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Comments to the European Union on its Proposed Chemicals Policy

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The following comments are submitted on behalf of the Competitive Enterprise Institute, a free-market policy group located in Washington, D.C. Submitted along with these comments is a CEI paper on Organization for Economic Cooperation and Development's (OECD) attempt to employ the EU chemicals policy.

We find that the proposed European Union (EU) chemicals policy is unlikely to generate benefits, and that it is likely to harm public health and well being. It is unlikely to produce benefits because it focuses on very low-level and questionable risks rather than substantial public health challenges. It is dangerous because it would divert resources from serious problems and will undercut the benefits of a free society by limiting economic growth. European consumers and others around the world will suffer higher prices and reduced access to consumer goods, many of which provide vital public health benefits. In particular, individuals suffering from poverty in the developing world will be hardest hit as the chemicals policy diverts resources and attention from the world's most serious health problems.

Advocates of the chemicals policy suggest that they can improve public health via a chemical registration and research policy. They contend that additional study will enable policymakers to prevent the introduction of new "dangerous" chemicals and force the elimination of existing "dangerous" chemicals. Supporters of this approach assume incentives for companies to ensure the safety of their products are lacking, and hence the public currently faces grave risks.

Neither assumption makes sense. Firms clearly have incentives to study chemicals to ensure safety for their customers. After all, they want repeat customers, and they don't want lawsuits alleging harm. In addition, existing regulations mandate considerable research, and both public and private scientific groups add to that body of research. None of these groups have the incentive to over-invest in cases where the data indicate that risks are apparently quite low. Governments, on the other hand, can mandate such research based on shortsighted, politically driven views about the perception of risk. But policymakers should seriously consider whether any substantial benefits will flow from directing considerably more resources to such studies or whether limiting access to chemicals will improve—or worsen—public well-being.

In a world of limited resources, public officials should take care not to divert resources away from addressing serious risks to tackle low-level risks. And they should take care not to

devote resources to policies that could prove harmful. Unfortunately, the EU chemicals policy represents a move in the wrong direction. While we may not know all the particulars of every chemical on earth, science shows that low-level environmental exposures to chemicals has not had a substantial impact on cancer rates nor proven to aversely impact the human endocrine system. As a result, expending resources in an attempt to discover minute, and largely theoretical, cancer risks will only divert resources away from more vital needs and adversely impact economic growth. In addition, the EU policy threatens to deprive consumer access to chemical products that produce important benefits. We already are seeing cases in which misguided allegedly "precautionary" approaches are proving deadly, particularly to people in the developing world. The EU chemicals policy simply promises to expand such failed approaches.

EU Chemicals Policy is Unlikely to Deliver Benefits

The EU white paper on the chemicals policy notes: "The lack of knowledge about the impact of many chemicals on human health and the environment is a cause for concern."¹ While, as the EU white paper notes, much data is lacking on specific chemicals, there is enough information about the general sources of cancer-related disease to cast into doubt just about all the benefits of the EU policy.

If chemicals were a source of health problems, one might expect that as chemical use has increased around the world, there would be some measurable adverse impact on life expectancy, cancer rates, or other illnesses. Yet in developed nations, where chemical use has greatly increased, people are living longer, healthier lives. According to the World Health Organization (WHO), the average worldwide human life span has increased from 45 years in 1950 to about 66 in 2000 and will most likely continue to increase to 77 years by 2050.²

It is true that developed nations have higher cancer rates than developing nations and that there was an increase in cancer incidence during the 20th century. The WHO reports that developed nations face cancer rates that are more than twice as high as that of developing nations.³ This finding has raised the question as to whether the rise of chemical use has caused elevated cancer rates. However, the data clearly indicate that chemical use and related pollution are not sources of this problem.

Other reasons explain these trends. In particular, cancer is largely a disease related to aging, which means that along with the improvements in life expectancy come increased cancer rates. In addition, rates will appear even higher because the median age of the population is getting older. Not surprisingly, the WHO reports that cancer deaths and incidence grew 22 percent between 1990 and 2000. These trends are expected to continue regardless of chemical use because, as the WHO reports, the number of individuals over 60 is expected to triple by 2050.

¹ Commission of the European Communities, "White Paper: Strategy for a Future Chemicals Policy," Brussels, 27.2.2001 COM (2001) 88 final, 4.

² International Agency for Research on Cancer (IARC), World Health Organization (WHO), *World Cancer Report* (Lyon: IARC Press, 2003), 320.

³IARC/ WHO, World Health Report.

In addition, developed nations experienced a dramatic increase of cancer in the past century because of an increase in smoking, which primarily causes lung cancer but can also cause several other types of cancer. The WHO says that tobacco is the main known cause of cancer, causing up to 30 percent of all cancers in developed nations.⁴ A large portion of cancer rate increases in developed nations occurred during the last century because of smoking rate increases.

For example, in the United States, researchers from the University of Alabama Schools of Medicine and Public Health report that smoking is responsible for making what was a rare occurrence — lung cancer — one of the most common cancers. They note: "When the mortality from all smoking-related cancers is excluded, the decline in other cancer from 1950 to 1998 was 31 percent (from 109 to 75 deaths per 100,000 person-years)."⁵ These researchers noted further: "A typical commentary blamed 'increasing cancer rates' on 'exposure to industrial chemicals and run-away modern technologies whose explosive growth had clearly outpaced the ability of society to control them." But their research finds: "There is no denying the existence of environmental problems, but the present data show that they produced no striking increase in cancer mortality."⁶

Hence the increase in cancer at that time did not result from the use of synthetic chemicals or pollution, but from personal lifestyle choices. Fortunately, economic growth has allowed for improvements in medical treatments and reduction of cancer risks. As a result, both cancer mortality and incidence are declining in developed nations.

The WHO's *World Cancer Report* includes some statistics on world cancer rates. We can see improvements in these data and clearly cannot find any chemically caused cancer crisis. For example, it notes that during recent decades, breast cancer incidence has increased in many developed nations, but it does not identify chemicals as the culprit. Instead of an actual increase in rates, the WHO notes that increased screening simply helped find more cancers. The good news is that starting in the 1980s, mortality began a downward trend in Europe, North America and Australia thanks to better screening and improved treatment techniques. Because smoking rates have declined, lung cancer has finally begun to decline in developing nations—trending downward among men during the past decade, and beginning to trend downward for women (reduction of smoking has been slower among women).⁷ Other areas show similar improvements.

However, the report does not systematically study cancer trends and explain all the nuances of why some areas appear to have cancer increases because the report is not meant to focus on trends, per se, but on the scope of the cancer challenge and means toward addressing that challenge. One of the best sources of cancer trend measurements for a developing country is the U.S. National Cancer Institute's report on cancer trends.

⁴ IARC/ WHO, World Health Report, 22.

⁵ Brad Rodu and Philip Cole, "The Fifty Year Decline of Cancer in America," *Journal of Clinical Oncology* 19, no. 1, January 1, 1001, 240-41..

⁶ Ibid., 239-41

⁷ IARC/WHO, World Cancer Report, 183.

The National Cancer Institute and a number of collaborators take into consideration various factors such as an aging population.⁸ Its figures are age adjusted, and they measure cancers per 100,000 people. These reports also attempt to explain increases or decreases within the various categories.

According to a recent report, "Cancer incidence for all sites combined decreased from 1992 through 1998 among all persons in the United States, primarily because of a decline of 2.9 percent per year in white males and 3.1 percent per year in black males. Among females, cancer incidence rates increased 0.3 percent per year. Overall, cancer death rates declined 1.1 percent per year."⁹ This report shows that the incidence has increased among women, but that increase is largely due to increased rates of smoking among women.

In recent years, cancer among women is also up because of an increase in breast cancer, which has increased 40 percent between 1973 and 1998.¹⁰ Yet again, the National Cancer Institute had not labeled this a burgeoning health crisis or tied it to chemical use. Instead, the National Cancer Institute notes that these trends in large part reflect better screening and increased detection "since the increase was limited to the early stage of the disease."¹¹ This scenario is highly likely given that, between 1987 and 1998, the percentage of women aged 40 to 49 who obtained mammograms nearly doubled – 32 percent to 63 percent. The percent of woman aged 50 to 64 who received a mammogram increased from 31 to 73 percent in that same time period.¹²

In addition, studies assessing alleged chemically caused cancers are not finding much of a link. U.S. researchers produced one of the largest studies among women in Long Island, New York, which could not find a link between the chemicals most often cited as a potential cause of breast cancer (DDT and other pesticides as well as PCBs) and an elevated level of cancers in that area.¹³

Not emphasized by anti-chemical activists who often claim that breast cancer is a chemically caused disease, is the fact that modern medicine and its chemicals are saving women from breast cancer. The National Cancer Institute report notes that, despite incidence increases, death rates from breast cancer decreased by 1.6 percent for all races combined from 1989

⁸ According to the National Cancer Institute, it produces its annual report in collaboration with The American Cancer Society, the North American Association of Central Cancer Registries, and the Centers for Disease Control and Prevention, including the National Center for Health Statistics and the Center for Chronic Disease Prevention and Health Promotion. See Holly L. Howe et al., "Annual Report to the Nation on the Status of Cancer (1973 Through 1998), Featuring Cancers with Recent Increasing Trends," *Journal of the National Cancer Institute* 93, June 6, 2001, 824-42.

⁹ Ibid.

¹⁰ Ibid.

¹¹ Ibid.

¹² U.S. Centers for Disease Control and Prevention (CDC), *CDC Fact Book 2000/2001* (Washington, D.C.: CDC, 2001), 46, http://www.cdc.gov/maso/factbook/Fact%20Book.pdf.

¹³ More discussion follows on breast cancer and chemicals in the section on endocrine disrupters. The Long Island study is available at: Marilie D Gammon Ph.D. et al., *Cancer Epidemiology Biomarkers Prevention* 11, no. 8 August 2002, 677-85.

through 1995. Between 1995 and 1998, the death rate declined at an even faster rate (3.4 percent).¹⁴

During the past several decades, cancer among women has also increased because of a rising number of smoking-related lung cancers. The National Cancer Institute reports that, starting in 1975, men were quitting smoking at a faster rate than women, but the rates of decline among both sexes began to coincide by 1985.¹⁵ Because of such trends, the reduction in lung cancer among women is taking longer. Fortunately, lung cancer incidence among women has leveled off, and it is hoped that this number will begin its decline in the near future.¹⁶

Likewise, the National Cancer Institute reports that prostate cancer incidence increased after 1973 at a rate of 2.9 percent annually, a number that went even higher when improved screening methods began identifying more cases. Some increases in prostate cancer could also result from the fact that people are living longer. Most prostate cancers occur after age 55 and most are not detected until age 70.¹⁷ Nonetheless, prostate cancer cases began to decline by 11 percent annually between 1992 and 1995, and have since leveled off. Mortality follows a similar trend, declining between 1995 and 1998 at a rate of 4.7 percent for white males and 3 percent for African American males.

The NCI reports demonstrate that as chemical use has gone up, cancer incidence and mortality have declined. Hence, chemicals cannot be a major source of cancer risk since there is an inverse relationship. The reality is that many chemicals are actually reducing cancer risks by reducing infections (which can cause cancer) and by helping in the production and composition of pharmaceuticals and medical equipment.

If the EU is actually concerned about cancer, they are clearly focusing on the wrong source of the problem. The WHO estimates that 1 to 4 percent of cancers can be attributed to environmental pollution in developed countries. Indeed, trace levels of chemicals and environmental pollution are not the key causes of cancer as noted by the WHO.

The WHO cites a world-renowned study by scientists Sir Richard Doll and Richard Peto. While Doll and Peto note that 80 to 90 percent of cancers are caused by "environmental factors," this phrase encompasses anything other than genetics. It does not include pollution alone. Environmental factors include smoking, diet, occupational exposure to chemicals, "geophysical factors" (such as naturally occurring radiation) manmade radiation, medical drugs and radiation, and pollution. According to Doll and Peto's report, pollution accounts for only 2 percent of all cancer. Neither Doll and Peto nor WHO mention exposure to chemicals through consumer products as a serious cause of cancer, which is a key focus of the chemicals strategy. In addition, the EU policy will not likely affect occupational exposures in the developed world since as the WHO notes, "most occupational carcinogens have been removed from the workplace."

¹⁴ Howe et al., "Annual Report to the Nation on the Status of Cancer."

¹⁵ Phyllis A. Wingo et al, "Annual Report to the Nation on the Status of Cancer, 1973-1996, With a Special Section on Lung Cancer," *Journal of the National Cancer Institute* 91, April 21, 1999, 675-90.

¹⁶ Howe et al., "Annual Report to the Nation on the Status of Cancer."

¹⁷ "Stat Bite: Incidence Rates by Age at Diagnosis for Breast and Prostate Cancers," *Journal of the National Cancer Institute* 93, March 21, 2001, 425.

Doll and Peto report that tobacco use accounts for about 30 percent of all annual cancer deaths,¹⁸ and dietary choices account for 35 percent of annual cancer deaths.¹⁹ The WHO confirms these figures, attributing 30 percent of cancers to smoking and 30 percent to dietary factors.²⁰ The WHO notes that chronic infections—which are a problem particularly for developing nations—cause about 18 percent of worldwide cancers.²¹ Genetic factors may lead to an additional 4 percent of cancers. That means less than 20 percent of cancers result from all other causes including pollution, alcohol, occupational exposures, medical drugs, food and water contaminants, radiation, immunosuppression problems, and reproductive factors and hormones.

Nonetheless, the developed world's aging population does indeed present new health challenges that are important to address. The WHO suggests that cancer prevention efforts should focus on three factors: tobacco use, diet, and infections, which together account for 75 percent of cancer cases worldwide.²² Efforts to encourage people to change personal habits by eating better are likely the most effective cancer prevention policy. The EU chemicals policy won't have much of impact on cancer rates or mortality. It may, however, absorb resources that could improve public health and well being in other areas.

Endocrine Disrupters

While chemicals may cause some small percentage of cancers, there is no definitive body of evidence demonstrating any human endocrine disruption impacts from environmental exposures to chemicals. In fact, humans are exposed to vastly higher doses of naturally occurring "endocrine disrupters" every day—without adverse impacts.

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, contractions during pregnancy, etc. 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. In a report on the topic, the American Council on Science and Health (ACSH) calls them "endocrine modulators."²³ The National Academy of Science (NAS) calls them "hormonally active agents."²⁴

Allegedly, because we have used and continue to use manmade chemicals the public and wildlife are widely suffering with everything from infertility, neurological disorders, cancer, and

¹⁸ Doll and 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.

¹⁹ Ibid.

²⁰ IARC/WHO, *World Cancer Report*, see page 22 for figure on tobacco and page 62 for figure on diet.

²¹ Ibid., 61.

²² Ibid., 321.

²³ American Council on Science and Health (ACSH), *Endocrine Disrupters: A Scientific Perspective* (New York: American Council on Science and Health, July 1999), 9.

²⁴ National Research Council, *Hormonally Active Agents in the Environment* (Washington, D.C.: National Academy Press, 1999).

developmental problems. But before rushing to regulate manmade chemicals on this basis, EU policymakers should review some of the science.

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 high level DES exposures to low-level environmental exposures to other chemicals is highly tenuous. 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."²⁵ Hence, the relevance of the DES cases to low-level endocrine modulators in the environment is dubious.

Indeed, a panel of ASCH scientists reported: "Aside for exposure itself, perhaps the two most important factors are potency and dose."²⁶ The ACSH report 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 that the synthetic chemicals DDT and PCBs (the most studied chemicals claimed to be endocrine disruptors) are up to *one million times less potent* than 17b-estradiol.²⁷

Given the low-dose levels and relatively low potency of synthetic environmental chemicals, it is not surprising that the NAS reported that it lacks data showing that "hormonally active" compounds caused any adverse impacts.²⁸

Yet public concern mounted on this issue when Danish researchers conducted a statistical 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."²⁹ But they noted that whether environmental estrogens were involved remained unclear. In addition, researchers Richard Sharpe and Niels E. Skakkebaek 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.³⁰ 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 manmade 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

²⁵ Stephen Safe, "Endocrine Disrupters: New Toxic Menace?" *Earth Report 2000* (New York: McGraw-Hill, 2000), 192.

²⁶ American Council on Science and Health, *Endocrine Disrupters: A Scientific Perspective*, 11.

²⁷ American Council on Science and Health, Endocrine Disrupters: A Scientific Perspective, 14-15.

²⁸ National Research Council, *Hormonally Active Agents in the Environment*.

²⁹ Elizabeth Carlsen, et al., "Evidence for Determining Quality of Semen During the Past 50 Years," *British Medical Journal* 305, no. 6854, September 12, 1992, 609.

³⁰ Richard M. Sharp and Niels E. Skakkebaek, "Are Oestrogens Involved in Falling Sperm Counts and Disorders of the Male Reproductive Tract?" *The Lancet* 341, no. 8857, May 29, 1993, 1392.

dates were lower.³¹ 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.³² A re-analysis of the 61 studies, which corrected for problems in the first analysis, found that male sperm counts actually increased in more recent times.³³ In addition, in contrast to studies that suggest falling sperm counts,³⁴ other studies undermined those findings by reporting no change or an increase in sperm counts.³⁵

The reality is that 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).³⁶

Similarly, 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 body fat of 58 women with breast cancer with 171 control subjects.³⁷ 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 breast cancer victims, indicating an association between the two phenomena.

Yet criticism of the study quickly appeared in the scientific literature. "Their literature review excluded substantial conflicting evidence, their discussion of the Serum 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," noted one group of researchers.³⁸

The National Academy of Sciences also noted that the size of the study was too small to provide much conclusive information; methodological problems could mean that the disease was

³¹ Peter Bromwich, et al., "Decline in Sperm Counts: An Artifact of Changed Reference Range of 'Normal'?" *British Medical Journal* 309, no. 6946, July 2, 1992, 19.

³² Stephen Farrow, "Falling Sperm Quality: Fact or Fiction?" *British Medical Journal* 309, no. 6946, July 2, 1994, 1.

³³ A. Brake and W. Krause, "Decreasing Quality of Semen; Letter: Comment," *British Medical Journal* 305, no. 6867, December 12, 1992, 1498; see also Richard J. Sherins, M.D., "Are Semen Quality and Male Fertility Changing? *New England Journal of Medicine* 332, no. 5, February 2, 1995, 327-328.

³⁴ 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, February 24, 1996, 467.

³⁵ L. Bujan; A. Mansat; F. Fontonnier; and R. Mieusset, "Time Series Analysis of Sperm Concentration in Fertile Men in Toulouse, France Between 1977 and 1992," *British Medical Journal* 312, no. 7029, February 24, 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, 887-893.

³⁶ 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*, August 26, 1995, 23.

³⁷ Mary S. Wolff, et al., "Blood Residues of Organochlorine Residues and Risk of Breast Cancer," *Journal of the National Cancer Institute* 85, April 21, 1993, 648-652.

³⁸ John F. Acquavella, Belinda K. Ireland, and Jonathan M. Ramlow, "Organochlorines and Breast Cancer, Correspondence," *Journal of the National Cancer Institute* 85, November 17, 1993, 1872-1875.

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).³⁹

Ironically, Wolff, who remains an advocate of the view that organochlorine pesticides likely play a role in breast cancer and other diseases,⁴⁰ participated other studies that failed to find associations.⁴¹ 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."⁴² Subsequent studies further undermine cancer claims.⁴³ 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.⁴⁴ Another study of more highly exposed populations in Mexico, where DDT was then used for insect control, found no significant difference among DDE levels among control and breast cancer groups.⁴⁵ The largest study on this topic is the recent study of Long Island populations. It analyzed 646 cases and 429 control subjects, but could find no link between various pesticides or PCBs and breast cancer.⁴⁶

In 1999, the NAS concluded 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."⁴⁷

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 that of synthetic chemicals. Humans consume these chemicals without adverse impact every day and some contend that these chemicals promote good health. In fact hundreds of plants appear to contain endocrine disrupters, and lab tests have discovered endocrine disrupters in 43 foods in the human diet.⁴⁸ Soy products, particularly soybean oil, are found in hundreds of products many of which we safely consume on a regular basis.⁴⁹ While we safely consume them, photoestrogens are 1,000 to

³⁹ The panel of scientists that produced that NAS study summed up these problems: *Hormonally Active Agents in the Environment*, 248-249.

⁴⁰ For example see: Mary S. Wolff and A. Weston, "Breast Cancer Risk and Environmental Exposures,"

Environmental Health Perspectives 105 Suppl., no. 4, June 4, 1997: 891-896.

⁴¹ 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, April 20, 1994, 589-599.

⁴² National Research Council, Hormonally Active Agents in the Environment, 250.

⁴³ For an overview of many key studies: Stephen H. Safe, "Endocrine Disrupters and Human Health – Is There a Problem? An Update," *Environmental Health Perspectives* 108, no. 6, June 2000, 487-493.

⁴⁴ David J. Hunter, et al., "Plasma Organochlorine Levels and the Risk of Breast Cancer, *New England Journal of Medicine* 337, no. 18, October 30, 1997, 1253-1258.

⁴⁵ L. Lopez-Carrillo, et al., "Dichiorodiphenyltrichloroethane Serum Levels and Breast Cancer Risk: A Case-Control Study from Mexico," *Cancer Research* 57/17, 1997, 3728-3732.

⁴⁶ Marilie D. Gammon Ph.D. et al., "Environmental Toxins and Breast Cancer on Long Island II: Organochlorine Compound Levels in Blood," *Cancer Epidemiology Biomarkers Prevention* 11, no. 8, August 2002, 677-85.

⁴⁷ National Research Council, *Hormonally Active Agents in the Environment*, 272.

⁴⁸ Jonathan Tolman, *Nature's Hormone Factory* (Washington, D.C.: Competitive Enterprise Institute, 1996), 4-5, http://www.cei.org/gencon/025,01455.cfm.

⁴⁹ Tolman, Nature's Hormone Factory, 5.

10,000 times more potent than synthetic estrogens. Because we consume far more photoestrogens in our diet, the estrogenic effects of the total amount we consume are as much as *40 million* times greater than that of the synthetic chemicals in our diets, yet they are still safe.⁵⁰

In addition, the estrogen that our bodies create, 17b estrodiol, which is included in oral contraceptives, may be entering waterways by passing through sewage treatment facilities. The impact of this chemical on wildlife is not yet clear. However, recent studies in some British rivers showed that natural hormones (17b estrodiol and estrone) and a component of birth control bills (ethynylestradiol) were responsible for estrogenized male fish.⁵¹ Despite the fact that it may have a greater impact on wildlife because it is far more potent, like phytoestrogens, it is not a large part of the debate related to environmental estrogens.

Certain wildlife appears to have been affected by high exposures to certain manmade chemicals, leading to developmental and reproductive problems. In one case, alligators in Lake Apopka in Florida were exposed to very high levels of sulphuric acid and pesticides from a nearby spill, and subsequently suffered from reduced hatching, small phallus size, and reduced life spans.⁵² Other studies have found similar problems in the Great Lakes. However, one should take caution before believing that such problems are widespread or that manmade chemicals cause every endocrine-related problem. 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.⁵³

Also of note, phytoestrogens can have similar effects. Agricultural researchers and farmers have discovered some such problems and have mitigated the impacts of such chemicals to protect their livestock. For example, former CEI staff member Jonathan Tolman notes in a study on the topic that the Australian Department of Agriculture discovered in 1946 that natural endocrine disrupters in clover had caused sheep sterility.⁵⁴

Fortunately, these were relatively isolated cases, and the level of these chemicals found in the environment has declined as we switched to better alternatives and discovered 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 include

⁵⁰ Tolman, Nature's Hormone Factory, 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.

⁵¹ C. Desbrow, et al., "Identification of Estrogenic Chemicals in STW Effluent," *Environmental Science and Technology* 32 no. 11, 1998, 1549-1558.

⁵² 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, 680-688.

 ⁵³ Pieter T. J. Johnson, et al., "The Effect of Trematode on Amphibian Limb Development and Survivorship," *Science* 284, no. 5415, April 30, 1999, 802-804; for an overview of the issue, see: Brian Doherty, "Amphibian Warfare," *Weekly Standard*, May 24, 1999, 16-18.

⁵⁴ Jonathan Tolman, *Nature's Hormone Factory*, 1.

progressive and substantial decline in PCBs and DDT found in eggs taken from bird colonies in the Canadian Atlantic region between 1972 and 1978 and decrease in PCBs and DDT in Bering Sea fish from 1982 to 1992."⁵⁵

Given the unlikely impacts of low-level chemicals on human endocrine systems, EU's policy to study and regulate chemicals on these grounds is unlikely to generate any substantial benefit to humans or wildlife. Resources are better devoted to likely problems and toward addressing limited cases in which wildlife is exposed to extremely high levels of chemicals or other pollution. In most cases, such exposures are related to poverty in which communities lack pollution control resources or because of accidental releases. The EU chemicals policy will address neither of these cases and instead could impede the economic growth necessary to address such problems.

"Precautionary" Stagnation is Dangerous

The EU white paper notes that the main rationale for this policy rests of the precautionary principle. It states:

"EU Chemicals Policy must ensure a high level of protection of human health and the environment as enshrined in the Treaty both for the present generation and future generations while also ensuring the efficient functioning of the internal market and the competitiveness of the chemical industry. Fundamental to achieving these objectives is the *Precautionary Principle*. Whenever reliable scientific evidence is available that a substance may have an adverse impact on human health and the environment but there is still scientific uncertainty about the precise nature or magnitude of the potential damage, decision-making must be based on precaution in order to prevent damage to human health and the environment. Another important objective is to encourage the substitution of dangerous by less dangerous substances where suitable alternatives are available."

This statement is much in line with radical environmentalist thinking in regard to chemicals and many other technologies. In his 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."⁵⁶ 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."⁵⁷

Yet no one can ever prove anything 100 percent safe. Not surprisingly, Thornton also advocates a "zero discharge" policy, which calls for the elimination of all "bioaccumulative"⁵⁸

⁵⁵ National Research Council, *Hormonally Active Agents in the Environment*, 66-67.

⁵⁶ Joe Thornton, *Pandora's Poison: Chlorine, Health, and a New Environmental Strategy* (Cambridge MA: MIT Press, 2000), 10.

⁵⁷ Ibid.

⁵⁸ 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.

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."⁵⁹ More recently, perhaps in recognition that this standard is politically untenable, he suggested that we continue using chlorine for "some pharmaceuticals" and some "water disinfection" but only until other options become available.⁶⁰

Yet chlorine is essential for public health around the world. Pushing politically selected alternatives that may not work as well could jeopardize public health. About 98 percent of U.S. water suppliers use some form of chlorination, preventing disease outbreaks and saving millions of lives every year. For example, since local engineers and industry introduced chlorination in 1880s, waterborne-related deaths in the United States dropped from 75 to 100 per 100,000 people to less than 0.1 deaths per 100,000 annually in 1950.⁶¹ Nearly 85 percent of pharmaceuticals that we now use require the use of chlorine in their production.⁶² Thanks to chlorine and other chemicals used for pharmaceuticals, combination drug therapy has reduced AIDS deaths by more than 70 percent from 1994 to 1997.⁶³ Fifty percent of the reductions of heart disease related deaths between 1980 and 1990 (total death rate decline of 30 percent) are attributable to medicines and the chemicals that compose them.⁶⁴

Places that lack adequate chlorination don't fare as well. In fact, more than 25,000 people die everyday in developing nations from waterborne diseases. According to the World Health Organization (WHO), in the developing world, diarrhoeal diseases (such as cholera and dysentery) kill about 2 million children under five every year because of such things as poor sanitation and unsafe drinking water.⁶⁵ Rather than curtailing the use of chlorination as Thornton suggests, public health officials should be in a mad rush to expand access.

With its statement, the EU will codify a version this impossible and dangerous standard. There will always be scientific uncertainty, as everything in life carries a risk. We take reasonable risks in life because of the tremendous benefits we gain. As CEI's Fred Smith notes: "Experience demonstrates that the risks of innovation, while real, are vastly less than risks of stagnation."⁶⁶ Indeed, he asks, what would the world be like if we never introduced penicillin because we could not prove it's 100 percent safe?

⁶⁴ 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, February 19, 1997, 535-542; abstract:

⁵⁹ Ivan Amato, "The Crusade against Chlorine," *Science* 261, no. 5118, July 9, 1993, pp.152-154. 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).

⁶⁰ Thornton, *Pandora's Poison*, 14.

⁶¹ 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.

⁶² Gordon W. Gribble, Chlorine and Health (New York: American Council on Science and Health, 1995); http://www.acsh.org/publications/booklets/chlorine.html.

⁶³ Frank J. Palella, et al., "Declining Morbidity and Mortality among Patients with Advanced HIV Infection," The New England Journal of Medicine 338, no. 13, March 26, 1998; abstract available at: http://www.nejm.com/content/1998/0338/0013/0853.asp.

http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9032159&dopt=Abstract ⁶⁵ 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, June 29, 2000.

⁶⁶ Fred L. Smith, "The Dangers of Precaution," *Financial Times*, February 23, 2000.

Some products are beneficial because of their innately risky nature. Chemicals that are designed to kill insects and pathogens that otherwise would harm the public must carry some risk or they would not provide the public health benefits they promise. Drugs pose risks and often carry side effects, but we take them nonetheless to ward off more serious public health consequences. In a world laden with risks, so-called "precautionary" policies that prevent technologies actually represent the truly risky approach.

In addition, EU's assumption that regulators can find less risky alternatives is also not based in reality. The reason a product succeeds in the marketplace is because consumers found that it is the best alternative. The idea that regulators can pick better alternatives is naïve and it ignores the fact that politics may play a larger role than science in government selection of alternatives. As a result, "politically correct" alternatives may win, while public health suffers.

Therefore, it makes sense to allow individuals maximum freedom to weigh the risks of various activities and then chose among risks for the maximum benefit. Members of the public make these risk-risk calculations and tradeoffs every day. Regulators, too, should consider the risks of their decisions to regulate as well as the risks they attempt to regulate. Rather than following a stagnating precautionary principle, regulators should follow a risk-risk principle, assessing even the risks of regulation. They should also recognize that regulation is the last resort because well-being is best promoted by maximizing freedom, which results in human progress.

Regulation in this area can be limited because, as demonstrated in the prior section of these comments, the risks associated with chemicals in commerce today are considerably low, particularly considering the benefits they generate. But the EU's "precautionary approach" will preempt products that pose tiny risks without regard to the cost to human well-being.

The idea that "decision-making must be based on precaution in order to prevent damage to human health and the environment" suggests that new products will be delayed or preempted based on mere potential of adverse effects. This is an unusually easy standard for those who seek to preempt products and impose bans for other reasons. In fact, regulations are already being used by some companies to push competitors out of the market, or by environmental activists who seek regulation of large firms simply because they don't trust industry, or by regulators whose job is justified by their exercise of power in the marketplace.

Today, precautionary approaches are already being employed and seriously adverse impacts are the result. Even in the United States where there is no official precautionary policy and where we are supposed to consider tradeoffs and weigh the risks, regulators are banning chemicals on specious grounds. They are employing excessively cautious risk assessment standards to justify banning, preempting, and delaying valuable products. The public health implications are very serious, and are far greater than miniscule risks posed by these products.

Consider some examples. An obvious example has already been raised: risks associated with chlorination elimination or reduction. Residents in Peru learned about the dire impacts of inadequate water disinfection in 1991. Inadequate chlorination has been cited in scientific

literature as a key factor in a cholera epidemic that started in Peru and spread then throughout the hemisphere, leading to about a million cases of cholera and thousands of deaths.⁶⁷

Another dramatic example is the ban of the pesticide DDT. While people in developed nations have not felt the adverse implications as most had eradicated malaria-carrying mosquitoes (many using DDT themselves), individuals in the developing world are suffering miserably because they followed the U.S. policy of banning DDT. Currently, about 2.1 billion people are at risk from mosquito-borne diseases every year, according to the WHO.⁶⁸ In Africa, 1.5 to 2.7 million people, mostly children, die from malaria alone every year.⁶⁹

When DDT was used in developing nations to eliminate malaria risks, rates declined substantially. After nations begun banning it, malaria cases have skyrocketed. Because of political pressures, South Africa stopped using DDT even though it was close to eradicating the malaria-carrying mosquitoes. After DDT use stopped, South African cases rose from 4,117 in 1995 to 27,238 by 1999 (or possibly as many as 120,000 if one considers pharmacy records).⁷⁰

According to tropical medicine specialist Dr. Don Roberts and his colleagues: "Separate analyses of data from 1993 to 1995 showed that countries that have recently discontinued their spray programs are reporting large increases in malaria incidence. Ecuador, which has increased use of DDT since 1993, is the only country reporting a large reduction (61%) in malaria rates since 1993."⁷¹

After millions of people have died from this policy, public health officials finally spoke against a worldwide DDT ban during the negotiations on the Persistent Organic Pollutants Treaty (POPs Treaty). During treaty negotiations, more than 350 public health officials—including three Nobel laureates—signed a 1999 letter supporting continued use of DDT to fight malaria.⁷² The final treaty allows for limited use of DDT, but creates serious hurdles for those countries that want to use DDT. It will require developing nations to navigate an expensive, bureaucratic process before they can employ DDT to save lives.

Developed nations have not suffered nearly as much because we banned DDT after eradicating malaria. We also have the wealth necessary to put screens on our windows and employ more expensive pesticides. However, pesticide regulations based on absurdly cautious standards are beginning to cause public health problems in developed nations as well. In

⁶⁷ Enrique Gersi and Hector Naupari, "Dirty Water: Cholera in Peru," *Environmental Health: Third World Problems* — *First World Preoccupations* (Oxford: Butterworth Heinemann, 1999); David L. Swerdlow et al., "Waterborne Transmission of Epidemic Cholera in Trujillo, Peru: Lessons for a Continent at Risk, *The Lancet*, July 4, 1992; "Of Cabbages and Chlorine: Causes of Cholera Epidemic in Peru," *The Lancet*, July 4, 1992.

 ⁶⁸ World Health Organization, *Tropical Diseases, Progress in Research, 1989-1990, Tenth Programme Report* (Geneva: UNDP/World Bank/WHO, 1991), http://www.chem.unep.ch/pops/indxhtms/ifcsall.html#4.
⁶⁹ Ibid.

⁷⁰ Amir Attaran and Rajendra Maharaj, "Doctoring Malaria, Badly: the Global Campaign to Ban DDT," *British Medical Journal*, no. 321, December 2, 2000, 1403-1405, http://bmj.com/cgi/content/full/321/7273/1403#resp1.

⁷¹ Donald R. Roberts, Larry L. Laughlin, Paul Hsheih, and Llewellyn J. Legters, "DDT, Global Strategies, and a Malaria Control Crisis in South America," *Emerging Infectious Diseases* 13, no. 3, July-September 1997, http://www.cdc.gov/ncidod/eid/vol3no3/roberts.htm. See also Amir Attaran. *et al.*, "Balancing Risks on the Backs of the Poor," *Nature Medicine* 6, 2000, 729-731.

⁷² A similar petition is available at <u>http://www.fightingmalaria.org</u>.

particular, numerous medical entomologists fear that excessive U.S. government regulation jeopardizes public health by reducing development of, and access to, much needed pesticides.

In 1992, a NAS report warned: "A growing problem in controlling vector-borne diseases is the diminishing supply of effective pesticides." Because all pesticides must go through an onerous registration process at the federal Environmental Protection Agency, "some manufacturers have chosen not to reregister their products because of the expenses of gathering safety data. Partly as a result, many effective pesticides over the past 40 years to control agricultural pests and vectors of human disease are no longer available."⁷³ The NAS continued, "The potential for vector-borne disease to emerge in the United States still exists ... any reduction in vector control efforts is likely to be followed by a resurgence of the vector population. For a disease agent that is known or suspected to be transmitted by an arthropod vector, efforts to control the vector can be crucial in containing or halting an outbreak."⁷⁴ Since the U.S. pesticide registration process is very similar to what the EU would implement with its policy, EU policymakers should pay heed to this lesson.

In addition, precautionary rhetoric has encouraged U.S. public health officials to decide against spraying pesticides during mosquito-born disease outbreaks. For example, shortly after discovering West-Nile-infected mosquitoes in East Meadow and Hempstead, N.Y., in 2001, local health officials there also followed activist advice and decided against spraying. "We believe the risk of infection for ... residents remains quite low," Nassau County's Health commissioner told the press in early August 2001. But apparently, the risk was not low enough for East Meadow residents Adeline Bisignano and Karl Fink. Both became ill with the virus at the end of that same month and died the following November. We don't know if spraying would have saved these lives, but it surely would have reduced the risks.

During the U.S. outbreak of West Nile virus last year, the United States saw 4,000 serious West Nile illnesses and nearly 300 deaths—a level that is unprecedented for this disease. Pesticides were used in many communities to limit the toll on public health. Louisiana state epidemiologist Dr. Raoult Ratard explained during last year's outbreak why it was important for localities in his state to spray. Mosquito populations can be reduced by 95 percent when an area is treated for the adult insects and larvae. Without such mosquito control, "there'd be many, many more cases," Ratard noted. Still, there were many communities that chose not to spray based on unrealistic assumptions about pesticide risks.

Alleged "precautionary" approaches are also adversely impacting the provision of health care. For example, environmental activists pushed U.S. hospitals to eliminate products using mercury. When hospitals caved to those demands and began removing mercury-containing blood pressure equipment, doctors found that inadequate substitutes can have devastating effects. *New York Times* science reporter Gina Kolata notes cases in which readings of alternative equipment were so far off the mark that doctors provided damaging treatment. In one case, the alternative equipment produced an incredibly high blood pressure reading for one patient whose

⁷³ Joshua Lederberg, Robert E. Shope, and Stanley C. Oaks, Jr. eds., *Emerging Infections: Microbial Threats to Health in the United States* (Washington, D.C.: National Academy Press, 1992), 166.

⁷⁴ Ibid., 160, 161.

pressure was actually on the low side. The reading led doctors to administer medicine that reduced the woman's blood pressure so much that she had a stroke.⁷⁵

The United States Food and Drug Administration (FDA), for example, has delayed lifesaving drugs, sometimes for decades. As thousands of people die, the FDA limits access to "be on the safe side." For example, the FDA delayed approval of the Omnicarbon heart valve for 15 years, finally granting approval in 2001. Meanwhile, this device was saving lives in Italy, Germany, France, Switzerland, and Japan since 1986, with nearly 30,000 such devices implanted during those years of FDA delay. In 1998, still years before "cautious" FDA granted approval, Dr. Steven Phillips of the U.S. National Institutes of Health reported to the U.S. Congress that that these valves "demonstrated a complication rate one-half that of equivalent valves approved by FDA."⁷⁶ In 2001, CEI's general counsel Sam Kazman commented: "The FDA is afflicted by deadly over caution. Delay may protect the agency politically, but it can mean death to patients in need."⁷⁷ It is not surprising that 1996 CEI poll of cardiologists found that 65 percent agreed with a statement that the FDA approval process is too slow.

The Competitive Enterprise has documented numerous other cases. During the late 1980s, FDA blocked the release of the first drug that had been shown to open blocked coronary arteries. While patients in Europe benefited from these treatments, FDA delayed two years. Given that it was shown to reduce in-hospital deaths of heart attack patients by 18 percent, about 22,000 deaths (18 percent of 700,000 for each of the two years) could have been prevented if FDA had not delayed.⁷⁸ Similarly, it took FDA three and a half years to approve the drug Interleukin-2 (IL-2), which is used to treat a fatal form of kidney cancer. The president of the National Kidney Cancer Association noted the absurdity of FDA delays (European nations approved the drug much sooner): "The odds of being helped by IL-2 are about one out of four ... The odds of dying from the therapy are about one out of 25. As gambles go these are not bad odds, particularly when ... there is almost certainty of death if no risk is taken."⁷⁹

It is true that there are risks associated with taking pharmaceuticals (far more than lowlevel exposures of chemicals in consumer products), but the key question is who shall decide. It is fine for governments to do studies and advise consumers, but there are very high costs when governments denies access to products, as FDA does here, and as EU will do if it passes the chemicals policy.

Biotechnology policies offer more examples of over precautionary polities harming and even killing people. "Precaution" in this area has even led some nations to refuse food donated to starving people. For example, in September of 2002, the government of Zambia withheld

⁷⁵ Gina Kolata, "Tools Gauging Blood Pressure Raise Questions," New York Times, June 16, 2002.

⁷⁶ As quoted in CEI Press Release, "CEI Criticizes FDA Delay In Approving New Heart Valve 15-Year Wait Prevented Patients from Using Life Saving Device," June 27, 2001; available online at:

www.cei.org/gencon/003,02443.cfm.

⁷⁷ Ibid.

⁷⁸ Sam Kazman, "Deadly Overcaution: FDA's Drug Approval Process," *Journal of Regulation and Social Costs* 1, no. 1, September 1990.

⁷⁹ Eugene P. Schoenfeld, Ph.D., as quoted in CEI press release, "Consumer Advocacy Group Attacks FDA for Slow Approval of Cancer Treatment," May 14, 1992.

food because it was produced using biotechnology despite the fact that citizens were starving. Eventually, people broke into sheds where the food was stored to avoid starvation.⁸⁰

If the EU continues down this path, additional products and their benefits will be placed at risk. For example, what limits and adverse implications will the EU policy have on agriculture? The EU can conduct prospective studies and hope they are right in their assessments, but unintended consequences are sure to arise, and many are likely to prove very negative.

The impacts could be dire since the world depends on modern farming with chemicals for food production. Such practices are why output 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 1980.⁸¹ The use of herbicides to control weeds decreases the need for tilling soil, which in turn reduces soil erosion by 50-98 percent.⁸²

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 that we now produce.⁸³ 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 of all the land in Africa (which is just under 12 million square miles).

Conclusion

Over precaution as embodied in the "precautionary principle" clearly jeopardizes the development of, and expanded access to, chemical products that are essential to public wellbeing. In fact, as demonstrated, it is already posing some of the greatest challenges to the essentials of public health: food, water, and health care. The freedom to develop and put to use thousands of manmade chemicals has played a crucial role in that progress by making possible such things as pharmaceuticals, safe drinking water, pest control, as well as numerous other items. If passed into law, the EU chemicals policy will jeopardize that progress.

⁸⁰ "Zambian Police Examine Starvation Reports, Gov't Arresting Critics," *Deutsche Presse-Agentur*, October 8, 2002. *BBC News*, "Famine-hit Zambia Rejects GM Food Aid," October 29, 2002.

⁸¹ Dennis Avery, "Saving the Planet with Pesticides," *The True State of the Planet* (New York: Free Press, 1995), 52-54.

⁸² Ibid., 74-76.

⁸³ Ibid., 71.