CANADA

PROVINCE OF QUEBEC

DISTRICT OF MONTREAL

DOCKET No. R-3770-2011

RÉGIE DE L'ÉNERGIE / ENERGY BOARD

AUTHORIZATION OF AN INVESTMENT BY HYDRO-QUEBEC DISTRIBUTION – ADVANCED METERING PROJECT PHASE 1

HYDRO-QUEBEC As Electricity Distributor

Petitioner

-and-

STRATEGIES ENERGETIQUES (S.E.) / ENERGY STRATEGIES (E.S.)

ASSOCIATION QUEBECOISE DE LUTTE CONTRE LA POLLUTION ATMOSPHERIQUE (AQLPA) / QUEBEC ASSOCIATION TO FIGHT AGAINST AIR POLLUTION

Interveners

UNITED STATES OF AMERICA, DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTE OF HEALTH NATIONAL CANCER INSTITUTE PRESIDENT'S CANCER PANEL

Reducing Environmental Cancer Risk. What We Can Do Now. 2008–2009 Annual Report. April 2010.

Excerpts.

http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP_Report_08-09_508.pdf.

Referred to in **David O. CARPENTER**, *Expert Report*, Revised on May 14, 2012, C-SE-AQLPA-0072, SE-AQLPA-7, Doc. 1.1, parag. 9, 33, 60a. Filed on May 14, 2012

Exhibit SE-AQLPA-7 - Document 6 UNITED STATES OF AMERICA, PRESIDENT'S CANCER PANEL, Reducing Environmental Cancer Risk. What We Can Do Now. 2008–2009 Annual Report. Excerpts. Attachment to the Expert Report of David O. Carpenter Filed by Stratégies Énergétiques (S.É.) / Energy Strategies (E.S.) and the AQLPA Régie de l'énergie / Quebec Energy Board - Docket no. R-3770-2011 Authorization of an investment by Hydro-Quebec Distribution – Advanced Metering Project Phase 1 2008–2009 Annual Report 🥑 President's Cancer Panel

REDUCING ENVIRONMENTAL CANCER RISK

What We Can Do Now







This report is submitted to the President of the United States in fulfillment of the obligations of the President's Cancer Panel to appraise the National Cancer Program as established in accordance with the National Cancer Act of 1971 (P.L. 92-218), the Health Research Extension Act of 1987 (P.L. 99-158), the National Institutes of Health Revitalization Act of 1993 (P.L. 103-43), and Title V, Part A, Public Health Service Act (42 U.S.C. 281 *et seq.*)

April 2010

For further information on the President's Cancer Panel or additional copies of this report, please contact

> Abby B. Sandler, Ph.D Executive Secretary President's Cancer Panel 6116 Executive Boulevard Suite 220, MSC 8349 Bethesda, MD 20814-8349 301-451-9399 pcp-r@mail.nih.gov http://pcp.cancer.gov

The President's Cancer Panel

LaSalle D. Leffall, Jr., M.D., F.A.C.S., *Chair* Charles R. Drew Professor of Surgery Howard University College of Medicine Washington, DC 20059

Margaret L. Kripke, Ph.D.

Vivian L. Smith Chair and Professor Emerita The University of Texas M.D. Anderson Cancer Center Houston, TX 77030

REDUCING ENVIRONMENTAL CANCER RISK

What We Can Do Now

Suzanne H. Reuben for The President's Cancer Panel

April 2010

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES National Institutes of Health National Cancer Institute

The President The White House Washington, DC 20500

Dear Mr. President:

Though overall cancer incidence and mortality have continued to decline in recent years, the disease continues to devastate the lives of far too many Americans. In 2009 alone, approximately 1.5 million American men, women, and children were diagnosed with cancer, and 562,000 died from the disease. With the growing body of evidence linking environmental exposures to cancer, the public is becoming increasingly aware of the unacceptable burden of cancer resulting from environmental and occupational exposures that could have been prevented through appropriate national action. The Administration's commitment to the cancer community and recent focus on critically needed reform of the Toxic Substances Control Act is praiseworthy. However, our Nation still has much work ahead to identify the many existing but unrecognized environmental carcinogens and eliminate those that are known from our workplaces, schools, and homes.

To jumpstart this national effort, the President's Cancer Panel (the Panel) dedicated its 2008–2009 activities to examining the impact of environmental factors on cancer risk. The Panel considered industrial, occupational, and agricultural exposures as well as exposures related to medical practice, military activities, modern lifestyles, and natural sources. In addition, key regulatory, political, industrial, and cultural barriers to understanding and reducing environmental and occupational carcinogenic exposures were identified. The attached report presents the Panel's recommendations to mitigate or eliminate these barriers.

The Panel was particularly concerned to find that the true burden of environmentally induced cancer has been grossly underestimated. With nearly 80,000 chemicals on the market in the United States, many of which are used by millions of Americans in their daily lives and are un- or understudied and largely unregulated, exposure to potential environmental carcinogens is widespread. One such ubiquitous chemical, bisphenol A (BPA), is still found in many consumer products and remains unregulated in the United States, despite the growing link between BPA and several diseases, including various cancers.

While BPA has received considerable media coverage, the public remains unaware of many common environmental carcinogens such as naturally occurring radon and manufacturing and combustion by-products such as formaldehyde and benzene. Most also are unaware that children are far more vulnerable to environmental toxins and radiation than adults. Efforts to inform the public of such harmful exposures and how to prevent them must be increased. All levels of government, from federal to local, must work to protect every American from needless disease through rigorous regulation of environmental pollutants.

Environmental exposures that increase the national cancer burden do not represent a new front in the ongoing war on cancer. However, the grievous harm from this group of carcinogens has not been addressed adequately by the National Cancer Program. The American people—even before they are born—are bombarded continually with myriad combinations of these dangerous exposures. The Panel urges you most strongly to use the power of your office to remove the carcinogens and other toxins from our food, water, and air that needlessly increase health care costs, cripple our Nation's productivity, and devastate American lives.

Sincerely,

Laber D. Lefall f.

LaSalle D. Leffall, Jr., M.D., F.A.C.S. Chair

Margaret L. Kripke, Ph.D.

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95

115

Executive Summary

Preface

PART 1

Overview

PART 2

Sources	and Types of Environmental Contaminants	25
Chapter 1	Exposure to Contaminants from Industrial and Manufacturing Sources	
Chapter 2	Exposure to Contaminants from Agricultural Sources	
Chapter 3	Environmental Exposures Related to Modern Lifestyles	
Chapter 4	Exposure to Hazards from Medical Sources	
Chapter 5	Exposure to Contaminants and Other Hazards from Military Sources	
Chapter 6	Exposure to Environmental Hazards from Natural Sources	

PART 3

Taking Action to Reduce Environmental Cancer Risk: What We Can Do

Conclusions	97
Policy, Research, and Program Recommendations	103
What Individuals Can Do: Recommendations	111

References

Appendices

Appendix A	President's Cancer Panel Meetings: Environmental Factors in Cancer—Participants	A-1
Appendix B	Recommendations of NIOSH Expert Panel for Improving Occupational Cancer Research Methods	A-5
Appendix C	Selected International, U.S., and European Carcinogen Classification Systems	A-9
Appendix D	Selected Federal Laws Related to Environmental Hazards	A-17
Appendix E	Federal Agencies Involved in Environmental Regulation or Research	A-31
Appendix F	Summary of Environmental and Occupational Links with Cancer	A-37
Appendix G	Electromagnetic Energy—Overview	A-47
Appendix H	Electromagnetic Energy Units of Measure	A-51
Appendix I	Research Recommended by PCP Meeting Participants	A-53







Executive Summary

Despite overall decreases in incidence and mortality, cancer continues to shatter and steal the lives of Americans. Approximately 41 percent of Americans will be diagnosed with cancer at some point in their lives, and about 21 percent will die from cancer. The incidence of some cancers, including some most common among children, is increasing for unexplained reasons.

Public and governmental awareness of environmental influences on cancer risk and other health issues has increased substantially in recent years as scientific and health care communities, policymakers, and individuals strive to understand and ameliorate the causes and toll of human disease. A growing body of research documents myriad established and suspected environmental factors linked to genetic, immune, and endocrine dysfunction that can lead to cancer and other diseases.

Between September 2008 and January 2009, the President's Cancer Panel (the Panel) convened four meetings to assess the state of environmental cancer research, policy, and programs addressing known and potential effects of environmental exposures on cancer. The Panel received testimony from 45 invited experts from academia, government, industry, the environmental and cancer advocacy communities, and the public.

This report summarizes the Panel's findings and conclusions based on the testimony received and additional information gathering. The Panel's recommendations delineate concrete actions that governments; industry; the research, health care, and advocacy communities; and individuals can take to reduce cancer risk related to environmental contaminants, excess radiation, and other harmful exposures.

Key Issues for Reducing Environmental Cancer Risk

Issues impeding control of environmental cancer risks include those related to limited research on environmental influences on cancer; conflicting or inadequate exposure measurement, assessment, and classification; and ineffective regulation of environmental chemical and other hazardous exposures.

Environmental Cancer Research

Research on environmental causes of cancer has been limited by low priority and inadequate funding. As a result, the cadre of environmental oncologists is relatively small, and both the consequences of cumulative lifetime exposure to known carcinogens and the interaction of specific environmental contaminants remain largely unstudied. There is a lack of emphasis on environmental research as a route to primary cancer prevention, particularly compared with research emphases on genetic and molecular mechanisms in cancer.

Environmental Exposure Measurement, Methodologic, Assessment, and Classification Issues

Efforts to identify, quantify, and control environmental exposures that raise cancer risk, including both single agents and combinations of exposures, have been complicated by the use of different measures, exposure limits, assessment processes, and classification structures across agencies in the U.S. and among nations. In addition, efforts have been compromised by a lack of effective measurement methods and tools; delay in adopting available newer technologies; inadequate computational models; and weak, flawed, or uncorroborated studies.

Some scientists maintain that current toxicity testing and exposure limit-setting methods fail to accurately represent the nature of human exposure to potentially harmful chemicals. Current toxicity testing relies heavily on animal studies that utilize doses substantially higher than those likely to be encountered by humans. These data—and the exposure limits extrapolated from them fail to take into account harmful effects that may occur only at very low doses. Further, chemicals typically are administered when laboratory animals are in their adolescence, a methodology that fails to assess the impact of *in utero*, childhood, and lifelong exposures. In addition, agents are tested singly rather than in combination.

Regulation of Environmental Contaminants

The prevailing regulatory approach in the United States is reactionary rather than precautionary. That is, instead of taking preventive action when uncertainty exists about the potential harm a chemical or other environmental contaminant may cause, a hazard must be incontrovertibly demonstrated before action to ameliorate it is initiated. Moreover, instead of requiring industry or other proponents of specific chemicals, devices, or activities to prove their safety, the public bears the burden of proving that a given environmental exposure is harmful. Only a few hundred of the more than 80.000 chemicals in use in the United States have been tested for safety.

U.S. regulation of environmental contaminants is rendered ineffective by five major problems: (1) inadequate funding and insufficient staffing, (2) fragmented and overlapping authorities coupled with uneven and decentralized enforcement, (3) excessive regulatory complexity, (4) weak laws and regulations, and (5) undue industry influence. Too often, these factors, either singly or in combination, result in agency dysfunction and a lack of will to identify and remove hazards.

Sources and Types of Environmental Contaminants

The line between occupational and environmental contaminants is fine and often difficult to demarcate. Many known or suspected carcinogens first identified through studies of industrial and agricultural occupational exposures have since found their way into soil, air, water, and numerous consumer products. People from disadvantaged populations are more likely to be employed in occupations with higher levels of exposure (e.g., mining, construction, manufacturing, agriculture, certain service sector occupations) and to live in more highly contaminated communities. The reality of this unequal burden is not just a health issue, but an issue of environmental justice.

While all Americans now carry many foreign chemicals in their bodies, women often have higher levels of many toxic and hormone-disrupting substances than do men. Some of these chemicals have been found in maternal blood, placental tissue, and breast milk samples from pregnant women and mothers who recently gave birth. Thus, chemical contaminants are being passed on to the next generation, both prenatally and during breastfeeding. Some chemicals indirectly increase cancer risk by contributing to immune and endocrine dysfunction that can influence the effect of carcinogens.

Children of all ages are considerably more vulnerable than adults to increased cancer risk and other adverse effects from virtually all harmful environmental exposures. In addition, some toxics have adverse effects not only on those exposed directly (including *in utero*), but on the offspring of exposed individuals.

Exposure to Contaminants from Industrial and Manufacturing Sources

Manufacturing and other industrial products and processes are responsible for a great many of the hazardous occupational and environmental exposures experienced by Americans. Many of these contaminantseven substances banned more than 30 years ago—remain ubiquitous in the environment because they break down very slowly, if at all. Other industrial chemicals or processes have hazardous by-products or metabolites. Numerous chemicals used in manufacturing remain in or on the product as residues, while others are integral components of the products themselves. Further, in the ongoing quest for more effective and efficient ways of making industrial and consumer products, new chemicals and other substances are being created continually and existing substances are being put to new uses. Limited research to date on unintended health effects of nanomaterials, for example, suggests that unanticipated environmental hazards may emerge from the push for progress.

Exposure to Contaminants from Agricultural Sources

The entire U.S. population is exposed on a daily basis to numerous agricultural chemicals, some of which also are used in residential and commercial landscaping. Many of these chemicals have known or suspected carcinogenic or endocrinedisrupting properties. Pesticides (insecticides, herbicides, and fungicides) approved for use by the U.S. Environmental Protection Agency (EPA) contain nearly 900 active ingredients, many of which are toxic. Many of the solvents, fillers, and other

chemicals listed as inert ingredients on pesticide labels also are toxic, but are not required to be tested for their potential to cause chronic diseases such as cancer. In addition to pesticides, agricultural fertilizers and veterinary pharmaceuticals are major contributors to water pollution, both directly and as a result of chemical processes that form toxic by-products when these substances enter the water supply. Farmers and their families, including migrant workers, are at highest risk from agricultural exposures. Because agricultural chemicals often are applied as mixtures, it has been difficult to clearly distinguish cancer risks associated with individual agents.

Environmental Exposures Related to Modern Lifestyles

Conveniences of modern life—automobile and airplane travel, dry cleaning, potable tap water, electricity, and cellular communications, to name a few-have made daily life easier for virtually all Americans. Some of these conveniences, however, have come at a considerable price to the environment and human health, and the true health impact of others is unconfirmed. For example, mobile source air emissions (e.g., from cars, trucks, other passenger vehicles, ships), especially diesel particulate pollution, are responsible for approximately 30 percent of cancer resulting from air pollution. Disinfection of public water supplies has dramatically reduced the incidence of waterborne illnesses and related mortality in the United States, but research indicates that long-term exposure to disinfection by-products such as trihalomethanes may increase cancer risk. Chemicals used for household pest control can become a component of carpet dust, posing a risk to children when they play on the floor.

Sharp controversy exists in the scientific community as to possible adverse health effects from exposure to low frequency electromagnetic energy. The use of cell phones and other wireless technology is of great concern, particularly since these devices are being used regularly by ever larger and younger segments of the population. At this time, there is no evidence to support a link between cell phone use and cancer. However, the research on cancer and other disease risk among long-term and heavy users of contemporary wireless devices is extremely limited. Similarly, current and potential harms from extremely low frequency radiation are unclear and require further study. In addition, ultraviolet radiation from excess sun exposure and tanning devices has been proven to substantially increase skin cancer risk.

Exposure to Hazards from Medical Sources

In the past two decades, improved imaging technologies, nuclear medicine examinations, and new pharmaceutical interventions have made possible significant strides in our ability to diagnose and treat human disease, including cancer. It is becoming increasingly clear, however, that some of these same technologies and drugs that have contributed so greatly to health status and longevity also carry risks.

While ionizing radiation exposures from radon, occupational, and other sources have remained essentially stable over the past 30 years, Americans now are estimated to receive nearly half of their total radiation exposure from medical imaging and other medical sources, compared with only 15 percent in the early 1980s. The increase in medical radiation has nearly doubled the total average effective radiation dose per individual in the United States. Computed tomography (CT) and nuclear medicine tests alone now contribute 36 percent of the total radiation exposure and 75 percent of the medical radiation exposure of the U.S. population. Medical imaging of children is of special concern; compared with adults, children have many more years of life during which a malignancy initiated by medical radiation can develop. Many referring physicians, radiology professionals, and the public are unaware of the radiation dose associated with various tests or the total radiation dose and related increased cancer risk individuals may accumulate over a lifetime. People who receive multiple scans or other tests that require radiation may accumulate doses equal to or exceeding that of Hiroshima atomic bomb survivors. It is believed that a single large dose of ionizing radiation and numerous low doses equal to the single large dose have much the same effect on the body over time.

Moreover, radiation dose for the same test can vary dramatically depending on the equipment used, technologist skill, application of dose-reduction strategies, and patient size, age, and gender. Licensure of imaging and radiation therapy technologists varies depending on the type of test performed by the technologist. Some states have only partial regulation; six states and the District of Columbia have no licensure or regulatory provisions of any kind.

In addition, pharmaceuticals have become a considerable source of environmental contamination. Drugs of all types enter the water supply when they are excreted or improperly disposed of; the health impact of long-term exposure to varying mixtures of these compounds is unknown.

Exposure to Contaminants and Other Hazards from Military Sources

The military is a major source of toxic occupational and environmental exposures that can increase cancer risk. Information is available about some military activities that have directly or indirectly exposed military and civilian personnel to carcinogens and contaminated soil and water in numerous locations in the United States and abroad. However, we may never know the full extent of environmental contamination from military sources. Nearly 900 Superfund sites are abandoned military facilities or facilities that produced materials and products for or otherwise supported military needs. Some of these sites and the areas surrounding them became heavily contaminated due to improper storage and disposal of known or suspected carcinogens including solvents, machining oils, metalworking fluids, and metals. In some cases, these contaminants have spread far beyond their points of origin because they have been transported by wind currents or have leached into drinking water supplies.

Hundreds of thousands of military personnel and civilians in the United States received significant radiation doses as a result of their participation in nuclear weapons testing and supporting occupations and industries, including nuclear fuel and weapons production, and uranium mining, milling, and ore transport. Hundreds of thousands more were irradiated at levels sufficient to cause cancer and other diseases. These populations include the families of military and civilian workers, and people—known as "downwinders"—living or working in communities surrounding or downstream from testing and related activities, and in relatively distant areas to which nuclear fallout or other radioactive material spread. Federal responses to the plight of affected individuals have been unsatisfactory. Those affected lack knowledge about the extent of their exposure or potential health problems they may face. Similarly, most health care providers are not aware of cancer and other latent radiation effects and therefore are unlikely to adequately monitor patients for these health conditions. Exposure to ionizing radiation related to nuclear weapons testing is an underappreciated issue worldwide.

Exposure to Environmental Hazards from Natural Sources

Most environmental hazards with the potential to raise cancer risk are the product of human activity, but some environmental carcinogens come from natural sources. For example, radon gas, which forms naturally from the breakdown of uranium mineral deposits, is the second leading cause of lung cancer in the United States and the leading cause of lung cancer among people who have never smoked. Radon-induced lung cancer is responsible for an estimated average of 21,000 deaths annually. People who smoke and also are exposed to radon have a higher risk of lung cancer than from either exposure alone.

Although human activities such as mining, ore processing, use of arsenic-containing pesticides, and burning of fossil fuels are major contributors to waterborne arsenic in the U.S., most inorganic arsenic in drinking water is from natural sources. Inorganic arsenic in drinking water has been linked to skin, lung, bladder, and kidney cancer in both sexes and with prostate cancer in men, as well as numerous non-cancerous conditions including endocrine, reproductive, and developmental effects.

Reducing Environmental Cancer Risk: A Call to Action

The burgeoning number and complexity of known or suspected environmental carcinogens compel us to act to protect public health, even though we may lack irrefutable proof of harm. Action is possible at several levels: conducting scientific research to enhance our understanding and by extension, our ability to prevent and respond to environmental carcinogens; enforcing existing policies and regulations that protect workers and the public; implementing policy and regulatory changes that support public health and reduce the burden of cancer; and taking personal action.

The Panel concludes that:

We Need to Determine the Full Extent of Environmental Influences on Cancer.

At this time, we do not know how much environmental exposures influence cancer risk and related immune and endocrine dysfunction. Environmental contamination varies greatly by type and magnitude across the nation, and the lifetime effects of exposure to combinations of chemicals and other agents are largely unstudied. Similarly, the cancer impact of exposures during key "windows of vulnerability" such as the prenatal period, early life, and puberty are not well understood. Nonetheless, while these diverse effects often are difficult to quantify with existing technologies and research methods, in a great many instances, we know enough to act.

The Nation Needs a Comprehensive, Cohesive Policy Agenda Regarding Environmental Contaminants and Protection of Human Health.

Environmental health, including cancer risk, has been largely excluded from overall national policy on protecting and improving the health of Americans. It is more effective to prevent disease than to treat it, but cancer prevention efforts have focused narrowly on smoking, other lifestyle behaviors, and chemopreventive interventions. Scientific evidence on individual and multiple environmental exposure effects on disease initiation and outcomes, and consequent health system and societal costs, are not being adequately integrated into national policy decisions and strategies for disease prevention, health care access, and health system reform.

Children Are at Special Risk for Cancer Due to Environmental Contaminants and Should Be Protected.

Opportunities for eliminating or minimizing cancer-causing and cancer-promoting environmental exposures must be acted upon to protect all Americans, but especially children. They are at special risk due to their smaller body mass and rapid physical development, both of which magnify their vulnerability to known or suspected carcinogens, including radiation. Numerous environmental contaminants can cross the placental barrier; to a disturbing extent, babies are born "pre-polluted." Children also can be harmed by genetic or other damage resulting from environmental exposures sustained by the mother (and in some cases, the father). There is a critical lack of knowledge and appreciation of environmental threats to children's health

and a severe shortage of researchers and clinicians trained in children's environmental health.

Continued Epidemiologic and Other Environmental Cancer Research Is Needed.

Available evidence on the level of potential harm and increased cancer risk from many environmental exposures is insufficient or equivocal. The Panel is particularly concerned that the impact, mechanisms of action, and potential interactions of some known and suspected carcinogens are poorly defined.

Meaningful measurement and assessment of the cancer risk associated with many environmental exposures are hampered by a lack of accurate measurement tools and methodologies. This is particularly true regarding cumulative exposure to specific established or possible carcinogens, gene-environment interactions, emerging technologies, and the effects of multiple agent exposures. Single-agent toxicity testing and reliance on animal testing are inadequate to address the backlog of untested chemicals already in use and the plethora of new chemicals introduced every year. Some high-throughput screening (HTS) technologies are available to enable testing of many chemicals and other contaminants simultaneously, but many remain to be developed to meet chemical testing needs. Support also is needed to develop methods for interpreting the wealth of data that HTS technologies generate. At this time, incentives to encourage development of this research are nearly non-existent.

Support for large, longitudinal studies to clarify the nature and magnitude of cancer risk attributable to environmental contaminants must continue. The capacity to collect biologic samples at the inception of studies is essential; even if current technologies do not allow these samples to be fully utilized at this time, it must be assumed that such technologies will evolve and enable use of collected biosamples to provide essential study baseline data. Personal health data privacy issues that currently limit research access to data and biosamples will need to be addressed.

Cancer risk assessment also is hampered by lack of access to existing exposure data, especially for occupational/industrial exposures, and regarding levels of radon, asbestos, and other contaminants in schools and day care centers.

An Environmental Health Paradigm for Long-Latency Disease Is Needed.

Recognizing that results of laboratory and animal studies do not always predict human responses, an environmental health paradigm for long-latency diseases is needed to enable regulatory action based on compelling animal and *in vitro* evidence before cause and effect in humans has been proven.

Existing Regulations for Environmental Contaminants Need to Be Enforced and Updated; Stronger Regulation Is Needed.

Weak laws and regulations, inefficient enforcement, regulatory complexity, and fragmented authority allow avoidable exposures to known or suspected cancercausing and cancer-promoting agents to continue and proliferate in the workplace and the community. Existing regulations, and the exposure assessments on which they are based, are outdated in most cases, and many known or suspected carcinogens are completely unregulated. Enforcement of most existing regulations is poor. In virtually all cases, regulations fail to take multiple exposures and exposure interactions into account. In addition, regulations for workplace environments are focused more on safety than on health.

Industry has exploited regulatory weaknesses, such as government's reactionary (rather than precautionary) approach to regulation. Likewise, industry has exploited government's use of an outdated methodology for assessing "attributable fractions" of the cancer burden due to specific environmental exposures. This methodology has been used effectively by industry to justify introducing untested chemicals into the environment.

Radiation Exposure from Medical Sources Is Underappreciated.

The use of radiation-emitting medical tests is growing rapidly. Efforts are needed to eliminate unnecessary testing and improve both equipment capability and operator skill to ensure that radiation doses are as low as reasonably achievable without sacrificing image or test data quality. At least one initiative is underway to improve and disseminate radiation reduction strategies and educate physicians, device manufacturers, their training staff, and others about radiation doses associated with specific tests. No mechanism currently exists to enable individuals to estimate their personal cumulative radiation exposure, which would help patients and physicians weigh the benefits and potential harm of contemplated imaging and nuclear medicine tests.

Medical Professionals Need to Consider Occupational and Environmental Factors When Diagnosing Patient Illness.

Physicians and other medical professionals ask infrequently about patient workplace and home environments when taking a medical history. Such information can be invaluable in discovering underlying causes of disease. Moreover, gathering this information would contribute substantially to the body of knowledge on environmental cancer risk.

Workers, Other Populations with Known Exposures, and the General Public Require Full Disclosure of Knowledge about Environmental Cancer Risks.

Individuals and communities are not being provided all available information about environmental exposures they have experienced, the cumulative effects of such exposures, and how to minimize harmful exposures. The disproportionate burden of exposure to known or suspected carcinogens experienced by specific populations (e.g., agricultural and chemical workers and their families, radiation-exposed groups such as uranium mine workers, nuclear industry workers, nuclear test site workers and "downwinders," residents of cancer "hot spots" or other contaminated areas) has not been fully acknowledged.

The Military Needs to Aggressively Address the Toxic Environmental Exposures It Has Caused.

Toxic materials produced for and used by the military have caused widespread air, soil, and water pollution across the United States and beyond our borders, including chemical and radiation contamination in and around current and former military installations, materiel production facilities, and mines. These contaminants, many of which may have serious long-term and latent effects including cancer, are a danger both to military personnel and civilians. Overall, the military has not responded adequately to health problems associated with its operations absent substantial pressure from those affected, advocacy groups, or the media. Of special concern, the U.S. has not met its obligation to provide for ongoing health needs of the people of the Republic of the Marshall Islands resulting from radiation exposures they received during U.S. nuclear weapons testing in the Pacific from 1946-1958.

Safer Alternatives to Many Currently Used Chemicals Are Urgently Needed.

The requisite knowledge and technologies exist to develop alternatives to many currently used chemical agents known or believed to cause or promote cancer. Many chemists require additional training to understand environmental hazards and reformulate products. Importantly, "green chemistry" alternative products themselves require longitudinal study to ensure that they do not pose unexpected health hazards.

The Panel believes that just as there are many opportunities for harmful environmental exposures, ample opportunities also exist to intervene in, ameliorate, and prevent environmental health hazards. Governments, industry, the academic and medical communities, and individuals all have untapped power to protect the health of current and future generations of Americans and reduce the national burden of cancer.

Policy, Research, and Program Recommendations

Based on its conclusions, the Panel recommends:

RECOMMENDATION

1. A precautionary, prevention-oriented approach should replace current reactionary approaches to environmental contaminants in which human harm must be proven before action is taken to reduce or eliminate exposure. Though not applicable in every instance, this approach should be the cornerstone of a new national cancer prevention strategy that emphasizes primary prevention, redirects accordingly both research and policy agendas, and sets tangible goals for reducing or eliminating toxic environmental exposures implicated in cancer causation. The proposed Kid Safe Chemicals Act introduced in the 110th Congress, or similar legislation, has the potential to be an important first step toward a precautionary chemicals management policy and regulatory approach to reducing environmental cancer risk. Optimally, it should shift the burden of proving safety to manufacturers prior to new chemical approval, in mandatory post-market studies for new and existing agents, and in renewal applications for chemical approval.

RESPONSIBLE AGENCIES, STAKEHOLDERS, AND OTHER ENTITIES*

President/Administration

Congress

Environmental Protection Agency (EPA)

Department of Labor (DOL)/ Occupational Safety and Health Administration (OSHA)

Department of Health and Human Services (HHS):

- Food and Drug Administration (FDA)
- National Institutes of Health (NIH)

Department of Agriculture (USDA)

State governments

Industry

 A thorough new assessment of workplace chemical and other exposures is needed to quantify current health risks. Previous estimates of occupational cancer risk are outdated and should no longer be used by government or industry.

- In large measure, adequate environmental health regulatory agencies and infrastructures already exist, but agencies responsible for promulgating and enforcing regulations related to environmental exposures are failing to carry out their responsibilities. The following are needed:
 - A more integrated, coordinated, and transparent system for promulgating and enforcing environmental contaminant policy and regulations, driven by science and free of political or industry influence, must be developed to protect public health.
 - Better concordance of exposure measures and standards is needed to facilitate interagency and international regulatory policy and enforcement and to identify research needs.
 - The United States should carefully consider the potential impact on consumers and commerce of the Globally Harmonized System for classifying carcinogens.

RESPONSIBLE AGENCIES, STAKEHOLDERS, AND OTHER ENTITIES*

Congress

National Academy of Science/ Institute of Medicine

National Science Foundation (NSF)

General Accountability Office

Other multidisciplinary group appointed for this task

HHS/National Institute for Occupational Safety and Health (NIOSH)

DOL:

- OSHA
- Mine Safety and Health Administration (MSHA)

EPA

HHS/FDA

USDA

DOL:

- OSHA
- MSHA

HHS/National Institute of Environmental Health Services (NIEHS)

EPA

DOL/OSHA

President/Administration

Congress

RECOMMENDATION	RESPONSIBLE AGENCIES, STAKEHOLDERS, AND OTHER ENTITIES*
 Information sharing among the public, researchers, regulatory agencies, industry, and other stakeholders must be a bedrock component of the environmental health regulatory system mission. 	EPA DOL: OSHA MSHA HHS: FDA Center for Disease Control and Prevention (CDC) USDA Department of Defense (DoD) Department of Energy (DOE) Environmental and cancer research communities Industry Media
 Environmental and public health advocates should be included in developing the environmental cancer research and policy agendas and in information dissemination. 	Advocates EPA HHS: • FDA • CDC DOE
4. Epidemiologic and hazard assessment research must be continued and strengthened in areas in which the evidence is unclear, especially research on workplace exposures, the impact of <i>in utero</i> and childhood exposures, and exposures that appear to have multigenerational effects. Current funding for federally supported occupational and environmental epidemiologic cancer research is inadequate.	Congress EPA HHS: • National Cancer Institute (NCI) • NIEHS • National Institute for Child Health and Human Development • NIOSH EPA NSF Nongovernmental research funders

 Measurement tool development and exposure assessment research, including the development of new research models and endpoints, should be accelerated to enable better quantification of exposures at individual, occupational, and population levels.

- High-throughput screening technologies and related data interpretation models should be developed and used to evaluate multiple exposures simultaneously. It may be possible to screen apparently similar suspect chemicals together and regulate these as a group as indicated by findings.
- Methods for long-term monitoring and quantification of electromagnetic energy exposures related to cell phones and wireless technologies are urgently needed given the escalating use of these devices by larger and younger segments of the population and the higher radiofrequencies newer devices produce.

6. The cancer risk attributable to residential radon exposure has been clearly demonstrated and must be better addressed. The following are needed:

- The Environmental Protection Agency (EPA) should consider lowering its current action level (4 pCi/L) for radon exposure, taking into account data on radon-related cancer risk developed since the existing action level was established.
- Public and health care provider education should be developed and broadly disseminated to raise awareness of radon-related cancer risk.
- Improved testing methods for residential radon exposure and better methods for assessing cumulative exposure should be developed. Tax deductions or other incentives should be implemented to encourage radon mitigation retrofitting of existing housing. Building code changes should be made to require radon reduction venting in new construction.
- All schools, day care centers, and workplaces should be tested at regular intervals for radon. Radon level data must be made available to the public. Buildings found to have levels in excess of the EPA action level should be mitigated.

RESPONSIBLE AGENCIES, STAKEHOLDERS, AND OTHER ENTITIES*

HHS

- NIEHS
- NIOSH

NSF

DoD/Applied Research Projects Agency

Industry

DOE

HHS/NIOSH

EPA

National Council on Radiation Protection and Measurements (NCRP)

EPA

HHS

Health care provider professional organizations

Media

Industry

Congress

Internal Revenue Service

State and local governments

State and local governments

- 7. Actions must be taken to minimize radiation exposure from medical sources. Specifically:
 - Health care providers, radiology technicians, and the public must be informed about the extent of radiation exposure from commonly used imaging and nuclear medicine examinations and the potential health risks of these procedures. Referring physicians are responsible for discussing with the patient the balance of benefit and risk associated with each imaging or nuclear medicine procedure being recommended. An educational/ decision-making tool that considers each patient's cumulative lifetime radiation exposure should be developed to facilitate these provider-patient communications.
 - The estimated effective radiation dose of all imaging and nuclear medicine tests performed should be a required element in patient records and should be a core data element in all electronic health records systems. In addition, patients should be assisted to reconstruct an estimate of the total medical radiation dose they have received.

- Radiation dose-lowering techniques must be implemented consistently and to the maximum extent feasible.
- Inspection of radiation-emitting medical equipment and pharmaceuticals must become more stringent, and uniform credentialing of technicians who administer scans is needed.

RESPONSIBLE AGENCIES, STAKEHOLDERS, AND OTHER ENTITIES*

Physicians and other health care providers

Health professional organizations

Advocates

Media

HHS:

- Agency for Healthcare Research and Quality
- NCI

Joint Commission for Accreditation of Healthcare Organizations (JCAHO)

HHS:

- FDA
- Centers for Medicare and Medicaid Services (CMS)
- CDC
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- Office of the National Coordinator for Health Information Technology (ONCHIT)

Department of Veterans Affairs (VA)

DoD

Physicians and other health care providers

Physicians and other health care providers

JCAHO

Radiation technologist professional organizations HHS/FDA

- 8. The unequal burden of exposure to known and suspected carcinogens must be addressed.
 - Individuals exposed to nuclear fallout and other nuclear contamination by biologically important radionuclides must be provided all available information on these exposures. A system must be developed to enable affected individuals to reconstruct and add radiation doses received so that they can adequately assess their cumulative exposure and potential health risks, including cancer.
 - The Advisory Committee on Energy-related Epidemiologic Research (ACERER) should be rechartered, or a similar body convened, to enable individuals exposed to nuclear testing fallout and other nuclear exposures to participate in policy making and other decisions that will affect their access to health care and compensation related to those exposures.
 - Geographic areas and vulnerable populations (including but not limited to children, migrant and other farm workers, and residents of high-poverty areas and cancer "hot spots") should be studied to determine environmental influences on cancer risk; identified risks must be remediated to the maximum extent possible.
 - The U.S. Government should honor and make payments according to the judgment of the Marshall Islands Tribunal.

RESPONSIBLE AGENCIES, STAKEHOLDERS, AND OTHER ENTITIES*

DoD DOE Nuclear Regulatory Commission HHS/NCI VA NCRP DOE

EPA HHS/NIEHS DoD USDA

President/Administration Congress

9. Physicians and other medical personnel should routinely query patients about their previous and current workplace and home environments as part of the standard medical history. This information will increase the likelihood that environmental factors in cancer and other illnesses are considered and will strengthen the body of information on environmental exposures and disease. Data on workplace and home environmental history should be incorporated into existing and developing automated medical records systems.

STAKEHOLDERS, AND OTHER ENTITIES*

RESPONSIBLE AGENCIES,

Physicians and other health care providers

HHS:

- ONCHIT
- NCI: Surveillance, Epidemiology, and End Results Program
- CDC: National Program of Cancer Registries
- CMS
- HRSA
- IHS

DoD: TRICARE

VA: Veterans Health Information System and Technology Architecture

Private insurer patient databases

10. "Green chemistry" initiatives and research, including process redesign, should be pursued and supported more aggressively, but new products must be well-studied prior to and following their introduction into the environment and stringently regulated to ensure their short- and long-term safety.

 Public health messages should be developed and disseminated to raise awareness of environmental cancer risks and encourage people to reduce or eliminate exposures whenever possible.

HHS/NIEHS

EPA NSF

HHS:

- FDA
- CDC
- HRSA
- CMS
- USDA

DOE

Federal Communications Commission

Advocates

Media

* The Panel recognizes that entities other than those listed may have a vital role or interest in implementation of the recommendations.

What Individuals Can Do: Recommendations

Much remains to be learned about the effects of environmental exposures on cancer risk. Based on what is known, however, there is much that government and industry can do now to address environmental cancer risk. The Panel's recommendations in this regard are detailed above. At the same time, individuals can take important steps in their own lives to reduce their exposure to environmental elements that increase risk for cancer and other diseases. And collectively, individual small actions can drastically reduce the number and levels of environmental contaminants.

CHILDREN

1. It is vitally important to recognize that children are far more susceptible to damage from environmental carcinogens and endocrine-disrupting compounds than adults. To the extent possible, parents and child care providers should choose foods, house and garden products, play spaces, toys, medicines, and medical tests that will minimize children's exposure to toxics. Ideally, both mothers and fathers should avoid exposure to endocrine-disrupting chemicals and known or suspected carcinogens prior to a child's conception and throughout pregnancy and early life, when risk of damage is greatest.

CHEMICAL EXPOSURES

- 2. Individuals and families have many opportunities to reduce or eliminate chemical exposures. For example:
 - Family exposure to numerous occupational chemicals can be reduced by removing shoes before entering the home and washing work clothes separately from the other family laundry.
 - Filtering home tap or well water can decrease exposure to numerous known or suspected carcinogens and endocrine-disrupting chemicals. Unless the home water source is known to be contaminated, it is preferable to use filtered tap water instead of commercially bottled water.
 - Storing and carrying water in stainless steel, glass, or BPA- and phthalate-free containers will reduce exposure to endocrine-disrupting and other chemicals that may leach into water from plastics. This action also will decrease the need for plastic bottles, the manufacture of which produces toxic by-products, and reduce the need to dispose of and recycle plastic bottles. Similarly, microwaving food and beverages in ceramic or glass instead of plastic containers will reduce exposure to endocrine-disrupting chemicals that may leach into food when containers are heated.

- Exposure to pesticides can be decreased by choosing, to the extent possible, food grown without pesticides or chemical fertilizers and washing conventionally grown produce to remove residues. Similarly, exposure to antibiotics, growth hormones, and toxic run-off from livestock feed lots can be minimized by eating free-range meat raised without these medications if it is available. Avoiding or minimizing consumption of processed, charred, and well-done meats will reduce exposure to carcinogenic heterocyclic amines and polyaromatic hydrocarbons.
- Individuals can consult information sources such as the Household Products Database to help them make informed decisions about the products they buy and use.
- Properly disposing of pharmaceuticals, household chemicals, paints, and other materials will minimize drinking water and soil contamination. Individuals also can choose products made with non-toxic substances or environmentally safe chemicals. Similarly, reducing or ceasing landscaping pesticide and fertilizer use will help keep these chemicals from contaminating drinking water supplies.
- Turning off lights and electrical devices when not in use reduces exposure to petroleum combustion by-products because doing so reduces the need for electricity, much of which is generated using fossil fuels. Driving a fuel-efficient car, biking or walking when possible, or using public transportation also cuts the amount of toxic auto exhaust in the air.
- Individuals can reduce or eliminate exposure to secondhand tobacco smoke in the home, auto, and public places. Most counseling and medications to help smokers quit are covered by health insurance or available at little or no cost.

RADIATION

- 3. Adults and children can reduce their exposure to electromagnetic energy by wearing a headset when using a cell phone, texting instead of calling, and keeping calls brief.
- 4. It is advisable to periodically check home radon levels. Home buyers should conduct a radon test in any home they are considering purchasing.
- 5. To reduce exposure to radiation from medical sources, patients should discuss with their health care providers the need for medical tests or procedures that involve radiation exposure. Key considerations include personal history of radiation exposure, the expected benefit of the test, and alternative ways of obtaining the same information. In addition, to help limit cumulative medical radiation exposure, individuals can create a record of all imaging or nuclear medicine tests received and, if known, the estimated radiation dose for each test.
- 6. Adults and children can avoid overexposure to ultraviolet light by wearing protective clothing and sunscreens when outdoors and avoiding exposure when the sunlight is most intense.

SELF-ADVOCACY

7. Each person can become an active voice in his or her community. To a greater extent than many realize, individuals have the power to affect public policy by letting policymakers know that they strongly support environmental cancer research and measures that will reduce or remove from the environment toxics that are known or suspected carcinogens or endocrine-disrupting chemicals. Individuals also can influence industry by selecting non-toxic products and, where these do not exist, communicating with manufacturers and trade organizations about their desire for safer products.

Regulation of Environmental Contaminants

The number and prevalence of known or suspected carcinogens is growing. Many environmental contaminants are manufactured synthetic chemicals; waste and by-products of industrial processes; chemical fertilizers, pesticides, and other chemicals used in farming and for landscaping; chemicals used in other commercial activities; combustion byproducts of petroleum-powered engines; water disinfection/chlorination by-products; and both man-made and natural sources of radiation.

Right now, the numbers for how many workers are exposed to most of the known carcinogens are 20 to 30 years old so we don't really know what the contemporary workforce is experiencing in terms of exposure.

> PAUL SCHULTE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

> > In the United States, about 42 billion pounds of chemicals are produced or imported daily. Many of these chemicals are used in massive quantities exceeding one million tons per year.⁸¹ Exposure limits have been set for some of these substances, but the vast majority are unregulated. Of equal concern, according to numerous speakers at the Panel's meetings, many of the current U.S. standards and related regulations for chemical and other exposures were set in the 1950s, and few are stringently enforced.

Reactionary versus Precautionary Approaches to Regulation

Even where reference doses and exposure limits have been established, a number of environmental health scientists and advocates believe that some exposure levels deemed safe by regulators are in fact too high. They maintain that exposures far below the reference dose are causing harm and in some cases, inducing cancer development. Moreover, they believe that some agents cause harm at very low doses that is not manifested at higher doses and that regulatory prudence is indicated until potential effects such as these are better understood.

However, the prevailing regulatory approach in the United States is reactionary in that it:

- Requires incontrovertible evidence of harm before preventive action is taken.
- Places the burden on the public to show that a given chemical is harmful.
- Does not consider potential health and environmental impacts when designing new technologies.
- Discourages public participation in decision making about the control of hazards and the introduction of new technologies, chemicals, or other exposures.⁸²

This reactionary approach typically engenders secondary prevention measures (e.g., screening, other methods for early detection of disease) once a health hazard has become evident, rather than action to remove the hazard from the environment (primary prevention).



An alternative approach to regulation that supports primary cancer and other disease prevention is precautionary.⁸³ In 1998, a conference of international environmental scientists, scholars, activists, treaty negotiators, and others convened to discuss implementation of the Precautionary Principle⁸⁴ asserted in a consensus statement that "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."⁸⁵ The core tenets of the Precautionary Principle are:

- Taking preventive action in the face of uncertainty.
- Shifting the burden of proof to proponents of an activity.
- Exploring a wide range of alternatives to possibly harmful actions.
- Including public participation in decision making.

According to one speaker, precaution should be a key component of a sound approach to managing and communicating risk and uncertainty about risk, but should be applied selectively.⁸⁶ Specifically, when there is no evidence of risk, precaution is not warranted and no action is needed. If confidence exists that there is a hazard, prevention is called for, not precaution. However, when credible evidence exists that there may be a hazard, a precautionary approach should be adopted and alternatives should be sought to remove the potential hazard and still achieve the same social benefit. Such an approach acknowledges the uncertainty of identifying cancer risks in complex, poorly understood environmental systems. The determination of when sufficient evidence exists for preventive action often depends on context and the consequences of inaction or acting in error.

One author cautions that operationalizing the precautionary principle using decision models rather than intuitions or inclinations can be challenging and has the potential to have unintended consequences.⁸⁷ If decision criteria are not carefully selected, it might be decided to stop the use of a chemical or technology that actually would not have adverse effects, or conversely, allow the use of agents that will have negative effects on people or the environment. In either case, the monetary, health, and social costs and benefits to consumers and producers may be incorrectly distributed.

...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 yet fully established scientifically... we don't need to wait until every single scientific question has been answered before we take action.

HEATHER LOGAN CANADIAN CANCER SOCIETY

Those who support a precautionary approach to the regulation of environmental agents emphasize that while at a specific point in time average individual risk from exposure to one or more carcinogens may be low, health problems due to these exposures may develop over time. When populations exposed to the same carcinogen(s) develop related health problems, the result may be both higher health care costs at the individual level and potentially significant public health issues and societal costs.

...OSHA has not moved fast enough to control exposure to known human carcinogens. Instead of the precautionary paradigm of decision-making in the face of uncertainty, we have a refusal to act in the face of certainty.

FRANK MIRER HUNTER COLLEGE

Participants at the Panel's meetings suggested that precautionary approaches may encourage innovation because once a chemical or other agent is identified as potentially hazardous, efforts to identify safer alternatives are likely to follow. This dynamic has recently been demonstrated. Consumers have become increasingly anxious about the estrogenic effects of an organic compound, bisphenol A (BPA) that is used to harden plastics (e.g., baby and water bottles) and line the inside of food and beverage cans, including infant formula cans. BPA, which is detectable at biologically active levels⁸⁸ in the urine of an estimated 93 percent of Americans,^{89,90} can leach into food when the plastic containers are heated in a microwave oven or washed in a dishwasher. Over the past decade, more

...we have companies that are formulating products in the United States that are different from those in Europe because there is no regulation [in the United States] requiring the more stringent standards.

> JEANNE RIZZO BREAST CANCER FUND

than 130 studies have linked BPA to breast cancer, obesity, and other disorders.⁹¹ In 2007, a group of 38 independent NIH-funded investigators concluded there was strong cause for concern that exposure could result in cancer and early puberty.⁸⁸ A 2008 study found that adults with higher urinary BPA levels had elevated rates of heart disease, diabetes, and liver abnormalities.⁹² Studies also suggest that BPA may interfere with cancer treatments.^{93,94}

Although the Food and Drug Administration (FDA) ruled in 2008 that BPA is safe even for infants (Letter from Stephen R. Mason, Acting Assistant Commissioner for Legislation, Food, and Drug Administration, to Rep. John D. Dingell, Chairman, House Committee on Energy and Commerce, 2008 Feb 25), Canada banned its use in baby bottles and infant formula cans the same year. More than 20 states (e.g., MN, CT, CA) and a number of municipalities in the U.S. (e.g., Chicago; Suffolk County, NY) are following suit with proposed or enacted BPA bans. In the face of consumer protests, many large retailers have pulled BPA-containing products from their shelves and manufacturers have moved rapidly to

replace BPA with other chemicals that can harden plastics. While this case shows that industry can and will respond to strong consumer concerns, it should be noted that the safety of the substitute chemical(s) is yet unknown. Due to public concern about BPA and scientific criticism of its 2008 ruling, FDA conducted another review of the scientific evidence regarding BPA health effects. In January 2010, the agency acknowledged that there is cause for concern about BPA's effects, but concluded that there was insufficient scientific evidence to support a product ban or even a requirement to label BPA-containing products.⁹⁵

In June 2007, the EC shifted to a markedly more precautionary approach to chemical regulation. The EC establishes health and safety policies that apply to the 27 EU member states. In addition to known carcinogens, the EC lists chemicals "of concern"—having a chemical on this list sends a signal to industry that a safer alternative should be sought. The Registration, Evaluation, Authorisation, and Restriction of Chemical Substances (REACH)⁹⁶ initiative is a major reform of the EC chemicals policy affecting all global supply chains that produce and use chemicals. REACH aims to improve protection of human health and the environment through better and earlier identification of intrinsic properties of chemical substances, while simultaneously encouraging the innovative capability and competitiveness of the EU chemicals industry. The initiative requires industry to take a greater role in managing risks from chemicals and to provide safety information on its products; these data will be registered in a central database available to consumers and professionals. REACH provisions are being phased in over an 11-year period.⁹⁷ U.S. chemical companies that wish to do business in EC member states must comply with REACH. The U.S. chemical industry has vigorously opposed suggestions that U.S. chemical management policy should use REACH as a model.

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