CHEMICAL RISK

OVERVIEW

The average worldwide human life span has increased from around 30 years at the beginning of the 20th century to more than 60 today, and it continues to rise.[1] In the United States, it has reached 76 according to a recent estimate.[2] The freedom to develop and put to use thousands of man-made chemicals has played a crucial role in that progress by making possible such things as pharmaceuticals, safe drinking water, pest control, and numerous other items.

Yet the public perception is that man-made chemicals are the source of every possible ill: from cancer to ozone depletion to infertility to brain damage. Ignoring the fact that nature produces far more chemicals at far higher doses[3] and that most chemicals are innocuous at low doses, activists capitalize on these fears. They scare the public by hyping the risks to ensure that the government passes volumes of laws and regulations focused entirely on the elimination of chemicals, without much regard for the trade-offs.

Advocates of such limits say that we need to make sure every chemical is safe before exposing the public to it. In his recent book, *Pandora's Poison*, Greenpeace's Joe Thorton calls on society to follow the "precautionary principle," which says "we should avoid practices that have the potential to cause severe damage, even in the absence of scientific proof of harm."[4] We should shift the burden of proof, he continues. Those individuals or firms introducing new chemicals must prove they are safe before introducing them into commerce, and those chemicals already in commerce that fail to meet this standard "should be phased out in favor of safer alternatives."[5]

The problem is, no one can prove anything is 100 percent safe. Not surprisingly, Thornton also advocates a "zero discharge" policy, which calls for the elimination of all "bioaccumulative"[6] chemicals. In particular, he has long called for the elimination of chlorine, about which he once noted: "There are no known uses for chlorine which we regard as safe."[7] More recently, perhaps in recogni-

[1] Nicholas Eberstadt, "World Population Prospects for the Twenty-first Century: The Specter of 'Depopulation?'" in *Earth Report 2000* (New York: McGraw-Hill, 2000), 65.

[2] U.S. Centers for Disease Control and Prevention (CDC), Bureau of the Census, *Health, United States, 2000* (Washington, D.C.: CDC, 2000), 7, http://www.cdc.gov/nchs/data/hus00.pdf.

[3] Bruce N. Ames and Lois Swirsky Gold, "Environmental Pollution, Pesticides and the Prevention of Cancer: Misconceptions," *FASEB Journal* (21 July 1997), http://socrates.berkeley.edu/mutagen/AmesGold.pdf.

[4] Joe Thornton, *Pandora's Poison: Chlorine, Health, and a New Environmental Strategy* (Cambridge, Mass.: MIT Press, 2000), 10.

[5] Ibid.

[6] For more information on bioaccumulative chemicals, see Daland R. Juberg, *Traces of Environmental Chemicals in the Human Body: Are They a Risk to Health*? (New York: American Council on Science and Health, April 1999), http://www.acsh.org/publications/booklets/traceChem.pdf.

[7] Ivan Amato, "The Crusade against Chlorine," *Science* 261, no. 5118 (9 July 1993): 152-54. For more information on chlorine issues, see Michelle Malkin and Michael Fumento, *Rachel's Folly: The End of Chlorine* (Washington, D.C.: Competitive Enterprise Institute, March 1996).

tion that this standard is politically untenable, he suggested that we continue using chlorine for "some pharmaceuticals" and for some "water disinfection," but only until other options become available.[8]

The Dangers of Precaution

Before we call for zero discharge of anything, however, we should think about what that means. Like anything, chemicals may create new risks, but they have been used to eliminate others — many of which wreaked havoc on civilization for centuries. As CEI's Fred Smith notes, "Experience demonstrates that the risks of innovation, while real, are vastly less than risks of stagnation."[9] Indeed, he asks, what would the world be like if we never introduced penicillin because we could not prove it's 100 percent safe?

Chemicals Transform Our Lives

Although we don't think much about it, man-made chemicals are essential to almost everything we do. They make our cars run; they clean everything from our teeth to our dishes; they reduce illnesses by disinfecting our bathrooms at home and the operating rooms in our hospitals; they are used on food products such as poultry to eliminate *E. coli* and other deadly pathogens; and they keep our computers, television sets, and other electronic products running. For example, consider a few of the critical functions man-made chemicals perform in making our lives better:

- Chlorination of water supplies has saved millions of lives. For example, since local engineers and industry introduced chlorination in the 1880s, waterborne-related deaths in the United States dropped from 75 to 100 per 100,000 people to fewer than 0.1 deaths per 100,000 annually in 1950.[10]

- Rather than curtailing the use of chlorination, as Thornton suggests, we should be expanding access. According to the World Health Organization (WHO), in the developing world, diarrhoeal diseases (such as cholera and dysentery) kill about two million children under five years of age each year because of such problems as poor sanitation and unsafe drinking water.[11]

- The Center for Disease Prevention and Control (CDC) notes that fluoridation of water (fluoride is yet another chemical targeted by environmentalists) had proven a tremendous benefit for oral hygiene.[12]

- Nearly 85 percent of pharmaceuticals that we use require the use of chlorine in their production.[13]

- Thanks to chemicals used for pharmaceuticals, combination drug therapy reduced AIDS deaths by more than 70 percent from 1994 to 1997.[14]

[8] Thornton, *Pandora's Poison*, 14.
[9] Fred L. Smith, "The Dangers of Precaution," *Financial Times*, 23 February 2000.
[10] Michael J. LaNier, "Historical Development of Municipal Water Systems in the United States, 1776 to 1976," *Journal of the American Water Works Association* (April 1976): 177.
[11] Statement by Dr. David L. Heymann, Executive Director for Communicable Diseases, World Health Organization, Before the Committee on International Relations, U.S. House of Representatives, 29 June 2000.
[12] "Ten Great Public Health Achievements — United States, 1900-1999," *Morbidity and Mortality Weekly Report* 48, no. 12 (2 April 1999): 241-243.
[13] Gordon W. Gribble, *Chlorine and Health* (New York: American Council on Science and Health, 1995), http://www.acsh.org/publications/booklets/chlorine.html.
[14] Frank J. Palella et al., "Declining Morbidity and Mortality among Patients with Advanced HIV Infection," *New England Journal of Medicine* 338, no. 13 (26 March 1998), http://www.nejm.com /content/1998/0338/0013/0853.asp.

- Fifty percent of the reductions of heart-disease-related deaths between 1980 and 1990 (a total death rate decline of 30 percent) are attributable to medicines and the chemicals that comprise them.[15]

- Chemicals called "phthalates" (there are several kinds of phthalates) are used in PVC — vinyl used for medical tubing, blood bags, and numerous other products. While environmentalists have tried to ban these products,[16] vinyl medical devices provide numerous lifesaving benefits. PVC is a safe, durable, sterile product that can withstand heat and pressure, as well as produce tubing that doesn't kink. It's particularly beneficial for vinyl blood bags because it stores blood twice as long as the next best alternative and doesn't break as glass alternatives do. With blood shortages looming, PVC blood bags are an essential tool in maintaining and transporting supply.[17]

- "Biocidal" chemicals may soon find their way into hospital uniforms and other textiles used in hospitals and thereby help prevent these materials from carrying viruses around the hospital and transmitting them to patients. Diseases acquired in hospitals account for as many as 80,000 deaths a year, and studies have found that bacteria can survive long periods on worker's uniforms — making them vehicles for disease-causing bacteria.[18] If the anti-technology activists don't try to ban them first, use of these biocidal chemicals in hospital uniforms may soon help save thousands of lives every year.

- Thanks to modern farming with chemicals, food production has outpaced population growth, providing people in both developed and developing countries with more food per capita. Per capita grain supplies have grown by 27 percent since 1950, and food prices have declined in real terms by 57 percent since 1980.[19]

- The use of herbicides to control weeds decreases the need for tilling soil, which in turn reduces soil erosion by 50 percent to 98 percent.[20]

- The use of high-yield farming (which employs chemical fertilizers, pesticides, herbicides, etc.) means we feed more people while farming less land — leaving more land for wildlife. If we had continued to farm with 1950s technology — when most of the world did not use pesticides and fertilizers — today we would have to plant 10 million square miles of additional land to generate the food we now produce.[21] That's more land than all of the United States, Canada, and Central America combined (which is about 8.6 million square miles) and almost as much as all the land in Africa (which is just under 12 million square miles).

Disregarding such benefits, most of the key U.S. environmental regulatory statutes follow the lead of groups like Greenpeace, focusing on the elimination of chemicals without considering the dangers of not having these technologies. The Clean Water Act, for example, makes the unattainable pledge: "it is the national goal that the discharge of pollutants into the navigable waters be eliminated by 1985."[22] While we can meet reasonable clean water goals, we can't meet a zero discharge without

[15] M.G. Hunink et al., "The Recent Decline in Mortality from Coronary Heart Disease, 1980-1990," *Journal of the American Medical Association* 277, no. 7 (19 February 1997): 535-42, http://www.ncbi.nlm.nih.gov:80/entrez query.fcgi?cmd=Retrieve&db=PubMed&list_uids =9032159&dopt=Abstract.
[16] Bill Durodie, *Poisonous Propaganda: Global Echoes of an Anti-Vinyl Agenda* (Washington, D.C.: Competitive Enterprise Institute, July 2000).
[17] See Angela Logomasini, "Blood Supply Besieged," *Washington Times*, 10 August 2000, http://www.cei.org /OpEdReader.asp?ID=1136.
[18] Gan Sun and Jeffrey Williams, "Dressed to Kill: Incorporating Biocidal Agents into Textiles Gives Added Protection Against Infectious Diseases," *Chemistry and Industry*, 6 September 1999.
[19] Dennis Avery, "Saving the Planet with Pesticides," in *True State of the Planet* (New York: Free Press, 1995), 52-54.
[20] Ibid., 74-76.
[21] Ibid., 71.
[22] 33 U.S.C. §1251(a)(1).

forcibly halting industrial processes that bring us lifesaving medicine, a safe food supply packaged to ensure that it will last, or even clothing. Likewise, regulations that EPA issued under the Safe Drinking Water Act actually set zero as the goals for certain chemical contaminants in drinking water — something that is impossible and totally unnecessary for public health purposes. With such goals, drinking water standards for chemicals are very stringent. For example, one standard demands that drinking water not contain more than 0.03 parts per *trillion* of a contaminant.[23] The high costs of such onerous standards mean that financial resources are diverted from other more essential needs, such as infrastructure upgrades and microbial contamination.[24]

Other statutes simply assume that using chemicals somehow makes a business suspect. Under the Toxic Release Inventory (TRI),[25] firms must report all chemical "releases," chemical uses, and processes that use chemicals. Environmentalists say this law encourages firms to reduce "pollution." But not all "releases" constitute pollution,[26] and not all pose public health consequences. The question should not be whether we use chemicals, but whether we use them responsibly and what we gain in return. To gain points with environmentalists, firms can reduce chlorine use, but are we willing to drink water swimming with microbial contaminants and give up life saving pharmaceuticals?

— Angela Logomasini

[23] Standard for dioxin (see EPA listing of drinking water standards at http://www.epa.gov/safewater/mcl.html). Dioxin is released into the air from both natural (such as forest fires) and industrial processes. Very low (and safe) levels find their way into many foods. For example, Ben & Jerry's Ice Cream contains 0.79 to 0.38 parts per trillion of dioxin (see http://www.junkscience.com/nov99/bjpress.htm). However, while dioxin is a key target of environmentalists, it has never been shown to cause any illness other than a skin disorder among very highly exposed individuals; see Michael Gough, "Reevaluating the Risks from Dioxin," *Journal of Regulation and Social Costs* 1, no. 3 (June 1991): 5-23.

[24] See briefs "Safe Drinking Water Act Overview" and "Rural Drinking Water" in the Safe Drinking Water Act section of *The Environmental Source.*

[25] TRI is a program created by the Emergency Planning and Community Right to Know Act, 42 U.S.C. § 11001 et seq.; see brief "Toxics Release Inventory" in the Solid and Hazardous Waste section of *The Environmental Source.*

[26] For example, "releases" include: materials that have been recycled; chemicals that are properly disposed of in modern landfills; wastes safely managed at the site of a facility; and liquids pumped from the ground and reinjected into the ground during oil drilling operations. While none of these activities would constitute pollution to most people, TRI counts the movements of such materials as pollution.

TRUE CAUSES OF CANCER

Environmental activists have long claimed that man-made chemicals are causing rampant cancer rates that could be addressed only by government regulation. Accordingly, lawmakers have passed laws directing government agencies to study environmental causes of cancer, estimate the number of lives allegedly lost, and devise regulations to reduce death rates. However, lawmakers should be aware of some key problems with how this system has worked in practice. First, the claim that chemical pollution is a major cause of cancer is wrong. Second, agencies have relied on faulty scientific methods that grossly overestimate potential cancer deaths from chemicals and potential lives saved by regulation. As a result, regulatory policy tends to divert billions of dollars from other lifesaving or quality-of-life-improving uses to pay for unproductive regulations.

In their landmark 1981 study of the issue, Sir Richard Doll and Richard Peto set out to determine the causes of preventable cancer in the United States. Their analysis and subsequent research have demonstrated conclusively that there is no "cancer epidemic."

- Cancer rates have remained nearly constant in the United States during the 20th century except for cancer rate increases caused by smoking. Improvements in medical technology, more accurate identification and reporting of cancer cases, and, most importantly, increasing life expectancies, only make it appear as if rates increased.[1]

- More recently, scientists Bruce Ames and Lois Swirsky Gold report that overall cancer rates, excluding lung cancer, have declined 16 percent since 1950, and that the rise in cancer among the elderly population is best explained by improved screening.[2]

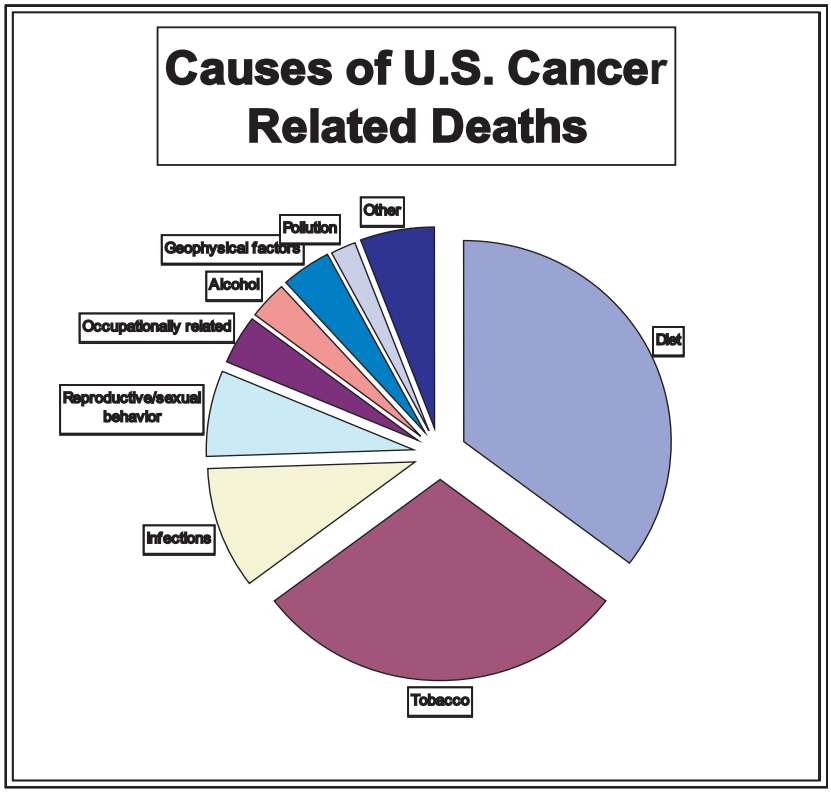
- Phyllis A. Wingo and seven other government scientists have reviewed national data on the occurrence of new cancer cases (incidence) and cancer mortality. Rates for overall cancer are down, and rates for almost all specific cancers also are falling; even lung cancer is falling as a result of reduced smoking rates over the last 25 or more years.[3] Wingo et al. do not mention environmental exposures in the discussion of cancer trends.

According to Doll and Peto, pollution accounts for 2 percent of all cancer cases and geophysical factors account for another 3 percent. They do note that 80 percent to 90 percent of cancers are caused by "environmental factors." While activists often trump this figure as evidence that industrial society is causing cancer, Doll and Peto explained that "environmental factors" simply means factors other than genetics. It does not mean pollution alone. Environmental factors include smoking, diet, occupational exposure to chemicals, "geophysical factors," such as naturally occurring radiation, man-made radiation, medical drugs and radiation, and pollution.

- Tobacco use accounts for about 30 percent of all annual cancer deaths.[4]

- Dietary choices account for 35 percent of annual cancer deaths.[5]

[1] Richard Doll and Richard Peto, "The Causes of Cancer: Quantitative Estimates of Avoidable Risks of Cancer in the United States Today," *Journal of the National Cancer Institute* 66, no. 6 (June 1981): 1257.
[2] Bruce N. Ames and Lois Swirksy Gold, "Environmental Pollution, Pesticides, and Prevention of Cancer: Misconceptions," *FASEB Journal* 11, (21 July 1997): 1041-1052.
[3] Phyllis A. Wingo et al., "Annual Report to the Nation on the Status of Cancer, 1973-1996, With a Special Section on Lung Cancer and Tobacco Smoking," *Journal of the National Cancer Institute* 91, no. 8 (April 1999): 675.
[4] Doll and Peto, "The Causes of Cancer."
[5] Ibid.



- Bruce Ames and Lois Swirsky Gold have come to similar conclusions, noting that smoking causes about a third of all cancers. They underline the importance of diet by pointing out that the quarter of the population eating the fewest fruits and vegetables had double the cancer incidence than those eating the most. Finally, they find, "There is no convincing evidence that synthetic chemical pollutants are important as a cause of human cancer."[6]

The Dose Equals the Poison

Before government officials, both domestic and international, advocate or issue regulations, they need to justify them on the basis of public health benefits. Accordingly, regulators and scientists at international organizations have developed various tests to assess risks. While these tests have a tremendous impact on what chemicals are chosen to be regulated and to what degree, there are serious problems with the methodologies and the claims that researchers make about their findings.

During much of history, scientists contended, "the dose makes the poison." Indeed, small levels of substances can be helpful or benign, but at high levels, they can sicken or kill. But during the latter part of the 20th century, regulators, many in the "environmental community," and a few scientists abandoned this idea. They contended that many chemicals can have adverse effects at any level and that risks increase linearly with any dose above zero. On the basis of those assumptions, regulatory policy around the world has focused on ways to regulate chemicals to reduce exposure as close to zero as possible. But many scientists question whether such "linearity" even exists. They contend that the old way of thinking was correct: many chemicals are safe under a given "threshold" or exposure level, with each chemical having its own threshold.

[6] Ames and Gold, "Environmental Pollution, Pesticides, and Prevention of Cancer," 1041.

- Scientist Philip Abelson notes that the "error in this approach is becoming increasingly apparent through experiments that produce data that do not fit the linear model." Indeed, he argues, "Pharmacologists have long stated that it is the dose that makes the poison."[7]

- Others note that the low-dose linearity model ignores the fact that the body may create defense mechanisms against chemicals when exposed to them at low doses, which means, low-level exposures might help fight off cancer and other illnesses. Scientist Jay Lehr notes that studies have found instances where people exposed to low levels of radiation actually experienced less incidence of leukemia than the general population, while highly exposed individuals experienced elevated rates of leukemia.[9]

How Many Cancers Can EPA Regulate Away?

As EPA proposes hundreds of regulations, each regulation often promises to save thousands of people from dying of cancer. Together, these would likely add up into the millions. But compared to the actual number of deaths and likely causes, do these claims hold water? Scientist Michael Gough demonstrates that we should consider such EPA claims as suspect.

Gough analyzed the findings of the landmark Doll and Peto study on the causes of cancer along with EPA estimates of cancer risks in EPA's report *Unfinished Business.* Dr. Gough came to conclusions similar to those of Doll and Peto. He noted that between 2 percent and 3 percent of all cancers could be associated with environmental pollution. Determining such numbers helps us understand what exactly the EPA can expect to accomplish when regulating pollutants for the purposes of reducing cancer. Michael Gough notes that the EPA action could address only a very small percentage of cancers.

Gough notes: "If the EPA risk assessment techniques are accurate, and all identified carcinogens amenable to EPA regulations were completely controlled, about 6,400 cancer deaths annually (about 1.3% of the current annual total of 435,000 cancer deaths) would be prevented. When cancer risks are estimated using a method like that employed by the Food and Drug Administration (FDA), the number of regulatable cancers is smaller, about 1,400 (about 0.25%)."[8]

- Another study found that increasing levels of low-level radon exposure is linked to *decreasing* cancer rates.[10]

- Increasingly, the idea that all chemicals are unsafe at any level is losing credibility.[11] In fact, the U.S. EPA proposed a rule that would have applied threshold assumptions in 1998. When EPA reversed its position, a federal court vacated the rule because EPA did not use the best peer-reviewed science, as required by the Safe Drinking Water Act.[12]

[7] Philip Abelson, "Radon Today, 'The Role of Flimflam in Public Policy,'" *Regulation* (Fall 1991): 97.
[8] See Michael Gough, "How Much Cancer Can EPA Regulate Away?" *Risk Analysis* 10, no. 1 (1990): 1-6, and "Estimating Cancer Mortality," *Environmental Science and Technology* 23, no. 8 (1989): 925-30.
[9] Jay Lehr, "Good News About Radon: The Linear Non-threshold Model Is Wrong," May 1996, http//:www.junkscience.com/newslehr.html. See also http://cnts.wpi.edu/RSH/index.html.
[10] B. L. Cohen, "Test of the Linear No-Threshold Theory of Radiation Carcinogenesis for Inhaled Radon Decay Products," *Health Physic* 68, no. 2 (1995): 157-74.
[11] For a discussion of thresholds, see James D. Wilson, "Thresholds for Carcinogens: A Review of the Relevant Science and its Implictions for Regulatory Policy," in *What Risk?* ed. Roger Bate (Boston: Butterworth, Heinemann, 1997): 3-36.
[12] See "Disinfection Byproducts" in the Safe Drinking Water Act section of *The Environmental Source.*

Mice, Men, and Carcinogens

When environmentalists and government agencies label chemicals as carcinogens, they often point to rodent tests. However, the tests have proven to be seriously flawed. They entail administering massive amounts of chemicals to rodents bred to be highly susceptible to cancer. Then researchers extrapolate the possible effects of such chemicals on humans who may be exposed to small amounts of the same chemical over their lifetimes.

First, we should ask, are the impacts on rodents relevant to humans? Richard Doll and Richard Peto note that some chemicals found to be carcinogenic in humans have not produced cancerous tumors in rodent experiments. In fact, for many years, cigarette smoke failed to produce malignant tumors in laboratory animals despite the fact that tobacco is perhaps the leading cause of cancer in the United States. These discordant effects of chemicals on animals and humans underline the difficulty of relying on animal results to estimate human risks.[13]

Second, are the very high doses administered in the lab relevant to low-level exposures in the real world? Bruce Ames and Lois Swirsky Gold demonstrate why we need not be concerned about low-level exposure to "rodent carcinogens."[14] Ames and Gold found that such chemicals pose no more of a risk than those posed by many natural, unregulated substances that are common and accepted parts of a healthy diet.

While 212 of the 350 synthetic chemicals examined by various agencies were found to be carcinogenic at the massive doses given to rodents, 37 out of 77 of the natural substances tested also were found carcinogenic in rodent studies employing the same methodology.[15]

Some Facts About Cancer Clusters

In recent years, Hollywood produced two major motion pictures — "A Civil Action" and "Erin Brockovich" — on the alleged impacts of chemicals on various communities. In both cases, tort lawyers claimed that drinking water contaminated by industrial facilities caused health-related problems in nearby areas.

Such cases raise public awareness about "cancer clusters," geographic areas where cancer rates exceed (or appear to) those of the general population. But despite the ability of trial lawyers to win such cases, it's nearly impossible to pin down the causes of such clusters. In 1990, the Centers for Disease Control and Prevention reported on 22 years of studies that covered clusters in 29 states and five foreign countries. They could not establish a clear cause for any cluster.[16]

Part of the problem is that many clusters occur by mere chance. Raymond R. Neutra of the California Department of Health Services finds that we can expect 4,930 such random cancer clusters to exist in any given decade in the United States. Cancer cluster surveillance systems also mistakenly focus on low-level exposure to chemicals in the environment when such risks may be impossible to detect.[17]

[13] Doll and Peto, "The Causes of Cancer," 1192-1308.
[14] Ames and Gold, "Too Many Rodent Carcinogens: Mitogenesis Increases Mutagenesis," *Science* 249 (31 August 1990): 970.
[15] Ames and Gold, "Too many Rodent Carcinogens," 970.
[16] G. G. Caldwell, "Twenty-two Years of Cancer Cluster Investigations at the Centers for Disease Control," *American Journal of Epidemiology* 1 suppl. (July 1990): S43-47.
[17] See "Why Community Cancer Clusters Are Often Ignored" *Scientific American*, Special Issue (September 1996): 85-86.

- We safely consume thousands of natural chemicals every day at much higher levels than chemicals labeled carcinogens on the basis of rodent tests. For example, humans consume thousands of natural pesticides, which plants produce as a biological defense mechanism.

- Ames and Gold estimate that 99.99 percent (by weight) of the pesticides humans consume are natural pesticides.[18]

- The average intake of natural carcinogens found in plant foods is about 1,500 mg per person each day, while the average intake of man-made pesticides is 0.09 mg per day.[19]

- The commonness of exposures to chemicals is demonstrated by the identification of 826 volatile chemicals in roasted coffee. Although only 21 of those chemicals have been put through laboratory risk assessments, all but five were found to be carcinogenic in laboratory rat tests. A cup of coffee contains at least 10 mg of "carcinogenic" chemicals.[20]

- Carcinogens that cause cancer in rodent studies exist in apples, bananas, carrots, celery, coffee, lettuce, orange juice, peas, potatoes, and tomatoes at levels thousands of times greater than exposures found in drinking water.[21]

There is neither convincing evidence nor solid biological theory to support the contention that environmental exposure to natural or man-made chemicals is a significant cause of human cancer. Regulation of environmental exposures to chemicals can be expected to have no discernible effect on human health. The open question is how much money and effort is to be spent on those efforts and how many lives will be lost as regulation impedes lifesaving technology.

— Angela Logomasini

Key Experts

Angela Logomasini, CEI, (202) 331-1010, alogomasini@cei.org.
Michael Gough, mgough@bellatlantic.net.

Recommended Readings

American Council on Science and Health. *Update: Is There a Cancer Epidemic in the United States?* New York: American Council on Science and Health, 1995, http://www.acsh.org/publications/booklets/cancer.pdf.

Ames, Bruce N. and Lois Swirksy Gold. "Environmental Pollution, Pesticides, and Prevention of Cancer: Misconceptions." *FASEB Journal* 11 (27 July 1997): 1041-52.

Doll, Richard and Richard Peto. "Causes and Prevention of Cancer: Quantitative Estimate of Avoidable Risks of Cancer in the United States Today." *Journal of the National Cancer Institute* 66, no. 6 (21 January 1981): 1191-1308.

[18] Ames and Gold, "Too Many Rodent Carcinogens," 970.
[19] Ibid.
[20] Ibid.
[21] National Research Council, Committee on Comparative Toxicology of Naturally Occurring Carcinogens, *Carcinogens and Anticarcinogens in the Human Diet: A Comparison of Naturally Occurring and Synthetic Substances* (Washington, D.C.: National Academy Press, 1996), Appendix A.

Gough, Michael. "Cancer Testing," *Technology* 6 (1999): 23-42.

Gough, Michael, "How Much Cancer Can EPA Regulate Away?" *Risk Analysis* 10, no. 1 (1990).

Junk Science

Science often is manipulated or abused to serve policy ends (the desire of government officials to justify onerous regulations), to hype fears and raise funds (in environmental activist literature and direct mail), to produce sensationalist news stories, or simply out of ignorance. Unfortunately, the result often is public policy that is counter-productive for the environment or needlessly onerous on small businesses and the public at large. To counter these trends, Steve Milloy has created the award winning Junkscience Web page (www.junkscience.com), a resource that sets the record straight on many key scientific claims and issues. It's a valuable resource for policy makers, the media, and the public at large.

ENDOCRINE DISRUPTERS

Having largely lost the intellectual debate on cancer (although their spurious claims still adversely affect policy), antichemical activists have decided to add more tools to their arsenal. Among their most powerful tools have been claims that chemicals are causing widespread problems by disrupting the endocrine systems of humans and animals. Accordingly, activists argue that we should ban or heavily regulate various chemicals, particularly pesticide products, based on the assertion that each may have an endocrine-related effect.

Endocrine systems in both humans and animals consist of a series of glands that secrete hormones and send messages throughout the body. Working in conjunction with the nervous system, these messages trigger various responses such as growth, maturation of reproductive systems, and contractions during pregnancy. Foreign chemicals can disrupt proper functioning of the endocrine system and lead to health problems. Environmentalists refer to such external chemicals as "endocrine disrupters," but others use more neutral terms because not all impacts will be negative or substantial. The American Council on Science and Health (ACSH) calls them "endocrine modulators," which is used in the subsequent discussion.[1] The National Academy of Science (NAS) calls them "hormonally active agents."[2]

The "endocrine disrupter" alarm tactic focuses primarily on synthetic chemicals. Allegedly, because we have used and continue to use man-made chemicals — particularly a class of chemicals called organochlorines (such as DDT and PCBs) — the public and wildlife are widely suffering with everything: infertility, neurological disorders, cancer, and developmental problems. But before rushing to ban and regulate all man-made chemicals, policy makers should review some facts.
To help place the issue in perspective, this section overviews the following key points:

- Scientific studies have not found any definitive adverse impacts to humans related to endocrine modulators in the environment.
- There are other, more significant sources of endocrine modulators than industrial chemicals, indicating that the risks of industrial chemicals are tiny in comparison.
- Wildlife impacts from industrial chemicals appear to have occurred, but they are isolated events rather than widespread phenomena, and they are related to relatively high-level exposures.
- Limited cases of potential wildlife impacts have declined considerably as the level of industrial endocrine disrupters in the environment has declined, reducing problems for wildlife.

Key Study Questionable

Concerns arose when it was discovered that children of women who took diethylstilbestrol or DES (a drug that was used between 1940 and 1970 to prevent miscarriages) experienced a higher incidence of reproductive tract problems. But the relevance of these cases to low-level environmental exposures to other potential endocrine modulators is highly tenuous.

[1] American Council on Science and Health, *Endocrine Disrupters: A Scientific Perspective* (New York: American Council on Science and Health, July 1999), 9.
[2] National Research Council, *Hormonally Active Agents in the Environment* (Washington, D.C.: National Academy Press, 1999).

- As toxicologist Steven Safe notes: "DES is not only a potent estrogen, but it was administered at relatively high doses ... In contrast, synthetic environmental endocrine-disrupting compounds tend to be weakly active."[3] Hence the relevance of the DES cases to low-level endocrine modulators in the environment is dubious.

- Indeed, a panel of scientists reported to the American Council on Science and Health: "Aside for exposure itself, perhaps the two most important factors are potency and dose."[4]

- ACSH notes that putting environmental exposures to synthetic chemicals in perspective requires that we compare the potency of such to that of the human-produced estrogen, 17b-estradiol. Scientists have found the synthetic chemicals DDT and PCBs (the most studied chemicals claimed to be endocrine disrupters) to be up to one million times less potent than 17b-estradiol.[5]

- Given the low-dose levels and relatively low potency of synthetic environmental chemicals, it is not surprising that the National Academy of Sciences recently reported that it lacks data showing that "hormonally active" compounds caused any adverse impacts.[6]

Declining Sperm Counts — More Myth than Reality

Yet more consternation resulted when Danish researchers conducted a statistical analysis (a type of study that scientists refer to as a "meta-analysis") of 61 papers that included data on male sperm counts. They reported a "significant decline in mean sperm count" between 1940 and 1990.[7] But they noted that whether environmental estrogens were involved remained to be determined.

Adding fuel to the fire, researchers Richard Sharpe and Niels E. Skakkebaek have made stronger suggestions that endocrine modulators play a role in alleged sperm count declines. In one article, the authors asserted, "a strong mechanistic case can be made" to explain how endocrine modulators could affect male reproductive functions.[8] While merely a series of speculations, this article and subsequent statements of the author have sparked continued mainstream press coverage and have become key sources among those who claim that man-made chemicals are reducing sperm counts. But problems with these papers abound:

- First, the 1992 Danish meta-analysis, which is the basis of the declining sperm count claims, garnered criticism for numerous flaws, including the author's selection of data that left out low sperm counts in the early dates, simply creating the illusion that sperm counts in the later dates were lower.[9]

- Others suggested that problems with data emerged because the authors included studies with far too small sample numbers, which "would not normally be admissible as evidence," said one critic.[10]

[3] Stephen H. Safe, "Endocrine Disrupters: New Toxic Menace?" in *Earth Report 2000,* ed. Ronald Bailey (New York: McGraw-Hill, 2000), 192.
[4] ACSH, *Endocrine Disrupters: A Scientific Perspective*, 11.
[5] Ibid., 14-15.
[6] National Research Council, *Hormonally Active Agents in the Environment.*
[7] Elizabeth Carlsen et al., "Evidence for Determining Quality of Semen During the Past 50 Years," *British Medical Journal* 305, no. 6854 (12 September 1992): 609.
[8] Richard M. Sharpe and Niels E. Skakkebaek, "Are Oestrogens Involved in Falling Sperm Counts and Disorders of the Male Reproductive Tract?" *Lancet* 341, no. 8857 (29 May 1993): 1392.
[9] Peter Bromwich et al., "Decline in Sperm Counts: An Artifact of Changed Reference Range of 'Normal'?" *British Medical Journal* 309, no. 6946 (2 July 1992): 19.
[10] Stephen Farrow, "Falling Sperm Quality: Fact or Fiction?" *British Medical Journal*, 309 no. 6946 (2 July 1994): 1.

- A reanalysis of the 61 studies found that an analysis published between 1970 and 1990 (which amounted to 88 percent of the population of the studies) found that male sperm counts have actually increased in more recent times.[11]

- To complicate matters further, while there were some additional studies that suggest falling sperm counts,[12] others studies have undermined those findings by reporting no change or an increase in sperm counts.[13]

- Claims of declining sperm counts remain largely speculative. And even Richard Sharpe, one of the strongest advocates of potential sperm declines, notes "it is only a hypothesis." He defends the hypothesis only based on the idea that "all the facts fit" (despite many findings to the contrary).[14]

Dubious Breast Cancer Claims

As in the prior case, concerns about breast cancer caused by endocrine modulators arose with the publication of one key study. This time, it was a 1993 study led by Mount Sinai Medical School professor Mary Wolff that compared DDT levels in the body fat of 58 women diagnosed with breast cancer with 171 control subjects.[15] Although still a small sample, the Wolff study was larger than prior studies, only one of which had more than 20 subjects. Wolff et al. found higher levels of DDE (the metabolite of DDT) in women with breast cancer, indicating an association between the two phenomena.

While including phrases of caution ("these findings are novel" and "require confirmation"), the study was full of other more explosive rhetoric. In the conclusion, the authors make strong statements about their "findings" (which lump together all organochlorine substances even though the study focused only on DDT metabolites) and make a plea for government action: "Our observations provide important new evidence related to low-level environmental contaminants with organochlorine residues to the risk of breast cancer in women. Given widespread dissemination of organochlorines in the environment, these findings have immediate and far-reaching implications for public health intervention worldwide."[16] As Stephen S. Sternberg, pathologist with Sloan-Kettering Cancer Center, noted, "With these statements, one can hardly consider that the investigators reported their conclusions cautiously." The result was media hype about breast cancer risks. "The jury isn't in, yet you would never know it from the media reports,"[17] said Sternberg. Criticism of the study quickly appeared in the scientific literature:

- Regarding the key breast cancer study alleging endocrine risks, one group of researchers noted: "Their literature review excluded substantial conflicting evidence, their discussion of the Serum

[11] A. Brake and W. Krause, "Decreasing Quality of Semen; Letter: Comment," *British Medical Journal* 305 no. 6867 (12 December 1992): 1498.
[12] Stuart Irvine et al., "Evidence of Deteriorating Semen Quality in the United Kingdom: Birth Cohort Study in 577 Men in Scotland Over 11 Years," *British Medical Journal* 312, no. 7029 (24 February 1996): 467.
[13] L. Bujan et al., "Time Series Analysis of Sperm Concentration in Fertile Men in Toulouse, France Between 1977 and 1992," *British Medical Journal* 312, no. 7029 (24 February 1996): 417; Geary W. Olsen et al., "Have Sperm Counts Been Reduced 50 Percent in 50 years? A Statistical Model Revisited," *Fertility and Sterility* 63, no. 4 (April 1995): 887-93.
[14] As quoted by Gail Vines, "Some of Our Sperm Are Missing: A Handful of Six Chemicals Are Suspected of Disrupting Male Sex Hormones; But Are These Oestrogens Really the Environmental Evil They Seem?" *New Scientist* (26 August 1995): 23.
[15] Mary S. Wolff et al., "Blood Residues of Organochlorine Residues and Risk of Breast Cancer," *Journal of the National Cancer Institute* 85 (21 April 1993): 648-52.
[16] Ibid.
[17] Stephen S. Sternberg, "DDT and Breast Cancer, Correspondence," *Journal of the National Cancer Institute* 86 (20 July 1994): 1094-96.

DDE and PCB measurements and the case-control analysis excluded important details, and their dose-response analysis, given their data used an inappropriate method. Also we do not believe that their data support their conclusion of a relationship between breast cancer and organochlorines as a class."[18]

- The National Academy of Sciences also noted the following problems with the breast cancer study: the size of the study was too small to provide much conclusive information; methodological problems could mean that the disease was causing higher levels of DDE rather than the other way around; adjustments that the Wolff study made to account for alleged losses of DDE levels because of lactation may have been inappropriate (controlling for these variables substantially increased estimated DDE levels in cancer victims).[19]

- Ironically, Wolff, who remains an advocate of the view that organochlorines likely play a role in breast cancer and other diseases,[20] participated in other studies that failed to find associations.[21]

- The NAS concluded that the Wolff study and all the ones published before 1995 "do not support an association between DDT metabolites or PCBs and the risk of breast cancer."[22]

- Subsequent studies further undermine cancer claims.[23] Key among these was a study of 240 women with breast cancer and a control group of the same size, which could not find a link.[24]

- Another study of more highly exposed populations in Mexico, where DDT was then used for insect control, found no significant difference in DDE levels among control and breast cancer groups.[25]

- Accordingly, the NAS concluded the following about the studies conducted after 1995: "Individually, and as a group, these studies do not support an association between DDE and PCBs and cancer in humans."[26]

Nature's Hormone Factory[27]

Ironically, the entire theory that industrialization is causing severe endocrine disruption falls apart when you consider exposures to naturally occurring endocrine modulators. Plants naturally produce endocrine modulators called "phytoestrogens" to which we are exposed at levels that are thousands and sometimes millions of times higher than those of synthetic chemicals. Humans consume these chemicals everyday without adverse effects, and some contend that these chemicals promote good health. In fact:

[18] John F. Acquavella, Belinda K. Ireland, and Jonathan M. Ramlow, "Organochlorines and Breast Cancer, Correspondence," *Journal of the National Cancer Institute* 85 (17 November 1993): 1872-75.
[19] The panel of scientists that produced that NAS study summed up these problems; see *Hormonally Active Agents in the Environment*, 248-49.
[20] For example, see Mary S. Wolff and A. Weston, "Breast Cancer Risk and Environmental Exposures," *Environmental Health Perspectives* 105 (4 June 1997), no. 4: 891-96.
[21] Nancy Krieger et al., "Breast Cancer and Serum Organochlorines: A Prospective Study Among White, Black and Asian Woman," *Journal of the National Cancer Institute* 86 (20 April 1994): 589-99.
[22] National Research Council, *Hormonally Active Agents in the Environment*, 250.
[23] For an overview of many key studies see Stephen H. Safe, "Endocrine Disrupters and Human Health — Is There a Problem? An Update," *Environmental Health Perspectives* 108, no. 6 (June 2000): 487-93.
[24] David J. Hunter et al., "Plasma Organochlorine Levels and the Risk of Breast Cancer, *New England Journal of Medicine* 337, no. 18 (30 October 1997): 1253-58.
[25] L. Lopez-Carrillo et al., "Dichiorodiphenyltrichloroethane Serum Levels and Breast Cancer Risk: A Case-Control Study from Mexico," *Cancer Research* 57 no. 17 (1997): 3728-32.
[26] National Research Council, *Hormonally Active Agents in the Environment*, 272.
[27] Title borrowed from Jonathan Tolman, *Nature's Hormone Factory: Endocrine Disrupters in the Natural Environment* (Washington, D.C.: Competitive Enterprise Institute, March 1996), http://www.cei.org/MonoReader.asp?ID=478.

- Hundreds of plants appear to contain endocrine disrupters, and lab tests have discovered endocrine disrupters in 43 foods in the human diet, including corn, garlic, pineapple, potatoes, and wheat.[28]

- Soy products, particularly soybean oil, are found in hundreds of products, many of which we safely consume on a regular basis.[29]

- While we safely consume them, phytoestrogens are 1,000 to 10,000 times more potent than synthetic estrogens. Because we consume far more phytoestrogens in our diet, the estrogenic effects of the total amount we consume are as much as 40 million times greater than those of the synthetic chemicals in our diets. Nevertheless, they are still safe.[30]

In addition, the estrogen that our bodies create, 17b estradiol, which is included in oral contraceptives, may be entering waterways by passing through sewage treatment facilities. The effects of this chemical on wildlife is not yet clear. However, recent studies in some British rivers showed that natural hormones (17b estradiol and estrone) and a component of birth control pills (ethynylestradiol) were responsible for estrogenized male fish.[31] Despite the fact that they may have a greater impact on wildlife because they are far more potent, like phytoestrogens, natural hormones are not a large part of the debate related to environmental estrogens.

In fact, when EPA set standards for its program to screen environmental estrogens (a program required under the Food Quality Protection Act), the committee refused to consider phytoestrogens and has delayed considering impacts from contraceptives. Instead, it will screen and test only "pesticide chemicals, commercial chemicals, and environmental contaminants."[32] When and if it considers the impacts from oral contraceptives (as environmental contaminants), EPA says that its consideration will be limited because pharmaceutical regulation is a Food and Drug Administration concern.

As a result, EPA's program will focus all energies on the smallest possible part of endocrine exposure and the lowest risk area. It serves regulators' interests to leave out of the picture consideration of these two sources of environmental estrogens. If they did screen for these, the massive amounts would dwarf those of pesticides and other chemicals they regulate. These findings would highlight the fact that low-level exposure to commercially related endocrine disrupters is relatively insignificant, a fact that would undermine the agency's ability to regulate commercial products on the allegation that they are a significant source of endocrine disruption.

Wildlife-Related Problems are Isolated to High-Level Exposures

Certain wildlife appears to have been affected by high exposures to certain man-made chemicals, leading to developmental and reproductive problems. In one case, a study of alligators in Lake Apopka that were exposed to very high levels of sulfuric acid and pesticides from a nearby spill suffered from reduced hatching, small phallus size, and reduced life spans.[33] Other studies have found similar problems in the Great Lakes. However, one should take caution before believing that such problems are widespread or that man-made chemicals cause every endocrine-related problem.

[28] Tolman, *Nature's Hormone Factory*, 4-5.
[29] Ibid., 5.
[30] Ibid., 8; Figures derived from research of Stephen Safe, "Environmental and Dietary Estrogens and Human Health: Is There a Problem?" *Environmental Health Perspectives* 103, no. 4 (April 1995): 349.
[31] C. Desbrow et al., "Identification of Estrogenic Chemicals in STW Effluent," *Environmental Science and Technology* 32, no. 11 (1998): 1549-58.
[32] Stephen Farrow, "Falling Sperm Quality: Fact or Fiction?" *British Medical Journal*, 309 no. 6946 (2 July 1994): 1.
[33] L. J. Guillette et al., "Developmental Abnormalities of the Gonad and Abnormal Sex Hormone Concentrations in Juvenile Alligators from Contaminated and Control Lakes in Florida," *Environmental Health Perspectives* 102, no. 4 (August 1994): 680-88.

For example, many have claimed that pesticides are causing deformities in frogs in various places around the country, but many other factors may come into play. A recent study revealed another possible cause: parasites.[34]

Also of note, phytoestrogens can have similar effects. Agricultural researchers and farmers have discovered some such problems and have mitigated the effects of such chemicals to protect their livestock. For example, CEI's Jonathan Tolman notes in a study on hormones that the Australian Department of Agriculture discovered in 1946 that natural endocrine disrupters in clover had caused sheep sterility.[35]

Fortunately, the level of endrocrine modulators found in the environment has declined as we switched to better alternatives and found ways to reduce the amount we use. The NAS reports that, while there are some exceptions:

- "The concentrations of some regulated halogenated organic compounds have decreased since the 1970s. For many other chemicals, there are inadequate data upon which to evaluate trends. The most studied chemicals are PCBs and DDT and the production of these has been banned in the United States for the past 20 years, resulting in declines in environmental concentrations. Examples or declines in other areas include progressive and substantial declines in PCBs and DDT found in eggs taken from bird colonies in the Canadian Atlantic region between 1972 and 1978 and a decrease in PCBs and DDT in Bering Sea fish from 1982 to 1992."[36]

— Angela Logomasini

Key Experts

Angela Logomasini, CEI, (202) 331-1010, alogomasini@cei.org.
Stephen H. Safe, Texas A&M University, Department of Veterinary Physiology and Pharmacology, s-safe@tamu.edu.

Recommended Readings

American Council on Science and Health (ACSH). *Endocrine Disrupters: A Scientific Perspective*. New York: ACSH, July 1999.

Safe, Stephen H. "Endocrine Disrupters: New Toxic Menace?" In *Earth Report 2000*. Edited by Ronald Bailey. New York: McGraw-Hill, 2000, 192.

Safe, Stephen H. "Endocrine Disrupters and Human Health — Is There a Problem? An Update." *Environmental Health Perspectives* 108, no. 6 (June 2000): 487-493.

Tolman, Jonathan. *Nature's Hormone Factory: Endocrine Disrupters in the Natural Environment*. Washington D.C.: Competitive Enterprise Institute, March 1996.

[34] Pieter T. J. Johnson et al., "The Effect of Trematode on Amphibian Limb Development and Survivorship," *Science* 284, no. 5415 (30 April 1999): 802-4. For an overview of the issue, see Brian Doherty, "Amphibian Warfare," *Weekly Standard*, 24 May 1999, 16-18.
[35] Jonathan Tolman, *Nature's Hormone Factory*, 1.
[36] National Research Council, *Hormonally Active Agents in the Environment*, 66-67.