NATIONAL CENTER FOR POLICY ANALYSIS

Biotech versus Precaution in Europe and America: Killing the Golden Goose[1]

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The human population is growing — especially in countries where people are already malnourished — and will probably plateau sometime this century between eight and nine billion people. With approximately six million square miles of land under cultivation, the world currently produces more than enough food to feed Earth's six billion people minimally adequate diets. However, as populations grow and developing countries strive for Western living standards, the world will need approximately three times more food than is currently produced.

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Executive Summary

Agricultural economist Dennis Avery estimates that:

- If all of the world's farmers adopted the best modern farming practices with high inputs of fertilizers and pesticides it might be possible to double current crop yields on the same amount of land.
- Alternatively, if farmers went totally "organic" — eschewing the use of "artificial" fertilizers, pesticides and biotechnologies — the amount of land under cultivation would have to double to yield enough food in 2050.
- A third option is the judicious use of biotechnology to create genetically modified crops, which would produce greater yields on the same amount of land as conventional agriculture, with less pesticide and fertilizer use per unit of food produced.

Indeed, genetically modified crops (also referred to as biotech or bioengineered crops) are already in widespread use around the world and have been shown to have no harmful effects to date.

The Precautionary Principle. Unfortunately, government bans and strict regulations threaten to undermine this process based on the precautionary principle — a theory rooted in the adage "better safe than sorry." While there are many variations of the precautionary principle, one of the most widely cited is the Wingspread Declaration, which states: "When an activity raises threats of harm to human health or to the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."

Most versions of the precautionary principle require that those proposing to introduce new technologies prove that no harm will occur before proceeding. Though a very difficult criterion for new technologies

to meet, this standard has been applied rigorously to biotech crops, especially in the European Union, where only one genetically modified crop has been approved for use. By contrast:

- Since 1998, 23 new genetically modified crops and more than 120 genetically modified products have been grown (and consumed) elsewhere in the world.
- The United States cultivates approximately 50 percent of the world's land used for genetically modified crops — 57.7 million hectares (143 million acres) in 2007.
- As of 2007, more than 114.3 million hectares (282.4 million acres) were planted with biotech crops in 23 different countries (12 developing countries, 11 industrialized countries).

Benefits of Biotech Crops. Biotech crops are already providing benefits to millions of people worldwide. For instance, the Rockefeller Foundation reports that golden rice — rice genetically altered to contain beta carotene (which readily converts to vitamin A) and new genes to overcome iron deficiency — is preventing thousands of cases of childhood blindness, and reducing anemia, which is suffered by more than two billion women.

Moreover, through genetic modification, crops can be altered to specifically reduce the risk of problems common to conventional breeding techniques, thus improving various crops' nutritional value and reducing the environmental impact of farming — both very important factors as the population and demand for food grow.

Policy Recommendations. The United States government should avoid new regulatory hurdles to the development and use of biotech crops. Additional regulations would only serve to stifle innovation and reduce the benefits expected from the expanded development of bioengineered crops. Internationally, the United States should work to ensure that European governments are not allowed, through international funding agencies or trade restrictions, to limit access to biotechnology advances in the developing world, which is most in need of these agricultural breakthroughs.

About the Author

H. Sterling Burnett is a senior fellow at the National Center for Policy Analysis. He received his Ph.D. in Philosophy from Bowling Green State University in Ohio in 2001. His work primarily focuses on the intersection between ethics, economics and politics in relation to environmental issues. He has numerous publications to his credit in academic journals, magazines and daily newspapers, including *Environmental Ethics, Ethics,* the *Texas Review of Law & Politics,* the *Washington Post, USA Today* and *Forbes*. He has provided invited testimony before the United States Congress and to various state legislatures.

Introduction

The world needs to increase food production. Agricultural economist Dennis Avery has pointed out that approximately 800 million people do not currently have nutritionally adequate diets.[2] Four hundred million people currently suffer from vitamin A deficiency, including millions of children who go blind each year. The human population is growing, especially in countries where people are already malnourished, and will probably plateau sometime this century between eight and nine billion people.[3]

Feeding the World. With approximately six million square miles of land under cultivation — an amount equal in size to the United States and Europe — the world currently produces more than enough food to feed Earth's six billion people minimally adequate diets.[4] However, populations in many developing countries are beginning to demand and work toward Western standards of living. Feeding nine billion people diets similar to those enjoyed by people in industrialized countries will require approximately three times more food than the world currently produces. Avery estimates that:

- If all of the world's farmers adopted the best modern farming practices with high inputs of fertilizers and pesticides it might be possible to double current crop yields on the same amount of land.

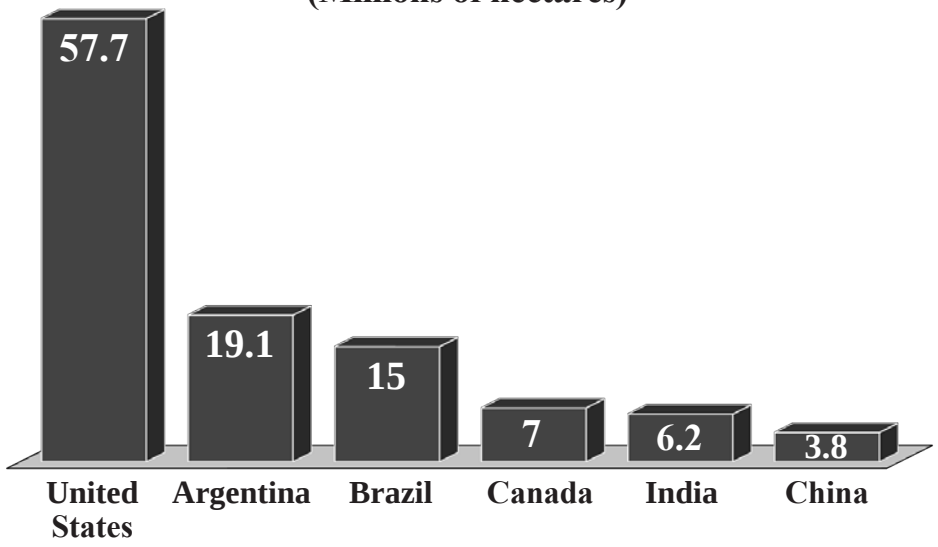
- Alternatively, if farmers went totally "organic" — eschewing the use of "artificial" fertilizers, pesticides and biotechnologies — the amount of land under active cultivation would have to double to yield enough food in 2050.

- A third option is the judicious use of biotechnology to create genetically modified crops, which would produce greater yields on the same amount of land as conventional agriculture, with less pesticide and fertilizer use per unit of food produced.

FIGURE I

Countries with the Most Biotech Crops in 2007

(Millions of hectares)



Source: "Global Status of Commercialized Biotech/Genetically Modified Crops: 2007," International Service for the Acquisition of Biotech Applications, ISAAA Brief 37, 2007. Available at http://www.isaaa.org/resources/publications/briefs/37/executivesummary/default.html.

Going organic would be disastrous for wildlife and native plants, says Avery, because the lands most likely to be converted to agriculture are forests, rangelands and other wildlands. Massive biodiversity losses from land conversion for organic food production is especially likely since the relatively undeveloped tropics — the most biodiverse region on Earth — is also where population growth is occurring, and where hunger and malnutrition are most widespread.

Spread of Biotechnology. Genetically modified — also called bioengineered or biotech — crops are already in widespread use, and there is very little evidence that these crops pose a threat to human health or the environment. In fact, between 1995 — when the first bioengineered crops were licensed for use — and 2007, farmers planted more biotech crops each year without negative repercussions. As of 2007, more than 114.3 million hectares (282.4 million acres) were planted with biotech crops in 23 different countries (12 developing countries, 11 industrialized countries).[5]

In 2007, the United States, followed by Argentina, Brazil, Canada, India and China, continued to be the principal adopters of biotech crops globally. The United States ranked first, planting 57.7 million hectares (50 percent of the global biotech acreage). [See Figure I.] Also, the number of small and resource-poor farmers planting biotech crops in developing countries in 2007 exceeded 10 million for the first time (of the total 12 million farmers using biotech).[6]

Thus, genetically engineered crops are already improving agricultural abundance, and hold the promise of improving various crops' nutritional value and reducing the environmental impact of farming. Genetically modified crops could be the harbinger of a sustainable green agricultural revolution.

"Genetically engineered crops can feed the world's increasing population."

The Danger of Excessive Precaution. Unfortunately, there is a specter haunting the world's farms, threatening to undermine agricultural progress and the ability to feed the planet's growing population: environmental activists lobbying for government bans on, or overregulation of, the creation and widespread dispersion of bioengineered crops.

The Precautionary Principle

Over the past three decades, the precautionary principle has become popular in discussions of public policy, especially in relation to health and environmental policy. There is no single, commonly accepted formulation of the precautionary principle. Indeed, a paper by Robert Hahn and Cass Sunstein notes no less than 19 different versions of the principle.[7] John D. Graham, founding director of the Harvard Center for Risk Analysis until 2001, provided a very strong version of the principle: "No human technology should be used or introduced into the environment until it can be shown to pose no threat of harm to humans or the environment."[8] Proponents of using the principle when shaping public policy argue that it is grounded in such common sense adages as "better safe than sorry," "look before you leap" and "haste makes waste."

A Popular Definition of the Precautionary Principle. While the precautionary principle has evolved over time, a gathering of environmentalists, scientists, lawyers and philosophers in 1998 produced the Wingspread Declaration: "When an activity raises threats of harm to human health or to the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."[9] This is one of the most widely cited definitions and it is the one used throughout this paper.[10]

The full Wingspread Declaration statement lays out key attributes shared by most, if not all, versions of the precautionary principle:

- First, existing public policies and regulations are made on the basis of inadequate risk assessments — science is unable to fully assess the range of future harm from novel innovations or applications of modern technology.

- Second, the government is not only justified, but obligated to prevent or reduce the risk of harm by improving the understanding of the nature and scope of potential risks from the use of a technology, and by disseminating information to those potentially affected by its use.

- In addition, the government should restrict the use of new technologies or novel applications of established technologies until the activity is shown to be safe.

For most precautionary principle proponents, this last point leads them to advocate a shift in the traditional burden of proof.[11] Abandoning the old maxim "innocent until proven guilty" for the new standard of "guilty until proven innocent," most versions of the precautionary principle require that those proposing to use new technologies in industry or agriculture, for example, show that no harm will occur before proceeding.

Influence of the Precautionary Principle on Public Policy. In one

form or another, the precautionary principle has been incorporated in domestic legislation in Europe and America, and in a number of international treaties. For instance, the 1987 Ministerial Declaration of the Second Conference on the Protection of the North Sea states, "In order to protect the North Sea from the possible damaging effects of the most dangerous substances, a precautionary approach...may require action to control inputs of such substances even before a causal link has been established by absolutely clear scientific evidence."[12]

Similarly, the 1992 Convention on Biological Diversity states, "Where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat."[13]

The 1990 Bergen Ministerial Declaration on Sustainable Development in the European Common Economic Region, the 1992 Rio Declaration on Environment and Development, and the 2000 Cartagena Protocol on Biosafety (an addendum to the 1992 Convention on Biological Diversity) all explicitly embrace and establish legal versions of the precautionary principle similar to that laid out in the Wingspread Declaration.

The extent to which the precautionary principle has become fundamental to policy within the European Union cannot be overstated. Indeed, the principle is part of the founding document of the European Union. The 1992 Maastricht Treaty created the European Union as a union of nations. Concerning environmental policy, the Treaty states, "Community policy on the environment…shall be based on the precautionary principle and on the principles that preventive actions should be taken."[14]

> *"The precautionary principle has been more widely accepted in Europe than in America."*

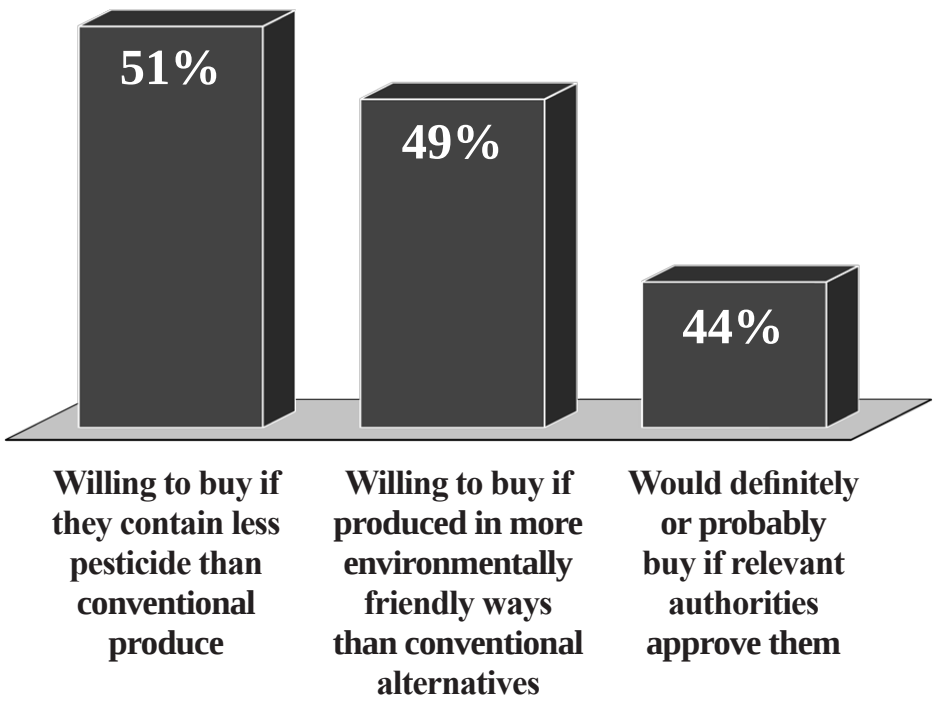
Certainly, as a formal principle, the precautionary principle has been more widely accepted (intellectually and in the law) in Europe than in America. In fact, the United States has refused to ratify a number of multilateral agreements and international treaties (many negotiated under the auspices of the United Nations) that include the precautionary principle. In some instances the principle was specifically cited as a significant problem. For example, the United States has not adopted either the Convention on Biological Diversity or its addendum, the Cartagena Protocol. In 2003, the United States, Canada and Argentina filed a grievance with the World Trade Organization that argued the European Union was illegitimately applying the Cartagena Protocol — to which none of the countries filing the grievance were party — and the precautionary principle it contained in order to block the licensing and sale of agricultural biotechnology products.[15]

Although the precautionary principle has had less influence on U.S. policy, the federal government has nevertheless incorporated some degree of precaution in its lawmaking. For instance, in 1976, Congress passed the Toxic Substances Control Act (TSCA), authorizing the Environmental Protection Agency (EPA) to regulate chemicals that pose an unreasonable risk to human health or the environment.[16] TSCA requires the EPA to review new chemicals that are manufactured, imported, processed, distributed in commerce, used or disposed of in the United States before they enter commerce, and it allows the EPA to review those already distributed.[17] Under these regulations, between 1979 and 2005 the EPA reviewed 32,000 new and 200 existing chemicals, and required companies to reduce the risk of 3,500 of these substances.[18]

Biotechnology Regulation in the United States and European Union. The disparity between the United States and Europe concerning the use and regulation of biotechnological products or genetically modified organisms is stark, but narrowing. According to the U.S. Regulatory Agencies Unified Biotechnology Web site, health and safety laws written prior to the advent of modern biotechnology are used to review genetically engineered products.[19] To date, the United States has not issued any new legislation for these products.

FIGURE II

Europeans' Attitudes Toward Genetically Modified Foods



Source: EuropaBio, "What do European Consumers Really Think about GM Foods?" 2009.

Products made using biotechnology in the United States are regulated by a variety of agencies depending upon their use, not the method of their creation. In other words, pesticides are regulated by the EPA under authority granted to it by the 1947 Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and food products are regulated by the Food and Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act (FFDC) of 1938.[20] This means that the regulations for any particular genetically modified food may fall under the authority of the EPA, the FDA or the U.S. Department of Agriculture (or any combination of the three), depending upon the type of modification.

Note that U.S. regulation of any biotechnology product stems not from it being produced through the modification of the organism at a genetic level, but rather the use to which the modified product will be put. As a study by the Pew Trust Initiative on Food and Biotechnology points out, "Federal requirements for [food products] apply regardless of how the food is produced… Thus, rice that has been genetically enhanced to provide beta carotene is subject to basically the same statutory and regulatory framework as rice to which beta carotene is added through product formulation."[21]

As noted above, Europe has incorporated the precautionary principle into its founding law and has set out instructions for how the principle applies to genetically modified products.[22] Indeed, the European Commission laid out a series of what they characterize as objective, science-based guidelines pertaining to genetically modified organisms and products.[23] Susan Carr of the United Kingdom's Open University Biotechnology Policy Group describes the guidelines as graduated levels of precaution.[24] They state:

- First, the precautionary measures should be proportional to the chosen level of protection.
- Second, the measures should be nondiscriminatory; that is, the measures should be comparable to those imposed in similar situations.
- Third, the measures should be consistent with similar measures already taken in equivalent areas in which all scientific data are available.
- Fourth, the measures should be based upon an examination of the benefits and the costs of action and inaction, with the goal of reducing risks to an acceptable level.
- And finally, the measures should be subject to review in light of new scientific data — with regular

monitoring required to review, modify or reverse precautionary actions.[25]

European genetic modification regulations were based on the premise that initially strong restrictions would relax as more experience with genetically modified products was gained, first in the laboratory and then in field trials. European politicians assumed that initial uncertainties concerning the potential harms (and their likelihood) would be clarified and resolved before the products (usually crops) became commercially viable. However, notes Carr, though graduated levels of precaution are part and parcel of Europe's genetically modified regulations, in practice the restrictions have become stricter as particular products have come closer to widespread or commercial use.[26] Furthermore, in response to objections from environmental pressure groups, the media and the general public, new precautionary measures were introduced.

The European Commission arguably violated its own guidelines for choosing and applying precautionary measures from the outset. For instance, critics of the Commission's standards claimed that the restrictions it ultimately placed on genetically modified products violated both the second and third guidelines (described above). Critics argued, first, that genetically modified crops and food stuffs were no different with regard to the risks they posed than food and products developed through conventional breeding, yet bans on the field testing and sale of genetically modified crops were not applied to conventionally developed foods. Second, they argued that no additional precautionary measures were justified for genetically modified crops beyond standard safety tests, because such precautions are not imposed on conventional crops and food even though they are known to have some adverse impacts.

"Since 1998, 23 new genetically modified crops have become available to farmers worldwide."

Restricting Genetically Modified Food in Europe. Beyond the European Commission and its tightening rules on biotech plants, genetically modified foods must overcome another precautionary legal hurdle before they can be used Europe-wide. European Union member states can evoke a "national safeguard clause," to keep bans on products in place even if the European Commission approves their production, import and use. Under this clause, if a member state has concerns remaining about a genetically modified crop's effect on human health or the environment, it can temporarily ban the product in its country on precautionary grounds while the European Commission reviews its findings.[27] Eight European Union member states have repeatedly invoked this clause to keep bans on products in place. When the Commission has confronted these countries' bans and required them to follow its directives, the countries have ignored the orders. Other member states that lack individual bans themselves have backed the objecting member states in this confrontation. They have also refused to allow new genetically modified products.

The European Commission's restrictions, combined with the national safeguard clause, offer further confirmation that the precautionary principle is keeping the European Union from allowing the introduction of novel technologies — even when the technologies have been proven safe. As evidence:

- The European Union has only approved one genetically modified crop for use — a genetically modified variety of maize.
- Since 1998, no new biotech crop has been allowed to reach the marketplace, although the European Food and Safety Authority has never given a negative recommendation to a genetically modified crop.[28]
- The European Commission has authorized the importation of 16 genetically modified crops since 2005, yet member nations refuse to change their domestic laws to allow the production, use or importation of those crops.[29]
- By contrast, since 1998, 23 new genetically modified crops and

TABLE I

Naturally Occurring Chemicals in Common Food Items

Food Item	Naturally Occurring Mutagens or Carcinogens
Tomatoes	Acetaldehyde, Benzaldehyde, Hydrogen peroxide, Quercetin glycosides
Apples	Acetaldehyde, Benzaldehyde, Caffeic acid, Estragole, Quercetin glycosides
Bread	Acetaldehyde, Acrylamide, Benzo(a)pyrene, Ethyl alcohol, Ethyl carbamate, Furan, Furfural
Coffee	Acetaldehyde, Benzaldehyde, Benzene, Benzo(a)pyrene, Benzofuran, Catechol, 1,2,5,6-dibenz(a)anthracene, Ethyl benzene, Furan, Furfural, Hydrogen peroxide, Hydroquinone, 4-methylcatechol

Source: American Council on Science and Health, "ACSH Holiday Dinner Menu."

more than 120 genetically modified products have become available to farmers (and thus have been consumed or used) elsewhere in the world.

In Europe, perceived public opinion and interest group pressure have been substituted for a rational, science-based assessment of risks when deciding whether to allow the introduction of new genetically modified organisms. However, recent opinion polls show Europeans are open to the idea of genetically modified foods. In fact, 44 percent of those polled said they would definitely or probably buy genetically modified foods if the relevant authorities approved it.[30] [See Figure II.]

The Burden of Proof

While the precautionary principle may sound reasonable in theory, it requires the impossible: prove a negative. As Henk van den Belt and Bart Gremmen put it, "The application of the precautionary principle… tends to impose an impossible burden of proof on proponents of new technologies. In the name of absolute safety they are asked nothing less than to demonstrate conclusively that the new technologies they advocate offer no possible harm. This is a formidable, perhaps even logically impossible task."[31]

All food, products and tools pose some risk. Without the use of fire, automobiles, antibiotics, coffee, water, salt and chlorine (to name a few), human life, in the words of the philosopher Thomas Hobbes, "would be nasty, poor, brutish and short." Yet, arguably, none of these would satisfy the standard set by the precautionary principle. Proponents of the precautionary principle hold a distinct but undefended bias toward natural, or at least existing, technologies, products and goods — even if they are known to be harmful or pose a significant risk of harm that new technologies might reduce.

Natural Pesticides. The focus on potentially negative consequences due to human technological alterations of natural goods ignores the significant risks from so-called natural products — and how these risks might be reduced through human tampering.

For instance, scientists Bruce N. Ames and Lois Swirsky Gold cite an array of studies that show 99.9 percent of the chemicals humans ingest are natural. They show the amounts of synthetic chemicals in plant foods, including pesticide residues, are insignificant compared to the amount of natural pesticides

produced by plants themselves.[32] In fact, according to the American Council on Science and Health, there are more than 30 naturally occurring substances that can cause mutations or cancer in rats (mutagens and carcinogens) found in just a small sampling of common food items and beverages. [See Table I.] It is important to note that the quantities of rodent carcinogens consumed in the human diet are highly unlikely to pose a risk of cancer.[33]

Natural pesticides are chemicals produced by plants to defend themselves:

- On average, Americans ingest 5,000 to 10,000 different natural pesticides and their breakdown products — eating about 1,500 milligrams of natural pesticides per person per day.
- This is 10,000 times more than they consume of synthetic pesticide residues.[34]
- In fact, the weight of the natural chemicals in a single cup of coffee that are *known* rodent carcinogens are about the same as the weight of synthetic pesticide residues that are also known rodent carcinogens the average person in the United States consumes in a year.

However, only 3 percent of the natural chemicals in roasted coffee have been adequately tested for carcinogenicity, whereas all synthetic pesticides are tested.[35] Indeed, only a small proportion of natural pesticides have been tested for carcinogenicity, but of the 63 that have been tested, more than 50 percent (35) are rodent carcinogens. Naturally occurring pesticides that are rodent carcinogens are ubiquitous in fruits, vegetables, herbs and spices.

While these natural pesticides pose little threat to humans in the quantity consumed, the contrast between the carcinogenicity of natural versus synthetic pesticides shows manmade technology is not necessarily more likely to be harmful than natural defenses.

> *"Plants naturally make mutagens and carcinogens."*

Avoiding Catastrophe. Proponents of the precautionary principle commonly argue that the use of new technology, chemicals, procedures or products could result in catastrophe. Even if the possibility is remote, they argue, it cannot be ignored and should be avoided at all cost. Many cling to Barry Commoner's third law of ecology, "nature knows best," as grounds for their advocacy of a strong precautionary principle.[36]

Yet proponents only focus on the potential harm to be prevented by using the precautionary principle, ignoring the fact that any particular action or inaction has benefits as well as costs. These advocates overlook the possibility that banning a particular activity or technology could very well result in disaster. Though supporters of the precautionary principle do not state it as such, their view seems to be that preventing hypothetical, speculative and/or minuscule threats of future harm should take precedence in regulatory policy over actions to reduce existing dangers or problems, some with known catastrophic consequences in the present.[37]

Waging War Against Genetically Modified Foods. Precautionary principle backers have attacked numerous industries and activities, including energy and chemical production and use. For instance, on December 31, 1999, citing the precautionary principle, environmentalists fought successfully to have Europe ban a group of six chemicals, called phthalates, that are used to make vinyl flexible. In addition, many environmental organizations, including Greenpeace and the Natural Resources Defense Council, have argued (using the precautionary principle) that governments should end the use of chlorine in plastics, pesticides and as a disinfectant in water. Their efforts to ban chlorine have thus far proved unsuccessful, perhaps because it occurs naturally and is ubiquitous, has over time demonstrated few detrimental health effects, and it has proven spectacularly useful — saving lives and helping make food more abundant.

No human use of technology, however, has come under as much scrutiny and criticism from supporters of the precautionary principle as the use of genetic engineering to modify plants for agriculture. This is

TABLE II

Countries Growing Bt-based Crops in 2004

Country	Crop
Australia	Cotton
Argentina	Cotton, Maize
Bulgaria	Maize
Canada	Maize
China	Cotton, Rice
Columbia	Cotton, Maize
Germany	Maize
Honduras	Maize
India	Cotton
Indonesia	Cotton
Mexico	Cotton
Philippines	Maize
Romania	Soybean
South Africa	Cotton, Maize
Spain	Maize
United States	Cotton, Maize
Uruguay	Maize

Source: Joseph Huesing and Leigh English, "The Impact of Bt Crops on the Developing World," *AgBioForum*, Volume 7, Nos. 1 & 2, Article 16.

important because, arguably, nothing is more important to the continued improvement of the human condition than the availability of nutritious food.

Growth of biotech crop usage has occurred, in large part, because of the efforts of the United States. Indeed, as noted above, there is a virtual ban on biotech crop production or use within the European Union. The United States, however, has led the charge against efforts to have the precautionary principle incorporated into various rules and principles developed by the Codex Alimentarius. The Codex Alimentarius Commission was created in 1963 by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) to develop food standards, guidelines and related texts, such as codes of practice, under the Joint FAO/WHO Food Standards Program. The main purposes of the Food Standards Program are protecting the health of consumers, ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and nongovernmental organizations.

In mid-2007, despite intense lobbying from environmental nongovernmental organizations and European member governments, the Commission excluded the precautionary principle from its food safety guidelines.[38] It ultimately accepted the United States' argument that "regulatory oversight and risk assessment should focus on the characteristics of the product rather than the molecular or cellular techniques used to produce it."[39] Scientifically, there is largely a consensus that the scope of oversight should be based on the risk-related characteristics of the product, whether inert or living organisms and whether organic, conventionally bred or genetically modified.

Advocates of using the precautionary principle to suppress the

introduction of biotech crops rarely acknowledge that that these foods are already providing benefits to millions of people worldwide. For instance, the Rockefeller Foundation reports that golden rice — rice genetically altered to contain beta carotene (which readily converts to vitamin A) and new genes to overcome iron deficiency — is preventing thousands of cases of childhood blindness and reducing anemia, which is suffered by more than two billion women in rice-dependent countries.[40]

Addressing the Fear of Genetically Modified Crops. Despite numerous studies and 13 years of commercial experience attesting to the safety of genetically modified foods, precautionary critics have raised a number of objections to the development, commercialization and dispersion of biotech crops:[41]

- Critics argue that there are risks posed by unintended gene transfer from genetically modified plants to wild relatives.
- They also argue that genetically modified crops could spur the evolution of superweeds or superbugs with immunity to those crops.[42]
- They raise an additional fear that the transfer of genes from one plant type to another might result in a crop uniquely toxic to humans or animals.
- Critics further object that the transfer of genes from one plant type to another may result in a plant that would induce allergic reactions in some people.[43]

The genetic modification of crops could, in fact, have any or all of the above results — but history has shown these outcomes to be extremely rare and similar to the risks posed by crops developed through conventional cross-breeding techniques. For instance, corn was the first plant to be genetically altered to contain the *Bacillus thuringiensis* bacteria (Bt). Bt-corn was developed to control the European corn borer, an insect that causes millions of dollars of losses to corn growers each year. Bt-corn effectively prevents infestations, reducing the need for costly pesticide applications and making it increasingly popular among corn growers.[44]

> *"Beta carotene in genetically altered rice prevents thousands of cases of childhood blindness."*

However, in 1999, laboratory studies found that if the pollen from Bt-corn drifts out of the fields in sufficient amounts and fall onto milkweed plants — on which Monarch butterflies lay their eggs and upon which newly hatched caterpillars feed — the caterpillars die at a rate far above average.[45] Thus began a media frenzy driven by environmental nongovernmental organizations to end the use of Bt-corn and place a hold on the creation of other biotech crops. The reaction from the food industry was quick and affected more genetically modified foods than Bt-corn. Fearing a consumer boycott, threatened by the Sierra Club and the U.S. Public Interest Group, baby food manufacturers Gerber and Heinz announced that they would stop using genetically modified crops in their products. Frito-Lay told its farmers it did not want Bt-corn in its chips. Seagram said that its wines and spirits would be free of biotech crops.[46]

However, the lead scientist involved in the research admonished that it was far too soon to say whether Bt-corn posed a real threat to butterflies or other beneficial insects, much less humans, stating, "Our study was conducted in a laboratory and, while it raises an important issue, it would be inappropriate to draw any conclusions about the risk to Monarch populations in the field based solely on these initial results."[47] His caution had merit, as later field experiments failed to show that Bt-corn posed a threat to Monarchs. In fact, the levels of corn pollen found on milkweed along the immediate edge of corn fields were less than half those used to produce caterpillar deaths in the laboratory — indeed, the levels just 10 meters from the cornfield fell to between 1/9th and 1/100th of the amount shown to cause harm.[48]

After the Bt-corn scare blew over, the bacteria was eventually introduced into other crops. Now, crops with the Bt modification are the fastest growing group of genetically modified crops in the world. Indeed, most of the 12 million farmers in the world planting genetically modified

crops are raising crops that use the Bt modification: 7.1 million in China (Bt-cotton), 3.8 million in India (Bt-cotton) and the balance of 100,000 in the Philippines (Bt-maize), South Africa (Bt-cotton, -maize and -soybeans) and the 13 other countries that grew Bt-crops in 2004. Even some countries in the European Union now grow Bt-corn.[49] [See Table II.]

"Zambia rejected biotech corn from the United States, putting 2.9 million people at risk of starvation."

Environmentalists also cite the case of the genetically modified soybean hybrid developed by Pioneer HiBred as an example of the threats posed by genetically modified crops. Pioneer transferred the genes from the Brazil nut into soybeans in an effort to improve the nutritional quality of animal feed. However, before commercial introduction, company research revealed that the gene that made the soybeans higher in protein also carried an allergenic trait that could produce immunological reactions in people suffering from Brazil nut allergies.[50] Thus, this result proves that the current regulatory regime and the common commercial practice of testing products before commercial introduction is more than adequate to protect the public and environment.

It is important to note that none of the risks feared by precautionary principle backers are unique to genetically modified plants. For instance, Henry Miller and Gregory Conko have pointed out that conventional breeding, of the trial-and-error variety, recently resulted in the production of squash, potatoes and celery varieties that contained dangerous levels of toxins.[51] Indeed, most of the major food crops have been so altered through conventional breeding that they hardly resemble their wild ancestors in appearance, fecundity or nutritional quality.[52]

Because biotechnology can target specific genes, it should reduce the risk of unwanted traits that are common to conventional cross-breeding. Genetic modification should also reduce the time necessary to create a new variety of plant with select (even multiple) desirable characteristics.

In the end, biotech crops go through greater regulatory scrutiny, even in the United States, than newly created conventionally bred varieties. The evidence indicates that the current testing regime is more than capable of finding virtually all potential problems before they result in substantial or irreversible harms to humans or the environment.

Abandoning the Precautionary Principle Does Not Mean Discarding Preventative Measures

The precautionary principle's greatest utility stems from applying it to itself. As the Social Issues Research Center in Oxford, England, noted, "If we apply the precautionary principle to itself — ask what are the possible dangers of using this principle — we would be forced to abandon it very quickly."[53]

Indeed, the wholesale adoption of the precautionary principle would, as its proponents argue, be a radical break with the principles and practices that have shaped public policy and regulations in the past. Therefore, before adopting the precautionary principle as a policy guide, the burden should be on its proponents to show: 1) current policies aimed at reducing risk and preventing harm to public health and the environment are inadequate, and 2) the precautionary principle is workable in practice and would prevent more harm than current policies.

With regard to the first point, proponents of the precautionary principle have failed to make a convincing case that current regulations consistently fail to protect public health. It is certainly true that technologies and products have sometimes reached the market and later proved to cause unanticipated harms. However, as noted by Arizona State University professor of law Gary Marchant, "Many of the risks now cited as exemplars showing the need for greater precaution were not, and perhaps could not have been, foreseen at the time of initial product deployment… [In these cases] the problem was ignorance rather than uncertainty about risks that were outside the scope of foreseeable effects."[54]

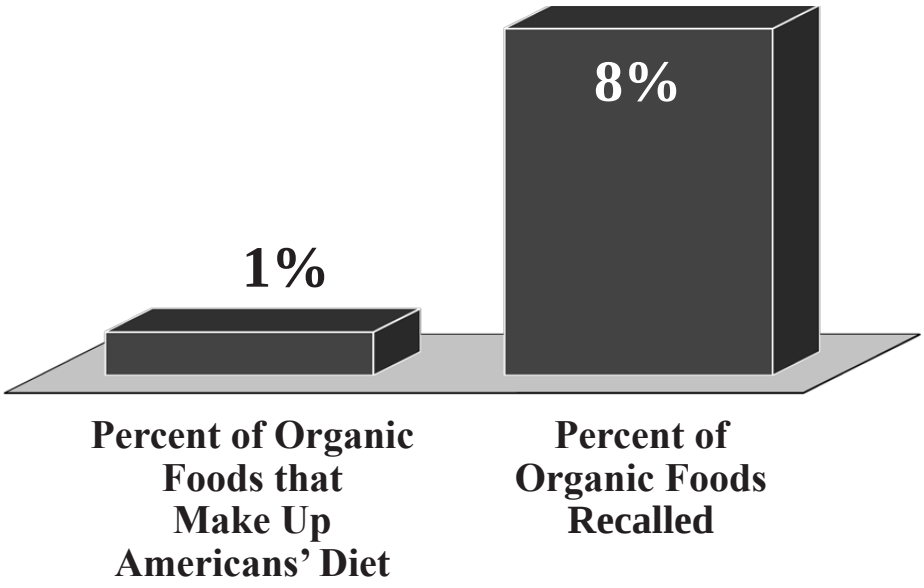
Because unanticipated effects cannot be foreseen or prevented, the precautionary principle simply cannot address unknown (rather than merely uncertain) risks and harms better than current policies. Marchant also notes that should the precautionary principle be substituted as a legal rule in place of current risk assessment policies to prevent type II errors — where an analysis concludes that there is no effect from an action or a policy, when in fact an effect does exist — this will almost certainly result in an increase in type I errors — where an analysis concludes that there is an effect when one does not exist. Such a result would hardly be an improvement over current practices.

The Precautionary Principle, Public Health and Law. There are indications that the precautionary principle, as it is incorporated into public policies and international laws, poses a threat to public health. To the extent that proponents of the principle are effective at restricting or limiting the use of existing genetically modified crops, or the creation and widespread dissemination of new biotech foods, untold harm could result.

Marchant provides the example of Zambia, which, citing the precautionary principle, rejected food aid from the United States that contained genetically modified corn. The aid was rejected even though the corn had not proved harmful and the Food and Agriculture Organization of the United Nations concluded that the decision would leave 2.9 million citizens at risk of starvation.[55]

FIGURE III

Americans' Diet and Organic Food Safety



Source: Center for Global Food Issues, "'Natural' and Organic Foods 8 Times More Likely to Have Safety and Recall Problems," 2002.

It may never be known how many, if any, died from Zambia's decision — a factor that weighs against giving legal standing to the precautionary principle. Indeed, environmental harms, human illnesses or deaths that result because a product or technology was not allowed to enter the marketplace are generally underreported or unaccounted for, and thus not considered when expanded legal use of the principle is proposed.[56]

As a basis for law, the precautionary principle is too ambiguous to provide consistent guidance for policymakers. One source of ambiguity is the fact that so many different versions are in popular use. Each specifies different levels of risk and uncertainty as triggers for precautionary action, failing to articulate what factors determine when the principle applies and when it does not. The different versions also fail to clarify how much precaution to apply in a given circumstance. Furthermore, except for strong versions of the principle — which specify the burden of proof is met when those introducing the technology can prove it poses no threat of harm — proponents of the precautionary principle fail to specify when their standard of certainty is met.

Marchant argues that the lack of specificity and inherent ambiguity

of the precautionary principle invite arbitrary legal applications and court rulings concerning when the principle applies and what it requires.[57] He notes that there have been hundreds of regulatory and judicial decisions in Europe and elsewhere that rely on the principle, but few of those decisions provided any analysis of why it applies in a particular case but not in others, or how the finding was reached. Rather, decisions generally cite the precautionary principle and then simply adopt the most restrictive protective action under consideration.

For example, the European Union applies the precautionary principle to genetically modified foods but not organic foods:

- Every genetically modified food product must undergo extensive testing without showing harmful effects to human health or the environment.
- By contrast, organic foods are typically not tested before commercialization, yet contaminated organic foods have resulted in known instances of human illness.
- Scientists have identified a range of possible risks from organic foods, including increased toxicity from the natural pesticides used on organic crops and *E. coli* infections from the manure used as fertilizer in organic farming.[58]

If anything, current evidence suggests that on a strictly precautionary basis, organic foods merit more scrutiny than genetically modified foods. In fact, in the United States organic foods account for 8 percent of all food recalls, but make up only about 1 percent of the population's diet.[59] [See Figure III.]

Because the precautionary principle is so vague, it gives regulators a great deal of discretion when determining whether or not, or to what extent, an action merits precautionary restrictions. As a result, some judges have questioned whether the precautionary principle allows for meaningful judicial review of agency actions. For instance, Marchant cites a European Union court that opined, "'Judicial review of the precautionary principle must be exercised with caution' in that courts can 'only exercise minimal review' of decisions based on the precautionary principle given the 'broad discretion' the precautionary principle gives to political authorities."[60]

"The precautionary principle isn't applied to organic foods."

If the precautionary principle undermines the courts' ability to exercise regulatory oversight, then it is seriously defective, as meaningful judicial review is generally considered to be a necessary component of any legal system that wants to claim legitimacy for the actions of its legislature or administrative agencies.

Conclusion

The U.S. government should not create new regulatory hurdles to the development and use of biotech crops. They are generally no different than crops developed through traditional selective breeding techniques and should be treated the same. The history of the development and use of genetically modified foods provides strong evidence that the current regulatory regime is more than adequate to protect the public health and environment from harms that might arise from genetic crop modification. Without evidence of regulatory failure, additional regulations would only serve to stifle innovation and reduce the expected human and environmental benefits from the expanded development of bioengineered crops.

Internationally, the United States government should work diligently to reduce restrictions on the use of genetically modified crops in Europe through negotiation or, if necessary, recourse to the World Trade Organization. Absent that effort, the United States should work to ensure that European governments are not allowed, through international funding agencies or trade restrictions, to limit access to biotech advances in the developing world, which is most in need of these agricultural breakthroughs.

Endnotes

1. This study is a modified version of the author's paper, "The Precautionary Principle: A Threat to Liberty and Human Welfare," *Social Philosophy and Policy*, Summer 2009, pages 378-410.

2. Dennis Avery, "Biotechnology: Trade Crisis or Path to Future," *Global Food Quarterly*, summer 1999, pages 1, 3; see also, Dennis Avery, *Saving the Planet with Pesticides and Plastic: The Environmental Triumph of High Yield Farming* (Indianapolis: Hudson Institute, 2000), page 33.

3. Population estimates are from the United Nations. See, "World Population to Increase by 2.6 Billion over Next 45 Years," 2005. Available at http://www.un.org/News/Press/docs/2005/pop918.doc.htm.

4. Dennis Avery, "Biotechnology: Trade Crisis or Path to Future," page 3.

5. "Global Status of Commercialized Biotech/Genetically Modified Crops: 2007," International Service for the Acquisition of Biotech Applications, ISAAA Brief 37, 2007. Available at http://www.isaaa.org/resources/publications/briefs/37/executivesummary/default.html.

6. Ibid.

7. Robert W. Hahn and Cass R. Sunstein, "The Precautionary Principle as a Basis for Decision Making," *The Economists' Voice*, Vol. 6, No. 2, Art. 8, 2005, pages 1-9. Hahn is cofounder and executive director of the American Enterprise Institute-Brookings Joint Center for Regulatory Studies. Sunstein is Karl N. Llewellyn Distinguished Service Professor in the Law School and Department of Political Science at the University of Chicago.

8. John D. Graham, "Making Sense of the Precautionary Principle," *Risk in Perspective*, September 1999, pages 1, 5. In 2001 Graham accepted the position of Administrator, Office of Information and Regulatory Affairs, United States Office of Management and Budget, where he served until 2005.

9. Wingspread Statement on the Precautionary Principle, January 1998. Available at http://www.sehn.org/wing.html.

10. Julian Morris calls the Wingspread Precautionary Principle the "international standard definition," noting that an Internet search lists literally hundreds of references to it. "Defining the Precautionary Principle," in Julian Morris, ed., *Rethinking Risk and the Precautionary Principle* (Oxford, England: Butterworth-Heinemann, 2000), pages 5-6.

11. Ibid. See also Henk van den Belt and Bart Gremmen, "Between Precautionary Principle and 'Sound Science': Distributing the Burdens of Proof," *Journal of Agricultural and Environmental Ethics*, Vol. 15, No. 1, March 2002, pages 103-122; and John Lemons, Kristen Shrader-Frechette and Carl Crandor, "The Precautionary Principle: Scientific Uncertainty and Type I and Type II Errors," *Foundations of Scienc*e, Vol. 2, 1997, pages 207-236. As will be discussed later, some precaution has been built into U.S. and European laws, particularly laws concerning medicines and chemicals, for many years. For instance, using scientific risk analysis, prescription drug manufacturers and pesticide manufacturers perform extensive efficacy and safety tests before their products are allowed onto the market. However, proponents of the precautionary principle argue that standard risk analyses are inadequate in the light of scientific uncertainty. Based on this view, they have been successful in Europe in placing a much higher burden of proof upon the manufacturers of chemicals, pesticides and medicines, especially in relation to genetically modified organism or biotech creations.

12. For ease of reference, the precautionary language in this variety of laws and treaties can be found in Jonathan Adler, "The Precautionary Principle's Challenge to Progress," in Ronald Bailey, ed., *Global Warming and Other Eco-Myths* (Roseville, Calif.: Prima Lifestyles, 2002), pages 278-280. Morris also notes the wide adoption of the precautionary principle, "Defining the Precautionary Principle," pages 2-7.

13. Jonathan Adler, "The Precautionary Principle's Challenge to Progress," in Ronald Bailey, ed., *Global Warming and Other Eco-Myths*, page 279.

14. Jonathan Adler, "The Precautionary Principle's Challenge to Progress," in Ronald Bailey, ed., *Global Warming and Other Eco-Myths*, page 279-280.

15. For a discussion of this case see, for instance, "U.S. vs. EC Biotech Products Case," Institute for Agriculture and Trade Policy, September 2005. Available at http://www.tradeobservatory.org/library.cfm?refid=76644. Though the World Trade Organization ruled for the plaintiff countries in 2006, as of 2008 member countries of the European Union have yet to comply with the ruling by removing their bans. See "Europe's biotech bans in WTO firing line," May 21, 2007. Available at http://www.euractiv.com/en/trade/europe-biotech-bans-wto-firing-line/article-152393. See also, "Commission hesitant to approve more GM crops," May 9, 2008. Available at http://www.euractiv.com/en/environment/commission-hesitant-approve-gm-crops/article-172209.

16. The description of how the TSCA works in the United States is taken from a GAO report to the Senate, "Chemical Regulation: Approaches in the United States, Canada and the European Union," U.S. Government Accountability Office, Publication No. GAO-06-217R, November 2005; available at http://www.gao.gov/new.items/d06217r.pdf.

17. TSCA excludes certain chemical substances, including pesticides that are regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and food, food additives, drugs, cosmetics or devices that are regulated under the Federal Food, Drug and Cosmetic Act (FFDCA).

18. "Chemical Regulation: Approaches in the United States, Canada and the European Union," U.S. Government Accountability Office, November 2005.

19. This discussion is based on material found at "U.S. Regulatory Agencies Unified Biotechnology Website," undated. Available at http://usbiotechreg.nbii.gov/index.asp.

20. FIFRA, as amended in 1972, 1988 and 1996. FFDC has been amended numerous times, most recently in 2007. None of the FFDC amendments (for registration, regulation or testing), however, treat genetically modified foods differently based on their origin as genetically modified foods as opposed to conventionally modified foods.

21. Pew Initiative on Food and Biotechnology, *Application of Biotechnology for Functional Foods* (Washington, D.C.: Pew Initiative on Food and Biotechnology, 2007), page 37. Available at http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/News/Press_Releases/Food_and_Biotechnology/PIFB_Functional_Foods.pdf.

22. The European Commission is the executive branch of the European Union. It is made up of 27 members, one from each member state, who are supposed to represent the interests of Europe as a whole rather than the parochial interests of their home state. The Commission has four main roles: to propose legislation to the European Parliament and Council, to administer and implement Community policies, to enforce Community law and to negotiate international agreements (mainly those relating to trade and commercial cooperation). For more information see "European Commission," undated. Available at http://ec.europa.eu/index_en.htm#.

23. The Biotechnology Policy Group conducts research which relates biotechnology to the broader issues of agriculture, sustainability, regulation and technological change. Most of the group's projects have focused upon the development of genetically modified organisms designed for agricultural uses. For more information see the Open University, "Biotechnology Policy Group," undated. Available at http://technology.open.ac.uk/cts/bpg.htm.

24. Susan Carr, "Ethical and Value-based Aspects of the European Commission's Precautionary Principle," *Journal of Agriculture and Environmental Ethics*, Vol. 15, No. 1, March 2002, pages 31-38.

25. Susan Carr, "Ethical and Value-based Aspects of the European Commission's Precautionary Principle," pages 36-37. The first and second points seem very similar, and research has not proved enlightening concerning the precise difference between the two. However, it seems that the second guideline concerns value judgments regarding whether or not one technology is comparable to another. If so, regulatory measures should not discriminate between the two. The third guideline concerns the difference in our knowledge about the risks posed by new technologies versus existing technologies. Technologies for which there is less scientific understanding of the sources and the nature of the risks involved in their introduction or use merit greater scrutiny than technologies within similar policy areas (say agriculture, for example) for which we have greater understanding of their impact.

26. Marian Debone and Patrick Du Jardin, "Deepening a Precautionary European Policy," *Journal of Agricultural and Environmental Ethics*, Vol. 15, No. 1, March 2002, pages 319-343, laud the increasing stringency of European precautionary regulatory policies, and argue for the need to make laws and regulations even more restrictive.

27. "Europe's biotech bans in WTO firing line," May 21, 2007.

28. "Commission hesitant to approve more GM crops," May 9, 2008; and "Europe's biotech bans in WTO firing line," May 21, 2007.

29. The European Food Safety Authority is a body of scientists established in 2002, mandated to conduct a scientific assessment of genetically modified foods and to report their findings to the European Commission.

30. EuropaBio, "What do European Consumers Really Think about GM Foods?" 2009. Available at http://www.europabio.org/positions/GBE/PP_101209_consumer.pdf.

31. Van den Belt is an assistant professor with the Applied Philosophy Group and Gremmen is a Professor of Ethical and Societal Aspects of Genomics at the Center for Society and Genomics, both at Wageningen University in the Netherlands. Henk van den Belt and Bart Gremmen, "Between Precautionary Principle and 'Sound Science': Distributing the Burdens of Proof," page 107. Van den Belt and Gremmen note others who have made the same point; for instance, Aaron Wildavsky observed that the only way to prove a negative is an impossibility theorem demonstrating that the contemplated action is contrary to the laws of nature. Aynsley Kellow made the point more graphically, stating: "Demanding that a negative be proved is the logical equivalent of asking people to prove that they are not witches." Aaron Wildavsky, *But is it True? A Citizens Guide to Environmental Health and Safety Issues* (Cambridge, Mass.: Harvard University Press, 1995); Aynsley Kellow, "Risk Assessment and Decision-Making for Genetically Modified Foods," Melbourne: Institute for Public Affairs, IPA Policy Backgrounder, 1999.

32. Bruce N. Ames and Lois Swirsky Gold, "Misconceptions About Environmental Pollution, Pesticides and the Causes of Cancer," National Center for Policy Analysis, Policy Report No. 214, March 1, 1998. Available at http://www.ncpa.org/pdfs/st214.pdf.

33. American Council on Science and Health, "ACSH Holiday Dinner Menu," October 12, 2004. Available at http://www.acsh.org/publications/pubID.103/pub_detail.asp.

34. Ibid.

35. Ibid.

36. Commoner is a biologist and in 1980 was the Citizens Party presidential candidate. Barry Commoner, "From Barry Commoner, The Closing Circle: Nature, Man and Technology, 1971," undated. Available at http://www3.niu.edu/~td0raf1/history261/nov1910.htm.

37. For critical comments concerning the regulatory bias of precautionary principle proponents in relation to type I versus type II errors see, for example, Frank B. Cross, "Paradoxical Perils of the Precautionary Principle," *Washington & Lee Law Review*, Vol. 53, No. 3, 1996. Also, Henk van den Belt and Bart Gremmen, "Between Precautionary Principle and 'Sound Science': Distributing the Burdens of Proof," page 107.

38. "Working Principles for Risk Analysis for Food Safety for Application by Governments," 2007. Available at http://www.codexalimentarius.net/web/more_info.jsp?id_sta=10751.

39. Henry I. Miller and Gregory Conko, "Genetically modified fear and the international regulation of biotechnology," in Julian Morris, ed., *Rethinking Risk and the Precautionary Principle* (Oxford: Butterworth-Heinemann, 2000), pages 84-104.

40. Dennis Avery, "Biotechnology: Trade Crisis or Path to Future," *Global Food Quarterly*, summer 1999, pages 1, 3.

41. One report discusses more than 150 government and industry financed studies. See the Committee on Identifying and Assessing Unintended Effects of Genetically Engineered Foods on Human Health, consisting of the Board on Life Sciences, Food and Nutrition Board, Board on Agriculture and Natural Resources, and the Institute of Medicine and National Research Council of the National Academies, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects* (Washington, D.C.: The National Academies Press, 2004). Another report discusses more than 47

peer reviewed articles published in scientific journals. See Christopher Preston, "Peer Reviewed Publications on the Safety of Genetically Modified Foods," 2005. Available at http://www.agbioworld.org/biotech-info/articles/biotech-art/peer-reviewed-pubs.html. The studies reviewed have found little or no evidence of harm from genetically modified foods.

42. The fear is that weeds or insects targeted by genetically modified crops, modified, for instance, with resistance to a particular pesticide, will either be cross-hybridized (in the case of the plants) or evolve immunity not only to the pesticide contained in the genetically modified plant but to other pesticides as well.

43. Anne Ingebourg Myhr and Terje Traavik, "The Precautionary Principle: Scientific Uncertainty and Omitted Research in the Context of Genetically Modified Organism Use and Release," *Journal of Agricultural and Environmental Ethics*, Vol. 15, No. 1, March 2002, pages 73-86; and Sue Mayer and Andy Stirling, "Finding a Precautionary Approach to Technological Developments — Lessons for the Evaluation of Genetically Modified Crops," *Journal of Agricultural and Environmental Ethics*, Vol. 15, No. 1, March 2002, pages 57-71.

44. Bt was so successful in corn that it was tested in other plants where it proved to be effective in controlling other insects as well.

45. Susan Milius, "New Studies Clarify Monarch Worries," *Science News*, Vol. 156, December 18 & 25, 1999, page 391.

46. Jim Ritter, "Genetic Food Fallout," Associated Press, February 28, 2000.

47. Steven J. Milloy, "The Greens' Ear-ie Ad," *Washington Times*, December 10, 1999.

48. Susan Milius, "New Studies Clarify Monarch Worries," page 391.

49. Joseph Huesing and Leigh English, "The Impact of Bt Crops on the Developing World," *AgBioForum*, Volume 7, Nos. 1 & 2, Article 16, 2004. Available at http://www.agbioforum.org/v7n12/v7n12a16-huesing.htm.

50. Julie A. Nordlee et al., "Identification of a Brazil-Nut Allergen in Transgenic Soybeans" *New England Journal of Medicine*, Vol. 334, No. 11, March 1996, pages 688-692.

51. Henry I. Miller and Gregory Conko, "The Toxic Politics of Biotech," *Tech Central Station*, October 6, 2004. Available at http://cei.org/gencon/019%2C04249.cfm. Miller was founding director of the U.S. Food and Drug Administration's Office of Biotechnology in 1989 and is currently a Senior Research Fellow at Stanford University's Hoover Institution. Conko is director of Food Safety Policy at the Competitive Enterprise Institute.

52. Alan McHughen, *Biotechnology & Food*, 2nd ed. (New York, N.Y.: American Council on Science and Health, 2000).

53. Social Issues Research Center, "Beware the Precautionary Principle," 1999. Available at http://www.sirc.org/articles/beware.html.

54. Gary E. Marchant, "From General Policy to Legal Rule: Aspirations and Limitations of the Precautionary Principle," *Environmental Health Perspective*, Vol. 111, No. 14, November 2003, page 1,799.

55. Gary E. Marchant, "From General Policy to Legal Rule: Aspirations and Limitations of the Precautionary Principle," page 1,802.

56. Marchant makes this same point, arguing that it is inherently more difficult to verify false positives (type I errors) than false negatives. Gary E. Marchant, "From General Policy to Legal Rule: Aspirations and Limitations of the Precautionary Principle," page 1,800.

57. Gary E. Marchant, "From General Policy to Legal Rule: Aspirations and Limitations of the Precautionary Principle," page 1,801.

58. See, for example, Anthony J. Trewavas, "Urban myths of organic farming," *Nature*, Vol. 410, March 2001, pages 409-410; or John Tierney, "Is food safe just because it's organic?" *New York Times*, August 25, 2000.

59. Center for Global Food Issues, "'Natural' and Organic Foods 8 Times More Likely to Have Safety and Recall Problems," 2002. Available at http://www.cgfi.org/2002/06/06/%E2%80%9Cnatural%E2%80%9D-and-organic-foods-8-times-more-likely-to-have-safety-and-recall-problems/.

60. Gary E. Marchant, "From General Policy to Legal Rule: Aspirations and Limitations of the Precautionary Principle," page 1,802.

The NCPA is a nonprofit, nonpartisan organization established in 1983. Its aim is to examine public policies in areas that have a significant impact on the lives of all Americans — retirement, health care, education, taxes, the economy, the environment — and to propose innovative, market-driven solutions. The NCPA seeks to unleash the power of ideas for positive change by identifying, encouraging and aggressively marketing the best scholarly research.

Health Care Policy.

The NCPA is probably best known for developing the concept of Health Savings Accounts (HSAs), previously known as Medical Savings Accounts (MSAs). NCPA President John C. Goodman is widely acknowledged (*Wall Street Journal*, WebMD and the *National Journal*) as the "Father of HSAs." NCPA research, public education and briefings for members of Congress and the White House staff helped lead Congress to approve a pilot MSA program for small businesses and the self-employed in 1996 and to vote in 1997 to allow Medicare beneficiaries to have MSAs. In 2003, as part of Medicare reform, Congress and the President made HSAs available to all nonseniors, potentially revolutionizing the entire health care industry. HSAs now are potentially available to 250 million nonelderly Americans.

The NCPA outlined the concept of using federal tax credits to encourage private health insurance and helped formulate bipartisan proposals in both the Senate and the House. The NCPA and BlueCross BlueShield of Texas developed a plan to use money that federal, state and local governments now spend on indigent health care to help the poor purchase health insurance. The SPN Medicaid Exchange, an initiative of the NCPA for the State Policy Network, is identifying and sharing the best ideas for health care reform with researchers and policymakers in every state.

NCPA President John C. Goodman is called the "Father of HSAs" by *The Wall Street Journal*, WebMD and the *National Journal*.

Taxes & Economic Growth.

The NCPA helped shape the pro-growth approach to tax policy during the 1990s. A package of tax cuts designed by the NCPA and the U.S. Chamber of Commerce in 1991 became the core of the Contract with America in 1994. Three of the five proposals (capital gains tax cut, Roth IRA and eliminating the Social Security earnings penalty) became law. A fourth proposal — rolling back the tax on Social Security benefits — passed the House of Representatives in summer 2002. The NCPA's proposal for an across-the-board tax cut became the centerpiece of President Bush's tax cut proposals.

NCPA research demonstrates the benefits of shifting the tax burden on work and productive investment to consumption. An NCPA study by Boston University economist Laurence Kotlikoff analyzed three versions of a consumption tax: a flat tax, a value-added tax and a national sales tax. Based on this work, Dr. Goodman wrote a full-page editorial for *Forbes* ("A Kinder, Gentler Flat Tax") advocating a version of the flat tax that is both progressive and fair.

A major NCPA study, "Wealth, Inheritance and the Estate Tax," completely undermines the claim by proponents of the estate tax that it prevents the concentration of wealth in the hands of financial dynasties. Actually, the contribution of inheritances to the distribution of wealth in the United States is surprisingly small. Senate Majority Leader Bill Frist (R-TN) and Senator Jon Kyl (R-AZ) distributed a letter to their colleagues about the study. In his letter, Sen. Frist said, "I hope this report will offer you a fresh perspective on the merits of this issue. Now is the time for us to do something about the death tax."

Retirement Reform.

With a grant from the NCPA, economists at Texas A&M University developed a model to evaluate the future of Social Security and Medicare, working under the direction of Thomas R. Saving, who for years was one of two private-sector trustees of Social Security and Medicare.

The NCPA study, "Ten Steps to Baby Boomer Retirement," shows that as 77 million baby boomers begin to retire, the nation's institutions are totally unprepared. Promises made under Social Security, Medicare and Medicaid are completely unfunded. Private sector institutions are not doing better — millions of workers are discovering that their defined benefit pensions are unfunded and that employers are retrenching on post-retirement health care promises.

Pension Reform.

Pension reforms signed into law include ideas to improve 401(k)s developed and proposed by the NCPA and the Brookings Institution. Among the NCPA/Brookings 401(k) reforms are automatic enrollment of employees into companies' 401(k) plans, automatic contribution rate increases so that workers' contributions grow with their wages, and better default investment options for workers who do not make an investment choice.

The NCPA's online Social Security calculator allows visitors to discover their expected taxes and benefits and how much they would have accumulated had their taxes been invested privately.

Environment & Energy.

The NCPA's E-Team is one of the largest collections of energy and environmental policy experts and scientists who believe that sound science, economic prosperity and protecting the environment are compatible. The team seeks to correct misinformation and promote sensible solutions to energy and environment problems. A pathbreaking 2001 NCPA study showed that the costs of the Kyoto agreement to reduce carbon emissions in developed countries would far exceed any benefits.

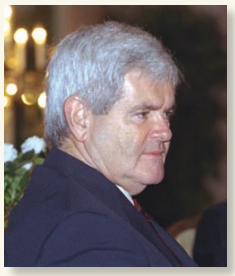
Educating the next generation.

The NCPA's Debate Central is the most comprehensive online site for free information for 400,000 U.S. high school debaters. In 2006, the site drew more than one million hits per month. Debate Central received the prestigious Templeton Freedom Prize for Student Outreach.

Promoting Ideas.

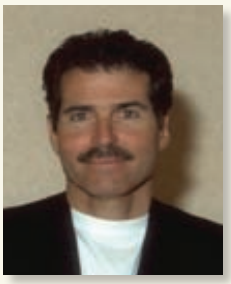
NCPA studies, ideas and experts are quoted frequently in news stories nationwide. Columns written by NCPA scholars appear regularly in national publications such as the *Wall Street Journal*, the *Washington Times*, *USA Today* and many other major-market daily newspapers, as well as on radio talk shows, on television public affairs programs, and in public policy newsletters. According to media figures from Burrelles*Luce*, more than 900,000 people daily read or hear about NCPA ideas and activities somewhere in the United States.

What Others Say About the NCPA



"The NCPA generates more analysis per dollar than any think tank in the country. It does an amazingly good job of going out and finding the right things and talking about them in intelligent ways."

Newt Gingrich, former Speaker of the U.S. House of Representatives



"We know what works. It's what the NCPA talks about: limited government, economic freedom; things like Health Savings Accounts. These things work, allowing people choices. We've seen how this created America."

John Stossel,
former co-anchor ABC-TV's *20/20*

"I don't know of any organization in America that produces better ideas with less money than the NCPA."

Phil Gramm,
former U.S. Senator

"Thank you . . . for advocating such radical causes as balanced budgets, limited government and tax reform, and to be able to try and bring power back to the people."

Tommy Thompson,
former Secretary of Health and Human Services

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