The Annapolis Center
For Science-Based Public Policy

"Our greatest responsibility is to be good ancestors."
…Jonas Salk

Absolute Safety is Absolutely Impossible:
A Rational Look At Progress vs. The Precautionary Principle

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We are pleased to attribute the cover photograph of the earth to Harrison H. Schmitt, Ph.D. This photograph was taken during the 1972 Apollo 17 flight on which Dr. Schmitt served as Lunar Module Pilot. Dr. Schmitt, the last person to step onto the moon, is Chairman Emeritus of The Annapolis Center.

Absolute Safety is Absolutely Impossible:
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The United States is a nation built by immigrants. Recently, an advertisement appeared in the New York Times with a headline that proclaimed, "Sometimes, the greatest risk is NOT taking one!" The reader's attention is drawn to a very large photograph featuring an immigrant family standing at the rail of a ship in New York Harbor while passing the Statue of Liberty.

The photo was interesting because it looked as if someone had erased large portions of the four people in it. It forces the reader to pause and contemplate what kind of a nation we would be today if our ancestors decided ***against taking the risk*** of coming here simply because they did not have a 100% guarantee that everything would turn out just fine.

But, they did…and we are today recognized as the greatest, most prosperous, most innovative nation on earth. Nonetheless, there are still those who profess that risk should be avoided by espousing the "precautionary principle," an extreme interpretation of the "better safe than sorry" approach to innovation and new technology.

To some, the concept of the precautionary principle may sound eminently logical. After all, they reason, we must protect ourselves against the unforeseen and unintended consequences of scientific innovation and technology, especially those innovations with the potential, however remote, to affect our planet and our lives.

Pesticides, cell phones, genetically modified crops, plastic food containers, medical devices, and pharmaceuticals – all have been challenged in the name of the precautionary principle whose adherents argue that the absence of evidence of no harm does not mean that something is not potentially harmful. They often insist that someone should have to prove that new products or technologies are not harmful before they are allowed see the light of day. Some even want to apply the precautionary principle retroactively as they argue that existing products - those that have already demonstrated their value in the marketplace - should be removed if it cannot be demonstrated that they are 100 percent risk-free. This, of course, is the question of "How do you (absolutely) prove a negative?"

By nature, some people are risk averse. They prefer to leave "well enough" alone rather than to venture into the unknown. This tendency notwithstanding, society can only move forward if it is willing to take manageable risks. Other people fear a lack of control. For example, many people prefer driving to flying because they believe they have more control over the risks on the road than placing their faith in a pilot. Yet, driving a car entails a far greater risk than commercial airline travel. The lack of perceived control should not stand in the way of making rational choices based on the best available evidence.

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Absolute Safety is Impossible

Inherent in the precautionary principle is a requirement that all hazards should be addressed. While most accept the obligation to examine all reasonably foreseeable hazards of a proposed activity, the precautionary principle imposes an open-ended requirement to evaluate scenarios that lack even the slightest causation for any proposed adverse effect or hazard. It's doubtful ANY innovation can fulfill such a requirement. Anyone can come up with a random adverse effect not included in the original analysis – without any hypothetical connection to the activity – then assert that the analysis was incomplete and therefore failed to meet precautionary standards. The precautionary principle apparently requires innovators to address an endless list of hypotheticals that have no basis in science. Even if resources are available for this analysis, it's a classic "Catch –22" to address issues that have no scientific relationship with any scientific substance.

Innovators do have substantial obligations to understand the impact of the proposed action. Other parties, including regulators and the public, should question the completeness of any analysis. However, these inquiries must have some logical basis. If the innovator must answer every unbounded and hypothetical inquiry, the innovation is held hostage by individuals and groups engaged in the endless pursuit of "perfect" analysis.

Benefits of the Unknown

We cannot know every potential risk in advance; neither can we always predict the life-enhancing and life-saving benefits that might emerge from a new technology or product. It is also true that we cannot always predict whether the benefits of a new technology will outweigh its hazards.

Many Activities Do Not Pass A "No-Risk" Standard:

Baseball, Basketball, Biking, Football, Power boating, Rugby, Skiing, Snowboarding, Soccer, Scuba diving… and the list goes on and on…

Still, risk should always be judged in the context of potential benefits. People are occasionally, and unintentionally, harmed by pharmaceuticals and vaccines, but imagine the consequences if these life-saving products were taken off the market. Even aspirin, a lifesaving medicine, can have unintended consequences as can vaccines that have prevented millions of deaths. Health officials and scientists in government and industry strive to minimize these risks, but there is almost always some element of risk associated with virtually any product or innovation. Recreational sports, including those we enjoyed

during the 2002 Winter Olympics (*e.g.,* snowboarding, bobsledding, downhill skiing) all pose significant risks. Should we prohibit these activities? Banning a product, technology or activity because there is some degree of danger – or because we do not have 100% knowledge of all risks – presents a very narrow choice for society. While decision-making rarely rests on science alone, risk management decisions based on scientific evidence are more likely to be accepted and therefore, more likely to stand the test of time.

In the final analysis, sensible precaution should include an unbiased assessment of a potential hazard including the level of uncertainty and the benefits that might be sacrificed if the products and technologies in question are restricted or called into question. This assessment should also include recognition of the uncertainties and risks that accompany potential alternatives as well.

Vorsorgeprinzip, but…

In broad terms, the precautionary principle originated in the 1960s in Germany as *vorsorgeprinzip* (meaning "foresight planning"). Since then, it has become a mantra for activists who believe that precaution should supersede the established principles of evaluation, risk assessment and management. This concept was afforded renewed credibility in 1998 when a group of activists met at the Wingspread conference facility in Racine, Wisconsin. After meeting for two days, a "Consensus Statement" was released which included this explanation: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken *even if some cause and effect relationships are not fully established scientifically* (emphasis added). In this context, the proponent of an activity, rather than the public, should bear the burden of proof."

At first glance, this may sound reasonable, but look again. Scientific evaluation, risk assessment, and risk management always include elements of precaution whether by human nature, by scientific logic, or by established cost-benefit principles. Why do we need a precautionary principle? More importantly, what are the risks of this principle when it is applied in its most extreme forms?

The Peril of Avoiding All Risk

If every possible ramification is not fully understood, or if every potential risk is not known, the precautionary principle says we should apply the brakes. The default assumption is to stand pat, the status quo accepted. But doing so sacrifices the potential benefits of discovery and innovation. The mantra has become: When in doubt, stop. Stop the human inclination towards exploration and innovation. Stop pushing the edges of the envelope of scientific knowledge and human accomplishment. As Samuel Johnson is quoted as saying, "Nothing will ever be attempted, if all possible objections must first be overcome."

Everything in life involves a degree of risk. A hammer remains a wonderful tool…even after you hit your thumb with it! We cannot simply wish away risk and to suggest we can prove the absence of any potential hazard is totally unrealistic. Rather than eliminating risk, mankind has always sought to minimize and manage it. A culture in which people shun risks altogether, where progress and development are abandoned "just to be on the safe side," is a society with a very bleak future.

Accepting risks can often lead to far-reaching benefits. We take electricity for granted, but it has made life more comfortable, convenient and productive than our immigrant ancestors could have possibly imagined. But electricity can also be very dangerous. Electrical fires happen. People do get electrocuted. Had the precautionary principle held sway when mankind first began to harness electricity, you might be reading this by candlelight (risking an accidental fire and inhaling the unhealthful fumes and soot, by the way).

Precaution in Moderation

Any society determined to shape its own destiny should carefully examine the ramifications of extreme precaution. The rejection of extreme precaution is NOT the same as the wholesale rejection of caution, because it is critical to risk management and has been an integral part of the safety assessments that have governed environmental and health regulation for many years. Instead of being used to replace risk assessment, precautionary considerations should continue to play a crucial role in that process.

Any practical consideration of precaution should focus on identifying the range of acceptable responses to a potential risk. Risk management measures should reflect its magnitude through sound scientific evidence and reject technologies for which the risk is unacceptable with no apparent means of reducing it. Precautionary approaches that reject the role of evidence destroy the innate ability of mankind to differentiate between acceptable and unacceptable risks.

It should be argued that the public well-being dictates precautionary actions follow a complete and objective examination of all available evidence. While not infallible, science has proved our best hope so far to increase knowledge, reduce uncertainty and improve confidence in public and private decision-making. It's axiomatic - the more we know, the better decisions we can make!

The precautionary principle falsely suggests that we can anticipate and accurately predict the ramifications of a technology in advance and, therefore, determine its ultimate benefits to society. When the optical laser was invented in 1960, no one knew the scope of its still-evolving applications. The optical laser is now integral to hundreds of everyday products and services, *e.g.*, printers, optical telephone networks, CD players, surgical procedures. Science moves forward. Concepts are tested. Issues are raised. Some

mistakes are inevitable. They are addressed, adjustments made…and innovation continues.

Risk Assessment

Risk assessment uses sound science to evaluate the likelihood and consequences of risk through the use of data and expert judgment. It identifies, characterizes and, to the greatest extent possible, quantifies the potential adverse effect of exposure to hazardous materials, activities or situations. It isn't enough to say that a hazard may exist. Risk assessment must delve into the nature of the risk by posing the following questions:

- What is the likelihood that a hazard does indeed exist?
- Under what conditions does it exist?
- If a hazard does exist, how significant – or negligible – is the risk?
- What is the nature of the hazard, *e.g*., how many people are exposed to the risk and how often?
- What are the consequences of the hazard; are they a simple nuisance or life threatening?
- What strategies (modification, education, elimination) are available to minimize the risk?

The precautionary principle only accepts the last of these.

For example, risk characterization for a chemical substance combines information about the degree of toxicity of the substance, the extent to which people are exposed to it, and the potential consequences of such exposure. Often, the actual risks are far less hazardous than initially imagined. By helping us better understand the nature and significance of hazards, risk assessment provides the information and perspective we need to judge acceptability. This information helps us establish priorities for addressing health, safety and environmental concerns. Realistic estimates of the size or seriousness of a problem are essential to making intelligent choices.

U.S. Environmental Protection Agency's Science Advisory Board: Relative Risk Reduction Strategies Committee, *Reducing Risk: Setting Priorities and Strategies for Environmental Protection* report recommended:

- Analyze a hazard's potential risk
- Compare the potential risks from that hazard versus risks of other hazards
- Prioritize the hazards you address based on risks

Defining Risk Management

Risk management is the process of deciding what should be done to eliminate or mitigate risk. It is primarily a policy-making tool used to determine what would be required to reduce the risk of a product or technology. There are usually a number of options. While analysis should take into consideration the degree of uncertainty associated with the risk, it can ***never*** be totally eliminated in an imperfect world.

A sound risk management process considers:

- To what extent a regulatory action will reduce the specific risk, or if the regulation itself will actually do the opposite and cause even greater risks.
- To what extent the regulation will create or reduce benefits.
- The relative risk reduction a regulation could achieve versus potential increased benefits of alternatives.

Risk management addresses the issues raised by advocates of precaution. A complete and unbiased risk assessment - adequately addressing all rational concerns - provides the basis for consideration of both the benefits and hazards of the proposed activity.

Risk Communication

Public involvement is central to the process. An informed, fully engaged public is necessary to establish acceptable priorities and to allocate appropriate resources. The public needs, deserves and expects to receive accurate information in order to make informed decisions. This means government, industry, activist organizations, and health advocates have the responsibility to inform the public about risks in accurate, meaningful, and actionable ways.

The public must be informed in language they can readily understand, particularly in the context of other risks that may be more familiar to them. We should provide a sense of perspective by using appropriate risk comparisons. The public should participate in a credible and viable process of assessment and subsequent decisions about the management of risks that will affect them. This process must be transparent, shared and understood.

Achievements Despite Uncertainty

Risk assessment and management continue to evolve. Just look at the astonishing achievements of the previous century – achievements that probably would not have been possible under the doctrine of radical precaution. Our lives today are better, healthier, and safer because we have been willing to take reasonable risks without stifling the inherent creativity and innovation necessary to ensure a better world for ourselves and our children. We are producing more food per acre of farmland than anyone could have imagined a mere 30 years ago. We feed more people, not because of fear and technological retrenchment, but because we sought innovative ways – however uncertain - to do so. Equally important, by improved efficiencies we have been able to incorporate more land into protected spaces, thus allowing future generations to enjoy our natural environment to a much greater extent than otherwise possible.

Through advances in science and technology, the 20th century was a time of remarkable change in American society, changes that allow us to live longer, healthier and more productive lives. Public health in the United States was abundant with innovation and achievements that most Americans now take for granted – new systems to purify and protect our food and water, innovative diagnostic technologies, advanced pharmaceuticals, vaccines and less evasive surgical procedures, to name but a few.

Consider these results:

- Life expectancy increased from 47 years in 1900 to 77 years in 2000.
- Infant mortality declined from 30 children per 1,000 in 1950 to 7.0 per 1,000 in 1999 through new technology applied to prenatal care, infectious disease control and sanitation. [1]
- Widespread water chlorination and sewage treatment virtually eliminated many water-borne diseases, including cholera and typhoid fever.
- Polio, once a terrifying prospect for all parents, has been virtually eliminated in North America through the use of vaccines.

These achievements were not void of uncertainty and risk. It was sound risk assessment and management – not total risk avoidance and hyper-precaution – that made all this possible. If we fear progress and are too timid to find new answers, how will we find the next life-saving technology?

Conclusions

Safe and comfortable shelter, abundant food supplies, clean drinking water, transportation, information technology, life-saving medicines, sports and recreation have been made possible through innovation, technology and scientific discovery.

Sound science supports and enhances decision-making by legislators, business leaders and individuals that is more likely to stand the test of time. This is especially true for regulatory decision-making because of new scientific findings built on existing knowledge. This process should not be sacrificed in the name of expediency nor should it be subverted by political or public policy agendas**.** Risk assessment, as part of a comprehensive system of risk management, is the best way to take the guesswork out of effective decision-making.

Reasonable precaution is essential to establishing the appropriate balance between benefit and risk. Because there is no such thing as zero risk, we must - and do - effectively manage risk. Virtually every consumer product, technology and activity can be harmful if misused. While scientific research should be used to better understand these risks, banning a product or technology because there is not total knowledge of every potential risk is shortsighted and the public interest is ill-served.

"Better safe than sorry" may sound reasonable, but it's too easy, too comfortable and too confining – especially when those espousing it do not help establish the reality of those risks. What if the precautionary principle were applied to itself? Its application carries the burden of untold risks and uncertainties. Thus, by its own definition, it should be abandoned.

A forward-looking society must adopt policies that give its citizens the greatest benefit in concert with the most efficient protections against harm. Can we afford to focus resources on those problems that pose lower risks while diverting resources from activities that would save more lives and prevent more harm? The answer is a resounding NO!

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[1] **Infant Mortality Statistics from the 1999 Period Linked Birth/Infant Death Data Set.** NVSR Volume 50, No. 4. 27 pp. (PHS) 2001-1120

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The Annapolis Center for Science-Based Public Policy supports and promotes responsible environmental, health, and safety decision-making. The Annapolis Center is a nonprofit 501(c)3 educational organization.

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