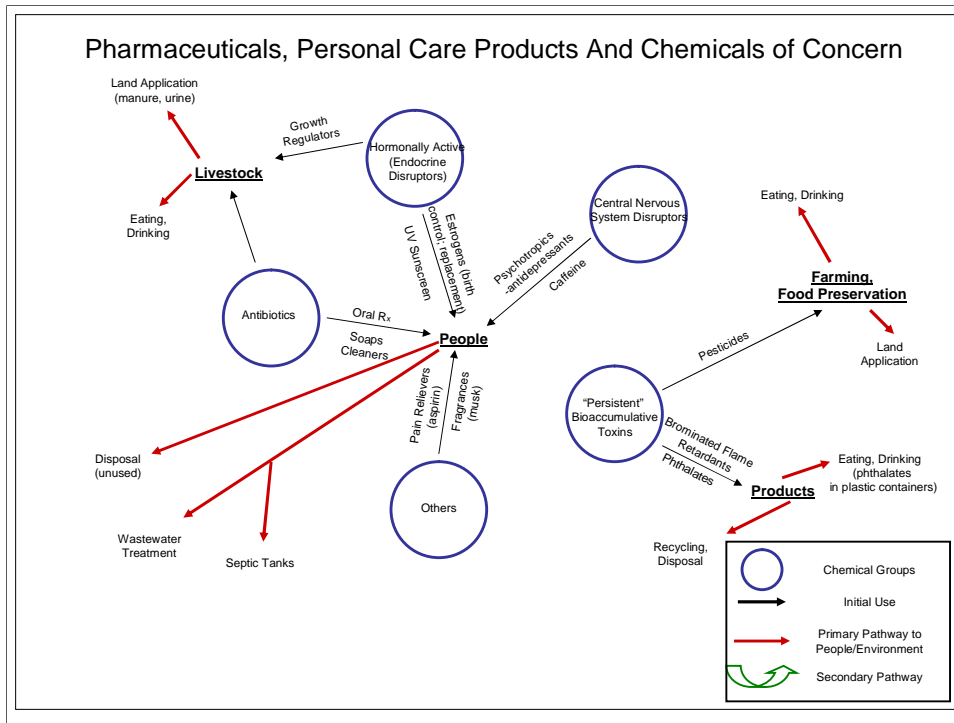


Here are some examples of each group and a representation of their initial uses.

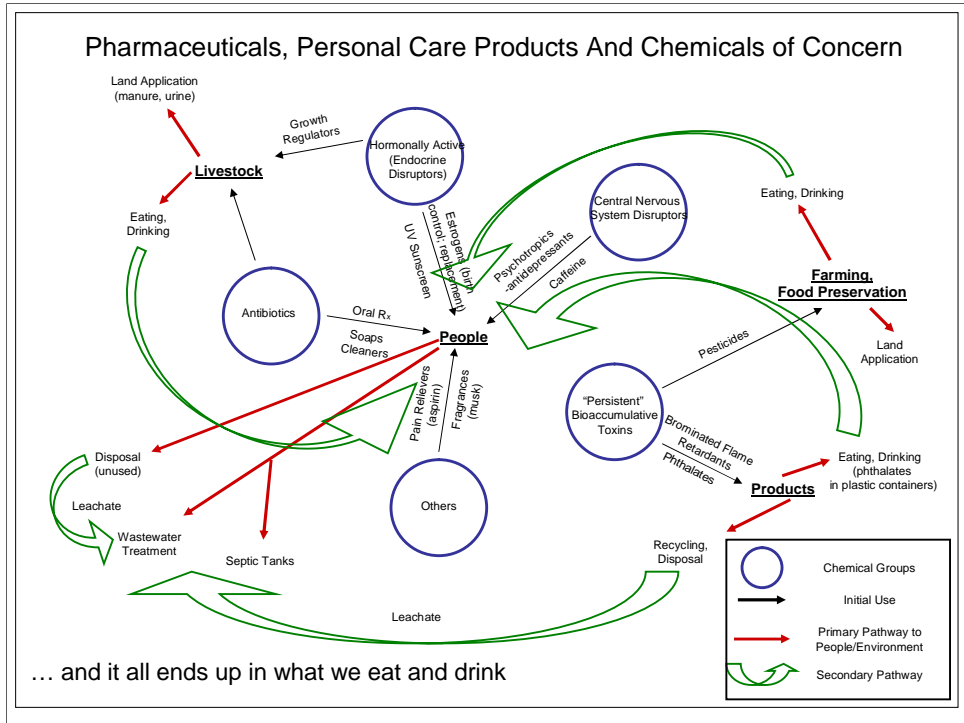
Examples

Chemical Group	Human Uses	Other Uses
Hormonally Active (Endocrine Disruptors)	Estrogens (birth control, replacement, mimics); Sunscreen UV filters; Phthalates (plastics);	Growth regulators (livestock)
Nervous System Disruptors	Psychotropic/mood altering (antidepressants, attention deficit disorder drugs); Caffeine	?
Antibiotics	Oral prescriptions; antibacterial soaps; antibacterial cleaners	Livestock disease prevention
Persistent Bioaccumulative Toxins	Brominated flame retardants; Phthalates (plastics); Pesticides	Pesticides
Other	Fragrances (musk); Pain relievers (aspirin, acetaminophen)	?

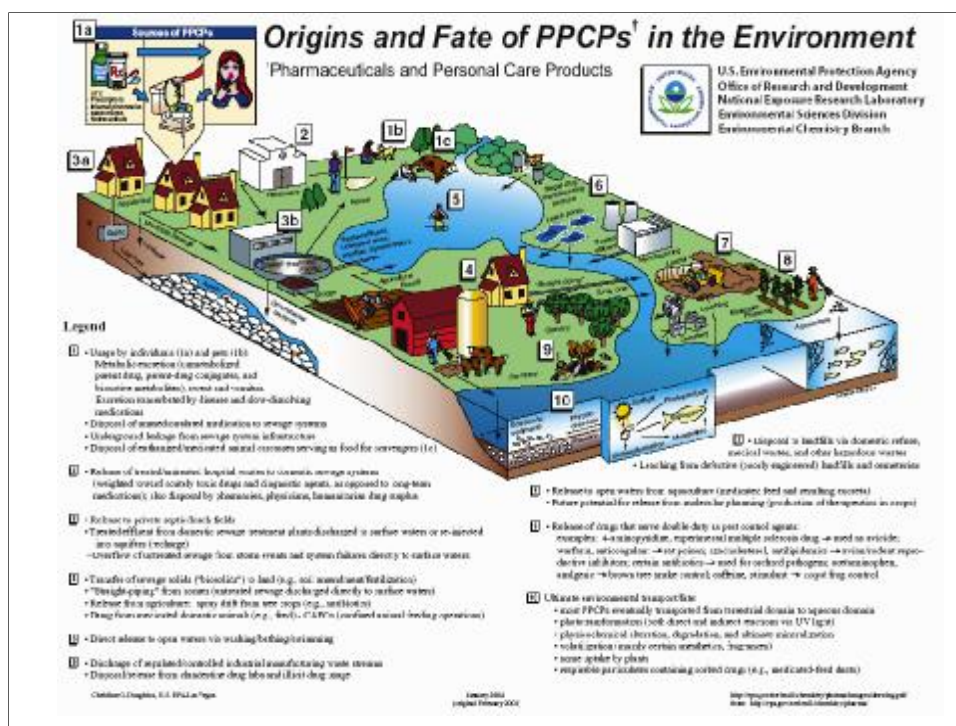
These are more examples of each chemical group.



The red arrows represent the primary pathway to people or the environment. Some proceed directly to people via eating or drinking or, in the case of phthalates, through contact with containers during eating or drinking. Pesticides and livestock antibiotics and growth regulators are land applied. Some products containing PBTs proceed to recycling or disposal. The antibiotics, endocrine disruptors, central nervous system disruptors and other chemicals (pain relievers, fragrances) that people ingest or topically apply proceed to disposal or are excreted into wastewater.

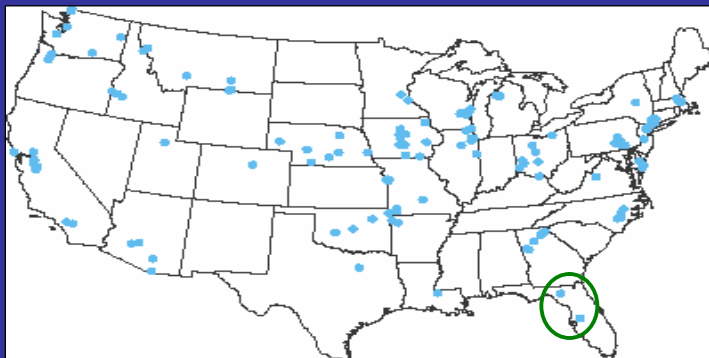


Finally, many of the primary pathways to people or the environment eventually make their way back to people in the food and water that we consume.



This second diagram is Christian Daughton's [USEPA] more complicated depiction of the origins and fates of pharmaceuticals and personal care products which is a general term encompassing the 5 chemical groupings on the first diagram. Daughton is the EPA's foremost researcher in the area of pharmaceuticals and personal care products. This and the preceding diagram show the origin, pathways and fates of these chemical groups. Now we will look at some of the science on the associations or relationships between these groups and their environmental impacts.

USGS Nationwide Reconnaissance 1999-2000



- Across 30 states, 139 streams believed to be susceptible to contamination were sampled
- 82 of 95 organic chemicals tested for were found – at least one found in 80% of the streams
- Most concentrations were low ($\mu\text{g/L}$ range)

“Low” means tens, hundreds or thousands of times less than existing drinking water standards, aquatic toxicity concentrations and therapeutic doses for these chemicals.

More on USGS Study

- Chemicals studied are used in households, agriculture, industry
- Human and veterinary drugs (including antibiotics)
- Natural and synthetic hormones
- Detergents
- Plasticizers
- Insecticides
- Fire retardants

Most commonly detected compounds?

- Cholesterol – plant & animal steroid
- N-N-diethyltoluamide – insect repellent
- Caffeine
- Triclosan – antimicrobial disinfectant
- Tri(2-chloroethyl)phosphate – fire retardant
- 4-nonylphenol – detergent metabolite
- Steroids, non prescription drugs, insect repellent were most frequently detected
- Detergent metabolites, steroids, plasticizers measured at highest concentrations

What does the science say?

Chemical Group	Impact on People	Impact on Other Species
Hormonally Active (Endocrine Disruptors)	? Y ?	Y
Central Nervous System Disruptors	?	Y
Antibiotics	? Y ?	Y
“Persistent” Bioaccumulative Toxins	?	Y
Other (Fragrances, Pain Relievers)	?	?

This table is a general summary of the science that we have examined to date. A “?” indicates that the science has not yet shown whether or not the reported concentrations of these chemicals are having an impact on people or other species. A “Y” means that the science seems to be converging or has already converged to some level of certainty that they are having an impact. A “? Y ?” means that some studies suggest that there may be an impact on people but the science is still inconclusive. A major bone of contention is the extent to which the impacts observed on other species can transfer to people.

Now to look at some of the science for each of the 5 chemical groups.

Mutating Fish

- Potomac River near Moorfield, W. VA
- Reports of fish with lesions
- 42% of male bass dissected had developed eggs inside their sex organs
- Cause is believed to be pollution in the water
 - drugs and compounds that interfere with the chemical signals that make fish grow and reproduce
- 2003 study found high rates of feminized male bass, e.g., immature eggs in the testes
- Subsequent lab studies showed that those rates of feminization were not normal
- Feminization found both below wastewater treatment outfalls and in the headwaters
- Suggests pharmaceuticals and municipal and industrial runoff a problem in the former, agricultural runoff in the latter
- "There are many, many compounds that can act as estrogens"
- "If the fish are getting their hormones fouled up ..., then you better believe it's a problem for us."



Let's start with the first chemical group on the diagram - hormonally active chemicals or endocrine disruptors. These slides are follow up studies based on the initial USGS study/survey

Endocrine Disruptors

- Endocrine glands release hormones which, when they contact a compatible receptor, alter that cell's proteins or protein production to create a reaction throughout the body
- US EPA's Endocrine Disruptor Screening Program since 1996 focuses on estrogens, androgens and thyroid hormones
- Disruptors may mimic or block a natural hormone; or directly inhibit or stimulate the endocrine system into over- or under-producing hormones
- Effects may be delayed for years or generations, e.g., diethylstilbestrol (DES) given during pregnancies in 1970's responsible for increased vaginal cancers in female children after puberty

US EPA has an Endocrine Disruptor Screening Program [http://www.epa.gov/scipoly/oscpendo/index.htm] "for screening and testing chemicals for potential endocrine disruption"

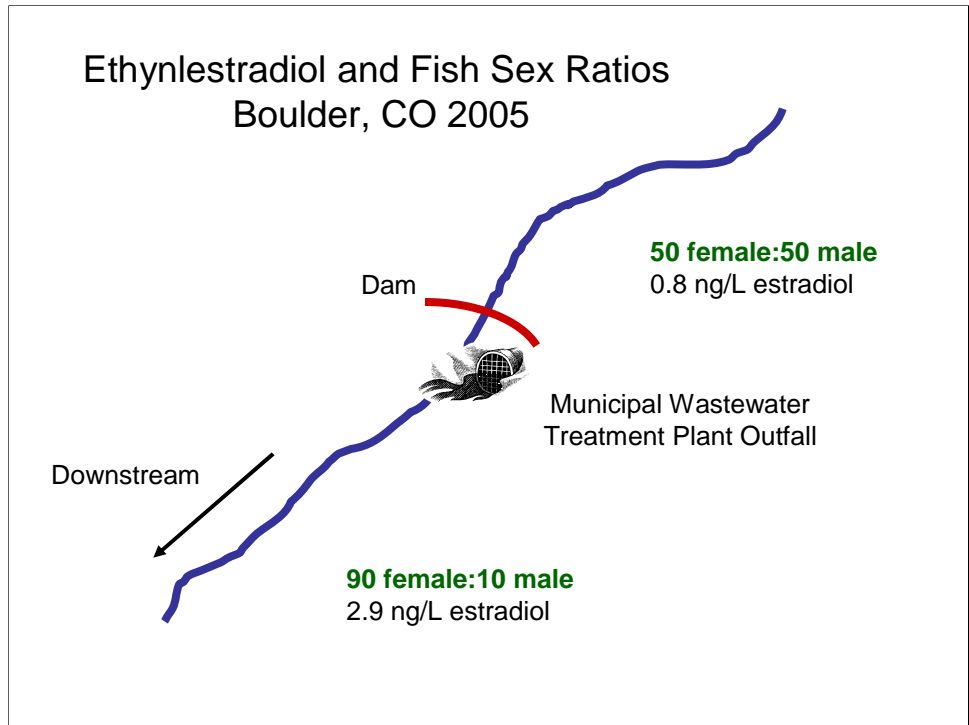
Estrogens – female sex characteristics

Androgens – male sex characteristics, e.g., testosterone

Thyroid - control biological processes such as growth, reproduction, development, and metabolism

"One example of the devastating consequences of the exposure of developing animals, including humans, to endocrine disruptors is the case of the potent drug diethylstilbestrol (DES), a synthetic estrogen. Prior to its ban in the early 1970's, doctors mistakenly prescribed DES to as many as five million pregnant women to block spontaneous abortion and promote fetal growth. It was discovered after the children went through puberty that DES affected the development of the reproductive system and caused vaginal cancer. Since then, Congress has improved the evaluation and regulation process of drugs and other chemicals. The recent requirement of the establishment of an endocrine disruptor screening program is a highly significant step."

-"What are Endocrine Disruptors?" [webpage] Accessed 1/20/06 from <http://www.epa.gov/scipoly/oscpendo/edspoverview/whatare.htm>



-At Boulder, CO, the municipal wastewater treatment plant discharge is just below (downstream of) the dam. The dam serves as a blockage preventing fish from moving upstream; the fish above the dam can get washed over it downstream, but the fish downstream can't swim up. So the upstream population of fish cannot be affected by what is happening in the water downstream. Thus it sets up an in-situ experiment. When they look at the sex ratios of sucker fish, they notice that the fish upstream have a relatively normal or expected ratio of 50:50 female:male. When they look immediately downstream of the dam and the wastewater discharge, they notice that the ratio is 80:10 to 90:10. So something is feminizing the fish downstream of the dam. This effect correlates with increased levels of ethynyl-estradiol, the synthetic birth control hormone, which is discharged from the municipal outfall. It is found at less than 0.8 nanograms per liter in upstream water, and at 2.9 ng/l near the outfall discharge, gradually diluting farther downstream. It is only a correlation, but a very interesting one. "Further study is warranted."

-Galvin, David, King County (WA) Hazardous Waste Program, 5/26/06 personal communication email to Raoul Clarke, FL DEP

Hormonally Active: Endocrine Disruptors

- “Boys will be girls – eventually: Extinction threat rises as creatures ingest 'gender-bending' chemicals from plastics and pesticides” 7/18/2004, The Observer (UK)
- Boulder, CO: 50:50 female:male fish upstream of dam, 90:10 downstream; ethynylestradiol concentrations measurably higher downstream
- Concern that, at some point, a species could no longer reproduce
- Creeping up the food web? “increasing evidence of falling sperm counts and infertility among men”

“The first national survey of 42 rivers by the [UK] Environment Agency has just been completed and it found that a third of male fish are growing female reproductive tissues and organs. Effects were most pronounced in younger fish, raising grave implications for future stocks. ... Blame has fallen on the increasing prevalence of a group of chemicals known as endocrine disruptors. These are found in plastics, food packaging, shampoos and pesticides and accumulate in the environment. They can mimic the female hormone oestrogen when ingested. ... As the effect of the chemicals starts to creep up the food chain, concern will mount over the potential effect on human health amid increasing evidence of falling sperm counts and infertility among men. ... [One researcher] warns that a point where a species can no longer reproduce is a very real concern.”

-Townsend, Mark (2004). “Boys will be girls – eventually:

Extinction threat rises as creatures ingest 'gender-bending' chemicals from plastics and pesticides” 7/18/2004, The Observer (UK)

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Hormonally Active: Phthalates and Children

- Consumer products
 - For humans, a wide range of consumer products (e.g., water bottles, cleaning products, personal products, cosmetics, garden chemicals) provide pathways of exposure via inhalation, ingestion, and dermal contact.
- Children's toys
 - Of particular concern is the potential for phthalate ester exposure in young children orally by chewing on toys and teething rings -(Steiner et al., 1999).

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the potential for phthalate ester exposure in young children orally by chewing on toys and teething rings (Steiner et al., 1999)."

- Steiner I, Kubesch K, Wildhack A & Fiala F (1999) Migration of phthalates from PVC-consumption goods.

Lebensmittelchemie,

53:147-148, cited in World Health Organization (2002), "Global Assessment of the State-of-the-Science of Endocrine Disruptors ", p. 92, accessed 1/24/06 from

http://www.who.int/ipcs/publications/new_issues/endocrine_disruptors/en/index.html.

Hormonally Active: UV Filters in Sunscreen

- 4-MBC (4-methylbenzylidene camphor) elevated levels in fish downstream from wastewater treatment plants in Switzerland
- Endocrine disrupting effects in rats at these levels
- Industry: EU evaluation found no estrogenic effect in humans; weigh environmental risk against skin cancer prevention
- Substitution of “safer” UV filter in sunscreens “a few years ago” due to bad publicity in Scandinavia
- 4-MBC levels in Switzerland decreasing since 2002 – “immediate environmental effect”

UV filters in sunscreen a good example of an ubiquitous endocrine disruptor and the dueling science surrounding its risk to human health

All of the 19 fish tested in the recent study had traces of two of the most commonly used UV filters in Europe-4-MBC (4-methylbenzylidene camphor) and OC (octocrylene). The fish had levels of 4-MBC 10 x higher than fish in remote mountain lakes (2004 study). Both chemicals biodegrade slowly and can bioaccumulate, according to the researchers. Washes off during swimming and showering.

Endocrine disrupting effects (alters

reproductive function and affects birth weight

What does the science say?

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Other (Fragrances, Pain Relievers)	?	?

information at www.environmentalhealthnews.org seems to suggest that the science is converging for endocrine disruptors.

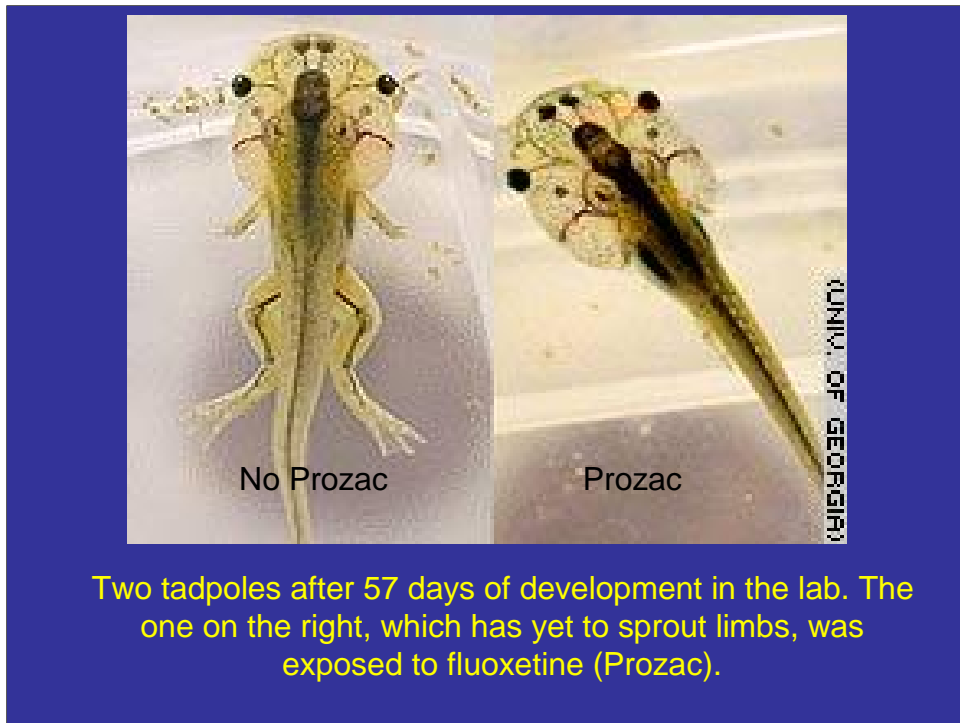
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Problems Have Been Found Outside the US

- Prozac (fluoxetine) has been found in drinking water in the UK
- Drug enters water systems via treated wastewater
- Fish near a Norwegian Arctic city
- High doses of caffeine, epileptic drugs and antidepressants
- Waters these fish reside in contained measurable traces of ibuprofen



The second chemical group on the diagram - central nervous system disruptors
Examples—more studies have been done in other areas around the world



A graphic example of what prozac in the water can do to a sentinel amphibian species that reacts quickly to changes in its environment.

Nervous System Disruptors: Fluoxetine (Prozac)

- UK doctors prescribed 4+ tons in 2004
- Criteria for deciding which pharmaceuticals to monitor include frequency of use and level of threat posed
- “Call for monitoring not due to increased threat, we simply now have the tools to do the monitoring”
- “If it’s there, is it a threat?”
- “If a threat, what do we do to reduce?”

Last year [2004] British doctors issued over five million prescriptions for the drug, adding up to over four tonnes of the compound. "When people take pharmaceuticals like fluoxetine small quantities can be excreted," said Derek Tinsley, the [Environment Agency's] head of air and chemicals policy. "This, and the disposal of unwanted medicines down household drains, creates the potential for these substances and their breakdown products to enter sewage works and rivers. "Although our sewage treatment plants remove most of these products small quantities can remain in the effluent that is returned to the rivers and seas." The agency has stressed it does not believe there is any threat to humans but wildlife may be at risk. "We don't know how much fluoxetine is finding its way into the environment," said Mr Tinsley. "What we do know is that it's a widely used substance, it's toxic to wildlife at low concentrations and once in the environment it persists for quite a while. "Previous research backed up by our own initial calculations suggests that fluoxetine will not be at levels in our rivers high enough to kill aquatic life. "However, we are unclear about the longer term and subtle impacts such as effects on reproduction and growth that very low but continuous concentrations might have on our aquatic species."

A spokesman for the agency said the call for industry help did not reflect any perceived increase in the problem, however, but purely that the research and monitoring tools were now in place to carry out the work. He said the criteria about which pharmaceuticals were monitored was decided by a number of criteria, but the main factors were the level of threat posed and how widely used a substance is and fluoxetine had appeared as a blip on the EA's radar primarily due to the frequency with which the drug was being prescribed. "If we do find the compound in the environment we will then need to see if it is

having an effect," he said. "If it is then we would need to look at what we can do to reduce it." "We would look at ways we can work with industry to address the situation."

-Bond, Sam (2005). "Industry urged to help track antidepressants in UK rivers" Environmental Data Interactive (UK)

20-May-2005, posted 5/23/06 to pharmwaste@lists.dep.state.fl.us.

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Antibiotic Resistant Bacteria -Topical Use-

- Antibiotic use clearly selects for antibiotic resistance
- Triclosan: commonly used antimicrobial in soaps (bar, liquid) and other personal care products
- Commonly found in 95 US streams surveyed by USGS 1999-2000
- No evidence of any extra health benefits for a healthy household [environmental advocacy group]
- Not necessary in everyday use, hand washing with ordinary soap and water is an effective way to prevent infection [attributed to Center for Disease Control]
- Soap and Detergent Association responds and cites studies "safe ... effective ... does not promote antibiotic resistance"

A third chemical group from the diagram – antibiotics. The concern here is that antibiotic use clearly selects for antibiotic resistance

Further it appears that the routine everyday use of antibiotics in soaps and other personal care products may not provide much of an extra health benefit: washing with ordinary soap and water looks to be just as effective. But . . . not everybody agrees . . . like the soap and detergent trade group.

-Smith, DL, Jonathan Dushoff, J. Glenn Morris, Jr. (2005) "Agricultural Antibiotics and Human Health" Public Library of Science Medicine 2:8 August 2005, accessed 7/1/05 from www.plosmedicine.org per 7/1/05 email from Stevan Gressit as posted to pharmwaste-admin@lists.dep.state.fl.us.

Triclosan

-"Antimicrobial pesticides are substances or mixtures of substances used to destroy or suppress the growth of harmful microorganisms whether bacteria, viruses, or fungi on inanimate objects and surfaces,"

"Triclosan has been used for over 30 years. Its uses were originally confined mostly to health care settings, first introduced in the health care industry in a surgical scrub in 1972. Over the last decade, there has been a rapid increase in the use of triclosan-containing products. A marketplace study in 2000 by Eli Perencevich, M.D. and colleagues found that over 75% of liquid soaps and nearly 30% of bar soaps (45% of all the soaps on the market) contained some type of antibacterial agent. Triclosan was the most common agent found – nearly half of all commercial soaps contained triclosan."

-"But no current data demonstrate any extra health benefits from having antibacterial-containing cleansers in a healthy household. For example, a study of over 200 healthy households found that those households that used antibacterial products did not have any reduced risk for symptoms of viral infectious diseases. The Centers for Disease Control and Prevention says that antibacterial soaps are not necessary in everyday use, and washing hands with ordinary soap and warm water is an effective way to ward off infections."

-"When used in hospitals and other health care settings, or for persons with weakened immune systems, triclosan represents an important health care and sanitary tool. But outside of these settings, it is unnecessary, and the constant exposure to triclosan becomes a health and environmental hazard."

-Glaser, Aviva (2004). "The Ubiquitous Triclosan - A common antibacterial agent exposed." Pesticides and You: Beyond Pesticides [National Coalition Against the Misuse of Pesticides], 24:3 (12-17). Accessed 1/10/06 at www.beyondpesticides.org/pesticides/factsheets

-Soap and Detergent Association (SDA). The trade group that represents manufacturers of cleaning products that often contain triclosan, issued a press release claiming that Beyond Pesticides' triclosan article was sounding a "false alarm."

- Kepner, John (2004-2005). "Triclosan Hazards...Continued: Trade group misleads on common antibacterial agent." Pesticides and You: Beyond Pesticides [National Coalition Against the Misuse of Pesticides], 24:4 (9-11). Accessed 1/10/06 at www.beyondpesticides.org/pesticides/factsheets

Antibiotics and Livestock -Systemic Use-

- Routinely used for growth enhancement and disease resistance
- Antibiotic resistant bacteria occasionally move from animals to humans (direct ingestion; runoff from CAFOs)
- Linking bacterial antibiotic resistance on farms to resistance in humans is controversial and poorly quantified

“Like SARS, Ebola, and other emerging infectious diseases, antibiotic resistance in bacteria may have a zoonotic origin [1]. Evidence suggests that antibiotic use in agriculture has contributed to antibiotic resistance in the pathogenic bacteria of humans, but the chain from cause to effect is long and complicated. Antibiotic use clearly selects for antibiotic resistance, but how far do these effects extend beyond the population where antibiotics are used? Antibiotics and antibiotic-resistant bacteria (ARB) are found in the air and soil around farms, in surface and ground water, in wild animal populations, and on retail meat and poultry [2-9]. ARB are carried into the kitchen on contaminated meat and poultry, where other foods are cross-contaminated because of common unsafe handling practices [10,11].

Following ingestion, bacteria occasionally survive the formidable but imperfect gastric barrier, and colonize the gut [12].

Patterns of colonization (asymptomatic carriage) and infection (symptomatic carriage) in human populations provide additional evidence that ARB occasionally move from animals to humans [13,14]. The strongest evidence comes from the history of the use of antibiotics for growth promotion in Europe. After first Denmark and then the European Union banned the use of antibiotics for growth promotion, prevalence of resistant bacteria declined in farm animals, in retail meat and poultry, and within the general human population [8,15].

Despite the evidence linking bacterial antibiotic resistance on farms to resistance in humans, the impact of agricultural antibiotic use remains controversial [16-19] and poorly quantified. This is partly because of the complex of population-level processes underlying the betweenspecies

("heterospecific") and withinspecies, host-to-host ("horizontal") spread of ARB. To emerge as human pathogens, new strains of ARB must (1) evolve, originating from mutations or gene transfer; (2) spread, usually horizontally among humans or animals, but occasionally heterospecifically; and (3) cause disease.

All three of these steps are complex and imperfectly understood.”

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Shampoo and Rats' Brain Cells

- Research shows that exposure to methylisothiazolinone (MIT) causes neurons in rats brains to die (Aizenman).
 - MIT, a biocide, is found in paint, hair color, shampoos, conditioners, body washes, etc.
 - MIT concentrations in hand cream was enough to kill neurons
 - Long exposure to low concentrations caused neuron communication malfunctions
- <http://householdproducts.nlm.nih.gov/index.htm>



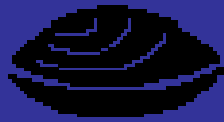
Human use antibiotics

-shows another effect (central nervous system disruptor) in addition to antibiotic resistant bacteria

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Musks and Mussels



- "Fragrances (musks) are ubiquitous, persistent, bioaccumulative pollutants that are sometimes highly toxic; amino musk transformation products are toxicologically significant." EPA, 1999 literature review
- Stanford University study: California mussels were found to have biological damage after short-term exposure to six widely used synthetic musk chemicals
- Musks compromise the mussels' immune system which allows for other chemicals to harm the organism
- May disable the efflux transporter that pumps toxins out of cells

The final chemical group: Others: fragrances and pain relievers.

What does the science say?

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It Gets More Complicated

**Multiple Effects,
Multiple Chemicals**

Multiple Effects of a Single Chemical - Triclosan

- In addition to possibly promoting antibiotic resistant bacteria, Triclosan may also:
 - Be toxic to aquatic organisms
 - Bioaccumulate
 - Transform into other toxic compounds
 - Methylate into methyl Triclosan
 - Photodegrade into dioxins
 - Chlorinate into chloroform

Triclosan is not the only contaminant of concern that may have multiple impacts and modes of action. This further complicates studying and understanding these contaminants.

Handout: Santa Clara Basin Watershed Management Initiative Emerging Contaminants Workgroup (2006). "Environmental Emergence of Triclosan: White Paper." Accessed 1/20/06 via 1/19/06 email attachment posted to Pharmaceutical Waste National Listserve [pharmwaste@lists.dep.state.fl.us]

Chemical Cocktails

- Standard lab analysis and field study examine the effects of one chemical at a time
- Multiple chemicals are typical in the environment and the effects of these “cocktails” are just starting to be studied



**“That pill they advertise all the time on TV.
I’m not sure what it is, but I want it!”**

And the media – our culture of a pill for every ill – wanting to try new drugs because the advertising is so compelling – free samples – noncompliance of the patient – changing prescriptions because of adverse reactions – etc.

You Can Help

- Don't ask for medications that you don't need
- Dispose of unwanted medications in the household trash taking precautions against accidental ingestion by humans or animals

Don't flush unwanted medications down the toilet or the drain.

Contacts for More Information

- Laurie Tenace
850.245.8759 laurie.tenace@dep.state.fl.us
- Jack Price
850.245.8751 john.l.price@dep.state.fl.us
- Raoul Clarke
850.245.8750 raoul.clarke@dep.state.fl.us

Florida Department of Environmental Protection