President's Cancer Panel
Evaluation Feasibility Study

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Executive Summary

The President's Cancer Panel is charged with identifying barriers to optimal development and implementation of all aspects of the National Cancer Program. The Panel does not have authority to mandate implementation of its recommendations; however, current Panel members have expressed an interest in conducting an evaluation with the goals of (1) identifying opportunities to improve activities of the Panel, (2) documenting progress relative to Panel recommendations, and (3) characterizing the Panel's role in National Cancer Program progress. To determine whether a large-scale evaluation of Panel activities and progress related to Panel recommendations would be possible and informative, an evaluation feasibility study has been conducted.

Evaluation Framework

Based on the evaluation goals listed above, it was decided that the Panel evaluation would include elements of three evaluation types: process, outcome, and attribution. Process evaluation was used to determine whether Panel reports and recommendations were disseminated to appropriate stakeholders. Outcome evaluation assessed awareness of and support for issues raised in select Panel recommendations and determined whether implementation of these recommendations has occurred. The Panel's role in promoting implementation was ascertained using attribution evaluation.

Feasibility Study of the Evaluation Framework

Three Panel recommendations were selected to pilot test the evaluation framework. An effort was made to select Panel recommendations that differed with respect to scope, specificity, and intended implementers in order to gain insight into the feasibility of evaluating various types of recommendations. Evaluation strategies based on the evaluation framework were tailored for each of the following three recommendations.

- Fertility preservation procedures and infertility treatment services should be covered by health insurance for cancer patients/survivors whose fertility will be or has been damaged by cancer treatment.
- Governmental and private research sponsors must place greater emphasis on and substantially increase funding for clinical and translational research. Funding mechanisms should promote collaborative science but should also include greater support through the R01 mechanism for more applied research.
- Coordinate U.S. agricultural subsidy and public health policy related to diet and nutrition to improve the food supply and help ensure that all people have access to affordable, healthy food. Specifically:
  - Structure farm supports to incentivize/encourage increased production of fruits and vegetables; limit farm subsidies that promote the production of high fructose corn syrup for use in food.
  - Support healthier food choices by restructuring regulations governing acceptable food choices allowed by Women, Infants, and Children, Headstart, and school lunch programs.

Evaluation feasibility study results indicate that it is feasible to conduct process evaluation of Panel activities and outcome evaluation of intermediate outcomes (i.e., implementation of Panel recommendations). Although it is also feasible to evaluate short-term outcomes such as changes in awareness of and support for an issue, this type of analysis is more resource-intensive and may not always be informative. While it is possible to draw direct links between the Panel and recommendation implementation activities in some instances, there are limitations to the practicality and utility of carrying out a large-scale attribution evaluation.

Recommendations for Future Evaluation Activities

Insights gained through the feasibility study were used to inform development of recommendations for future Panel evaluation activities. These include:

- **Conduct a process evaluation of Panel dissemination activities**. A more thorough process evaluation of this area would identify opportunities to improve and expand current Panel dissemination activities to better reach and influence intended implementers and key stakeholders.
- **Revamp the Matrix of Recommendations**. The current system for tracking progress related to Panel recommendations could be improved to facilitate more consistent and thorough monitoring of progress and inform future Panel activities and/or evaluations.
- **Evaluate intermediate outcomes of a subset of related recommendations**. Future evaluation of Panel recommendations should focus on a subset (or subsets) of related recommendations with the goal of informing future Panel activities. Based on an initial assessment of intermediate outcomes (i.e., recommendation implementation), a decision should be made about whether evaluation of short- or long-term outcomes would be informative. Efforts to attribute progress to Panel activities should be limited to collecting anecdotal examples of Panel influence.

Background and Purpose

The President's Cancer Panel (PCP, the Panel), a Federal Advisory Committee funded by the National Cancer Institute (NCI), is charged with identifying barriers to optimal development and implementation of all aspects of the National Cancer Program (NCP). Established in 1971 under the National Cancer Act, the Panel is composed of three persons appointed by the President, who, by virtue of their training, experience, and background, are exceptionally qualified to appraise the National Cancer Program. Members serve three years and can be reappointed. The Panel holds at least four meetings per year to monitor development and execution of NCP activities.

Evaluation Goals

The Panel does not have authority to mandate implementation of its recommendations; however, it has a keen interest in ensuring that critical recommendations are addressed by the NCP. To this end, current Panel members have expressed an interest in conducting an evaluation with the following goals:

- Identify opportunities to improve activities of the Panel.
- Document NCP progress relative to Panel recommendations.
- Characterize the Panel's role in NCP progress.

Feasibility Study Goals

To determine whether a large-scale evaluation of Panel activities and progress related to Panel recommendations would be possible and informative, NCI commissioned an evaluation feasibility study. Elements of the feasibility study include:

- Develop an evaluation framework
- Pilot test the evaluation framework (evaluation of select Panel recommendations and report dissemination)
- Recommend a plan for future evaluation activities.

Evaluation Framework

The first step of the feasibility study was development of an evaluation framework. Before beginning an evaluation, it is helpful to establish clear understanding regarding the program or activities being assessed. This facilitates discussion and decision-making regarding the focus and design of the evaluation, which leads to development of meaningful questions as well as corresponding metrics.

President's Cancer Panel Logic Model

Logic models, which are graphic depictions of relationships between a program's activities and its intended outcomes, can be useful for illustrating important features of a program and are helpful for planning and conduct of an evaluation.

The logic model in Figure 1 provides a summary of activities and intended outcomes of the President's Cancer Panel. The Panel continually monitors activities and progress of the NCP through literature review, attendance at national meetings, and general participation within the cancer community. Each year, the Panel identifies an area of importance, interest, and/or concern, giving weight to issues associated with barriers to optimal execution of the NCP.

The Panel invites experts and stakeholders in the field of interest to give testimony at a series of meetings. Information collected at the meetings is supplemented with additional research. Based on evidence gathered, the Panel develops recommendations for changes it believes would improve the NCP. These recommendations are included in an annual report to the President of the United States. The report is also disseminated to numerous stakeholders within the cancer community as well as others with potential to influence the NCP.

Panel reports and recommendations are designed to increase awareness of important issues and build support among key stakeholders, particularly those with the capacity to create or motivate change. The Panel hopes that increased awareness and support will lead to implementation of its recommendations and ultimately result in a diminished cancer burden.

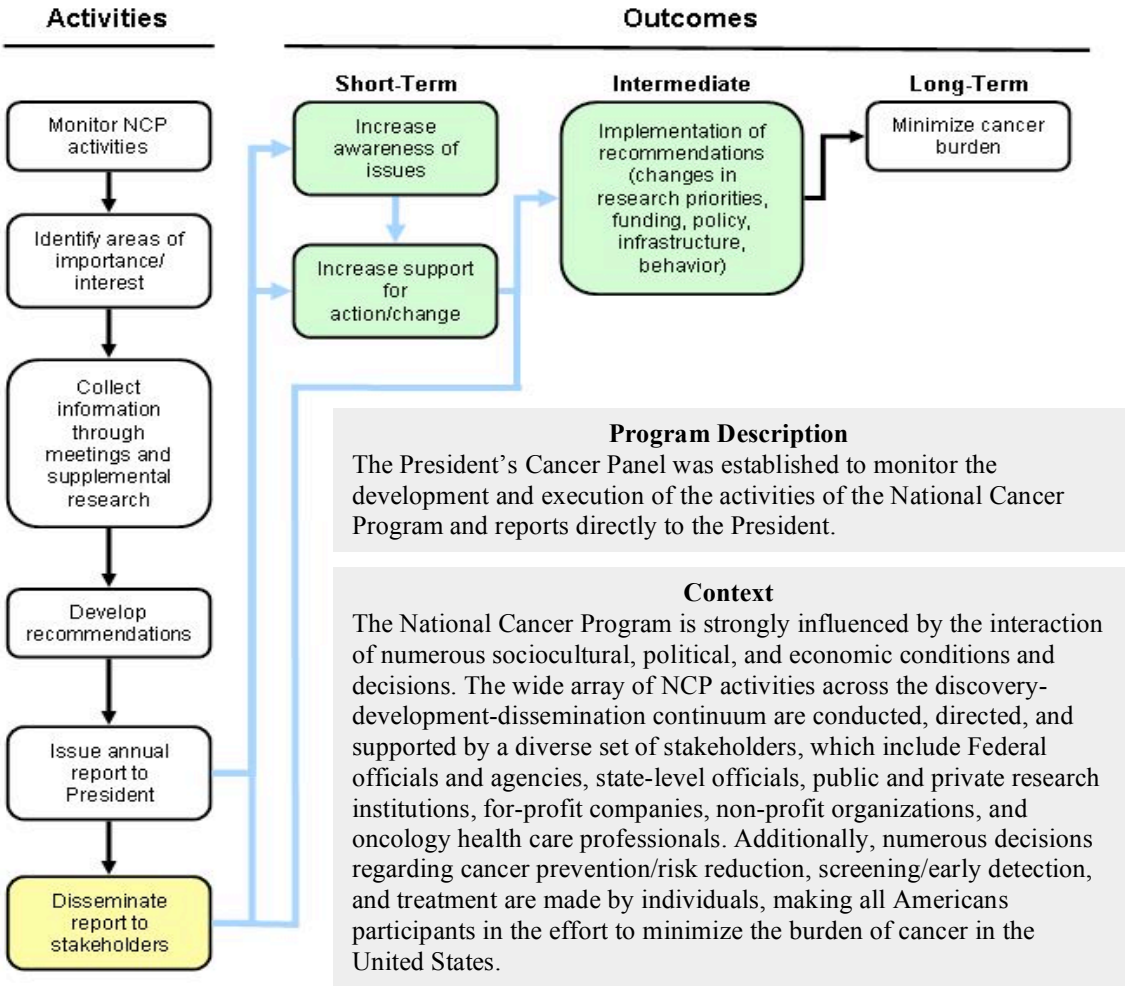
It is important to note that the Panel is an advisory body—it does not have authority to require implementation of its recommendations. Thus, implementation of Panel recommendations involves a "transfer of accountability," which refers to the fact that action is required by other persons or organizations. In the case of the Panel, accountability is transferred to numerous and varied stakeholders, whose decisions and activities are strongly influenced by a combination of scientific, sociocultural, political, economic, and personal factors.

Evaluation Focus and Design

The focus and design of an effective evaluation should be informed both by evaluation goals and characteristics of the program. The goals set forth for the Panel evaluation include identification of opportunities to improve activities of the Panel, documentation of NCP progress relative to Panel recommendations, and characterization of the Panel's role in NCP progress (see Background section and Table 1).

Based on these goals, it was decided that the Panel evaluation would include elements of three evaluation types: process, outcome, and attribution.[1] **Process evaluation** documents whether a program has been implemented as intended and identifies reasons why this is or is not the case.

Figure 1. President's Cancer Panel Logic Model



Outcome evaluation assesses progress related to desired outcomes of a program. **Attribution evaluation** demonstrates a link between program activities and desired outcomes.

A series of six core questions related to process, outcome, and attribution were developed to serve as the framework for the current evaluation feasibility study.

1. Have Panel reports/recommendations been disseminated to appropriate stakeholders (i.e., intended implementers, advocates)?
2. Has awareness of the issue of interest increased among relevant stakeholders?
3. Has support for the issue of interest increased among relevant stakeholders (concurrence with Panel recommendation)?
4. Has the recommendation of interest been fully or partially implemented (have there been changes in research priorities, funding, policy, infrastructure, behavior, etc., that are consistent with the recommendation)?

5. Are increases in awareness and/or concurrence partially or fully due to Panel activities?
6. Are relevant changes in research priorities, funding, policy, infrastructure, behavior, etc., partially or fully due to Panel activities?

The relationships of these questions to the evaluation goals and the Panel logic model are shown in Table 1. The questions address select Panel activities (report dissemination), intended short-term and intermediate outcomes of the Panel's recommendations, and the role of the Panel in driving change within the NCP.

Table 1. Evaluation Framework

Process Evaluation
Goal: Identify opportunities to improve the activities of the Panel.

Logic Model Element	Key Questions
Disseminate report to stakeholders	1. Have Panel reports/recommendations been disseminated to appropriate stakeholders (i.e., intended implementers, advocates)?

Outcome Evaluation
Goal: Document NCP progress relative to Panel recommendations.

Logic Model Element	Key Questions
Increase awareness of issue	2. Has awareness of the issue of interest increased among relevant stakeholders?
Increase support for action/change (concurrence)	3. Has support for the issue of interest increased among relevant stakeholders (concurrence with Panel recommendation)?
Implementation of recommendation	4. Has the recommendation of interest been fully or partially implemented (have there been changes in research priorities, funding, policy, infrastructure, behavior, etc. that are consistent with the recommendation)?

Attribution Evaluation
Goal: Characterize the Panel's role in NCP progress.

Logic Model Element	Key Questions
Arrows between Panel activities and short-term outcomes	5. Are increases in awareness and/or concurrence partially or fully due to Panel activities?
Arrows between Panel activities and intermediate outcome	6. Are relevant changes in research priorities, funding, policy, infrastructure, behavior, etc. partially or fully due to Panel activities?

The questions are intended as a framework for evaluation of individual Panel recommendations. Depending on a number of factors (e.g., time since recommendation was issued, stakeholders involved, type of action necessary for implementation), different core questions may be

emphasized in the evaluation of individual recommendations. An evaluation matrix based on the framework was created for each recommendation selected for the feasibility study and used to guide development of evaluation strategies and survey instruments (Appendix A).

Feasibility Study of the Evaluation Framework: Evaluation of Select Panel Recommendations

Selection of Recommendations

Three recommendations were selected for the evaluation feasibility study. An effort was made to select Panel recommendations that differed with respect to scope, specificity, and intended implementers in order to gain insight into the feasibility of further evaluating various types of recommendations. The recommendations and rationale for their selection are listed below.

Recommendation 1: Fertility preservation procedures and infertility treatment services should be covered by health insurance for cancer patients/survivors whose fertility will be or has been damaged by cancer treatment.

- Calls for specific measurable change
- Implementers include state legislators and insurance companies
- High potential for advocacy organization involvement in promoting implementation

Recommendation 2: Governmental and private research sponsors must place greater emphasis on and substantially increase funding for clinical and translational research. Funding mechanisms should promote collaborative science but should also include greater support through the R01 mechanism for more applied research.

- Calls for large, broad change
- Implementers include government research organizations (e.g., NCI)

Recommendation 3: Coordinate U.S. agricultural subsidy and public health policy related to diet and nutrition to improve the food supply and help ensure that all people have access to affordable, healthy food. Specifically:

Structure farm supports to incentivize/encourage increased production of fruits and vegetables; limit farm subsidies that promote the production of high fructose corn syrup for use in food.

Support healthier food choices by restructuring regulations governing acceptable food choices allowed by Women, Infants, and Children; Headstart; and school lunch programs.

- Calls for broad change
- Implementers include Federal legislators (i.e., Congress).

Feasibility Study Results

The following sections of the report summarize results of the evaluations of these three recommendations. Each section includes a brief description of the evaluation strategy for each recommendation as well as evaluation results and conclusions. More detailed information about methods used for the evaluations is provided in Appendix B. Data collected for the report dissemination analysis (process evaluation) portion of the feasibility study is contained in Appendix C. Appendix D lists practical lessons learned through conducting the feasibility study.

Recommendation 1

Fertility Preservation for Cancer Patients and Survivors

In 2003 and 2004, the Panel held a series of meetings to learn more about burdens and challenges faced by the millions of cancer survivors in the United States. In its 2003 report *Living Beyond Cancer: Finding a New Balance,* the Panel identified infertility and risk of infertility due to cancer treatment as a significant issue facing cancer survivors diagnosed as children, adolescents, and adults of childbearing age. Despite availability of several fertility preservation techniques for males and females, many patients (and/or their parents) were not made aware of the infertility risks associated with cancer treatment. Furthermore, those who did pursue fertility preservation usually found that procedure costs were not covered by health insurance, making them prohibitively expensive. In response to these findings, the Panel issued a number of recommendations regarding fertility, including the recommendation that:

> **Fertility preservation procedures and infertility treatment services should be covered by health insurance for cancer patients/survivors whose fertility will be or has been damaged by cancer treatment.**

This recommendation was revisited in the 2005-2006 report *Assessing Progress, Advancing Change*. The recommendation addresses both fertility preservation (actions to preserve fertility prior to initiation of cancer treatment that has potential to damage fertility) and infertility treatment (interventions to help achieve pregnancy, often after a certain amount of time trying to conceive unassisted). The evaluation of this recommendation focused on insurance coverage for fertility preservation services, since this issue is more specific to cancer patients.

Evaluation Strategy

Changes in insurance coverage for numerous services and procedures have occurred because of legislation; thus, identifying legislative activity relevant to this recommendation was a central part of this evaluation. Many changes in insurance coverage have resulted from state-level mandates[*] so a survey of state legislators was conducted. A representative from an advocacy organization whose mission and services are tightly aligned with this recommendation was also interviewed—the thought being that this organization would be knowledgeable about activities relevant to the recommendation as well as factors that have impeded its implementation.

For a more detailed description of the methods used for evaluation of this recommendation, see Appendix B.

[*] Diagnosis and treatment of infertility (not related to cancer) as well as breast reconstruction following cancer treatment are among those services for which insurance coverage is regulated/mandated on a state-by-state basis.

Evaluation Results

Federal Legislative Activity

A search of the Congressional legislative database THOMAS revealed no Federal legislation addressing cancer-related infertility or fertility preservation for cancer patients. Efforts to promote Federal policy in this area were undertaken by Fertile Hope in conjunction with a Washington DC-based lobbying firm with support from the Lance Armstrong Foundation. In 2005-2006, several meetings were held on Capitol Hill with the goal of increasing awareness of cancer-related fertility issues. As a result, a nonbinding resolution was introduced into both the House and Senate in 2005.[2,3] The resolution cites the President's Cancer Panel report and closely parallels recommendations made by the Panel. These resolutions were referred to committee in both the House and Senate, but were not further addressed by Congress. At that time, Fertile Hope was advised that the national political climate would not support substantial change related to cancer and infertility. It was suggested that the organization attempt to influence state-level policy; however, the state-by-state approach seemed overwhelming and the small advocacy organization decided not to pursue this strategy.[4]

State Legislative Activity

A custom search of the NCI State Cancer Legislative Database (SCLD) in August 2009 revealed no state legislation mandating coverage for the reproductive side effects of cancer treatment. However, Nebraska's Medical Assistance Program (NMAP) provides some coverage for infertility when it is a symptom of a medical problem, with "brain tumor" included as an example.[5] Also, at least one state, Illinois, which normally defines infertility as inability to conceive after one year of unprotected sexual intercourse, allows a waiver of this one-year requirement if a physician determines that the patient has experienced involuntary sterilization due to chemotherapy or radiation treatments.[6]

Legislation related to fertility preservation for cancer patients has been introduced in at least one state. A New Jersey legislator contacted Lindsay Nohr Beck, Founder and Executive Director of Fertile Hope, for help developing a bill that would extend the state's current law requiring health insurers to provide coverage for the diagnosis and treatment of infertility to include coverage for prevention of infertility (i.e., oocyte cryopreservation) in women undergoing cancer treatment that may damage their reproductive systems.[7,8] Unfortunately, the bill never gained traction in the New Jersey legislature.

None of the respondents to our survey identified any legislative (or nonlegislative) activities in their states that would increase or mandate insurance coverage for fertility preservation for cancer patients whose fertility may be damaged by their treatment.

Survey of State Legislators

A Web-based survey was developed and administered to selected state legislators to determine their awareness of the President's Cancer Panel, the Panel's recommendation related to insurance coverage for fertility preservation for cancer patients, and issues related to cancer and infertility; to learn about activities relevant to this recommendation and barriers to implementation; and to identify sources of information and influence for policymakers. A summary of survey responses is provided in this section. The survey questions and more detailed response data can be obtained from the office of the President's Cancer Panel.[9]

Response Rates and Respondent Information

Health/insurance-related committees were initially identified in nine states; two "replacement states" were later selected when early efforts to contact some states were unsuccessful (see Table 2). In total, successful contact was made with and survey links sent to six committees. Of the six successful contacts, four completed the survey. See Appendix B for additional details.

Table 2. Potential Survey Respondents

State	Legislative Branch	Committee	Chair Party Affiliation	Geographic Region
Georgia	House	Insurance	Republican	South
Illinois	House	Health care access and availability	Democrat	Midwest
Massachusetts	Senate	Joint Committee on Public Health	Democrat	Northeast
Mississippi	House	Insurance	Democrat	South
Nebraska (replaced Washington)	Senate	Health and Human Services	Nonpartisan	Midwest
New Jersey	Assembly	Health and Senior Services	Democrat	Northeast
Ohio	House	Healthcare Access and Affordability	Democrat	Midwest
Oklahoma (replaced Texas)	House	Public Health	Republican	South
Texas	Senate	Health and Human Services	Republican	South
Utah	House/Senate	Heath and Human Services (Joint)	Republican	West
Washington	House	Health Care and Wellness	Democrat	West

Reponses were received from four states: Georgia, Illinois, Massachusetts, and Ohio. Three respondents answered the majority of questions, but one respondent skipped a significant number of questions. The following summarizes information provided by respondents about themselves (one respondent did not provide this information):

- Senior committee staff, affiliated with committee l to 4 years
- Senior committee staff, affiliated with committee more than 10 years
- Committee chairperson, affiliated with committee 1 to 4 years

Awareness of the President's Cancer Panel and Recommendation

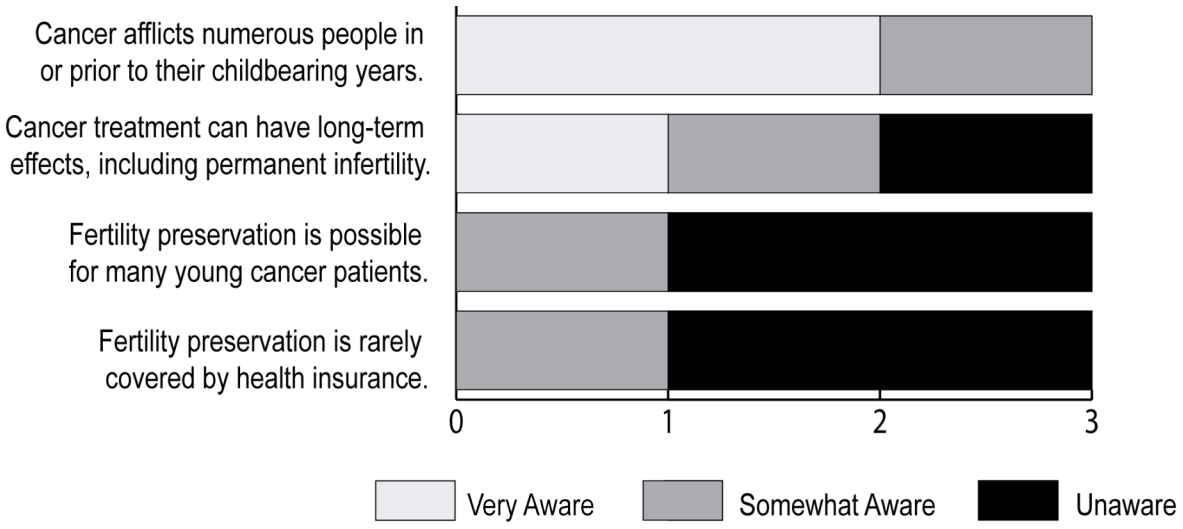
Of the four respondents, only one was familiar with the Panel prior to receiving the survey; this respondent reported hearing about the Panel from a colleague, constituent or advocate, advertisement/media, and emails from the NCI Office of Government and Congressional

Relations. None of the respondents reported being aware of the Panel's recommendation that fertility preservation services should be covered by insurance.

Awareness of Cancer Treatment-Related Infertility

The three respondents who answered the question regarding awareness of issues surrounding cancer treatment-related infertility reported being very aware or aware that cancer afflicts numerous people in or prior to their childbearing years. However, only two of three were at least somewhat aware that cancer treatment can have long-term effects, including permanent infertility. There was even less awareness that fertility preservation is an option for these patients and that these procedures are rarely covered by insurance (see Figure 2).

Figure 2. Awareness of Cancer and Infertility



Barriers to Implementation

All three respondents indicated that insurance companies, employers and other group insurance buyers, state governments, and the Federal government should play a role in ensuring that fertility preservation procedures are covered by health insurance for cancer patients whose fertility may be damaged by their disease or treatment (i.e., all respondents selected all options). The respondents were then asked to comment on the awareness and perceptions of each of these stakeholder groups regarding this issue and identify barriers to implementation of the Panel recommendation.

Insurance Companies

Taken as a whole, respondents felt that insurance companies are aware of the risk of infertility associated with cancer and that lack of awareness among insurers is not a barrier to implementation. The primary barriers identified were:

- Insurance companies do not believe fertility preservation is medically necessary.
- Insurance companies think it would be too expensive to provide coverage for fertility preservation for cancer patients.

Employers/Other Group Insurance Buyers

There was not concurrence among the respondents regarding whether employers and other group insurance buyers are aware of the risk of infertility associated with cancer and cancer treatment (although lack of awareness was identified as a barrier). The primary barriers identified were:

- Employers/other group insurance buyers are not willing to increase the cost of their policies to provide coverage for fertility preservation.
- Employers/other group insurance buyers are not aware of the risk of infertility associated with cancer and cancer treatment.
- Employers/other group insurance buyers do not consider fertility preservation for cancer patients to be a high priority relative to other healthcare needs.

Public Officials

Two respondents indicated that public officials are not aware of the risk of infertility associated with cancer and cancer treatment. Primary barriers identified included:

- Public officials are not aware of the risk of infertility associated with cancer and cancer treatment.
- Public officials do not think fertility preservation for cancer patients is important because they do not think it is medically necessary.
- Public officials do not think the effectiveness of fertility preservation has been adequately demonstrated.
- Public officials think it would be too expensive to provide coverage through public health insurance programs.
- Public officials do not think public health insurance programs should provide coverage for fertility preservation because they believe it is medically unnecessary.
- Public officials do not think public health insurance programs should provide coverage for fertility preservation because they do not consider it a high priority relative to other healthcare concerns.
- Public officials do not want to mandate private health insurance providers to provide coverage for fertility preservation for cancer patients.

In summary, respondents felt that insurance companies, employers and other group insurance buyers, state governments, and the Federal government should be involved in ensuring fertility preservation services are covered by health insurance. Although barriers identified for each of these stakeholders varied somewhat, perception of cost was cited as a barrier for each group.

It is important to note that barriers identified represent opinions and perceptions of respondents and thus may not be indicative of views of insurance companies, employers/buyers, or even other public officials (e.g., although respondents believed that insurance companies are aware of the risk of infertility associated with cancer, this survey does not provide any information about whether or not this is in fact the case). Another caveat to this analysis (and testament to the limitations of small sample size) is that, of the three respondents, one identified all the options as barriers, one responded “not sure” to all of the options, and only one selectively identified barriers; thus, the overall trend in barriers identified was driven by a single respondent.

Interestingly, this respondent identified him/herself as a committee chairperson, suggesting that more thoughtful responses might be obtained from elected officials than from their staff.

Influences on Policy

Respondents were asked to identify people/organizations to which they turn for information relevant to cancer-related health policy and to rate the influence of these parties. Constituents, advocacy organizations, health professional organizations, insurance companies, and employers were cited as frequently used sources of information and were all rated as very or somewhat influential regarding cancer-related health policy decisions. Neither the Panel nor the Institute of Medicine (IOM) was cited as an important information source. Although IOM was rated as somewhat influential, the Panel was largely judged not at all influential.

Non-Legislative Activities

Working With Employers and Insurance Companies

Employers and insurance companies are also potential implementers of this recommendation. Although data were not collected directly from these groups as part of this feasibility study, some relevant information about efforts to engage these stakeholders was obtained through the interview with Fertile Hope.

Following meetings with Fertile Hope representatives, one large, self-insured investment bank agreed to change the language of its health insurance policy to provide coverage for fertility preservation for cancer patients. This company has since declared bankruptcy and been liquidated. Fertile Hope met with a few other large employers about their insurance policies, but although they seemed receptive to the idea, none made changes to their policies.

Fertile Hope developed a plan to interact with insurance companies as part of its involvement in the Oncofertility Consortium Community Advisory and Action Board (CAAB), which was created to advocate on behalf of patients and potential patients of the Consortium (more on the Oncofertility Consortium below). CAAB solicited the help of an economist at Northwestern University's Kellogg School of Management, who advised the Board that it would be more effective to work directly with insurance companies rather than work through state legislatures to secure coverage for fertility preservation. The economist was asked to estimate the costs that would be incurred by insurance companies if coverage was provided for fertility preservation services, but, unfortunately, the cost estimate has not been completed. To date, neither CAAB nor Fertile Hope has worked directly with insurance companies regarding coverage of fertility preservation.

Educating Health Care Professionals

Efforts are under way to increase awareness of cancer-associated infertility among health care professionals, particularly oncologists. American Society of Clinical Oncology (ASCO) recommendations on fertility preservation in cancer patients were published in 2006 (this paper

was in preparation during the *Assessing Progress* series).[10,*] These guidelines are available on the ASCO Web site along with related tools for use by oncologists and a link to informational resources regarding fertility preservation designed for patients.[11] Cancer-associated infertility and fertility preservation have also been the focus of several educational sessions and abstracts presented at recent ASCO meetings.[12,13,14,15,†] These efforts should raise awareness of this issue, at least among oncologists.

Barriers to Implementation

In addition to information about barriers to implementation of this recommendation gathered through the legislative survey, insight was gained through the interview with Fertile Hope. One challenge cited by the advocacy organization is that it is exceedingly difficult to calculate a cancer patient's risk of infertility. In addition to making it difficult for patients to decide whether to pay out-of-pocket for fertility preservation, this information void may deter insurance companies and policymakers from addressing this issue.

Research on cancer-associated infertility is needed to help address this barrier. Investment in this area seems to have increased in recent years. In 2007, as part of the Roadmap for Medical Research, the National Institutes of Health (NIH) provided $21.1 million for establishment of the Oncofertility Consortium, a multi-institutional, interdisciplinary effort focused on numerous aspects of cancer-associated infertility and fertility preservation.[16] The body of knowledge gained through the Consortium and other related research efforts may help provide insurance companies, employers/buyers, and legislators the information they need to develop policies that increase coverage for fertility preservation for cancer patients.

Conclusions for Recommendation 1

Process Evaluation

Has this recommendation and/or the reports in which it was issued been disseminated to appropriate stakeholders?

Partially—potential implementers of this recommendation include Federal legislators, state legislators, insurance companies, employers or other group insurance providers, and advocacy organizations (indirect implementers).

Analysis of dissemination records revealed that Federal legislators and multiple highly relevant advocacy organizations received *Living Beyond Cancer* and *Assessing Progress, Advancing Change*. In addition, both reports were sent to the Centers for Medicare and Medicaid Services. American Health Insurance Plans and State Farm Insurance Company received a copy of

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[*] This publication cites the President's Cancer Panel and reinforces Panel recommendations issued in *Living Beyond Cancer: Finding a New Balance* stating that all people of reproductive age who are diagnosed with cancer and parents of children diagnosed with cancer should be given information about the possible effects of treatment on fertility and options for fertility preservation before cancer therapy is selected or initiated.

[†] Two of the educational sessions presented at ASCO meetings were presented by Dr. Kutluk Oktay, who personally committed to doing so at a Panel meeting during the *Assessing Progress, Advancing Change* series.

Assessing Progress. However, reports were not sent to state legislators or to employers. It is recognized that it would not be feasible (or efficient) to disseminate Panel reports to all employers, but one idea that surfaced during the feasibility study was to target companies that have obtained CEO Cancer Gold Standard™ accreditation.

For a more detailed list of stakeholders relevant to this recommendation who received reports, see Appendix C.

Outcome Evaluation

Has there been increased awareness of or concurrence with this recommendation?

The opinion of the Fertile Hope representative interviewed was consistent with the limited data collected through the survey—awareness of cancer-associated infertility is relatively low among lawmakers and even among many in the fields of medicine and oncology. The limited traction gained by the resolutions/bills introduced at the Federal and state levels supports the view that legislators are largely unaware of this issue, although it is somewhat encouraging that there was enough interest in and support for the issue to at least get them introduced. Recent ASCO publications and activities suggest that awareness of this issue may be increasing among oncologists. It should be noted that this study did not measure changes in awareness and concurrence as baseline data were not available.

Has the recommendation been implemented?

No. Insurance coverage for fertility preservation for cancer patients whose fertility may be damaged by cancer treatment is not routinely provided. One large employer changed its policy to provide coverage for fertility preservation, but this firm has since filed for bankruptcy and been liquidated, so, to our knowledge, coverage for fertility preservation is not an explicit component of any group insurance policy plan.

Attribution Evaluation

Has the Panel played a role in changing awareness/concurrence or promoting implementation of this recommendation?

Yes. Although progress has been limited, the Panel's name and recommendations have been cited by ASCO and in the Congressional resolutions introduced in 2005. In addition, Fertile Hope reported frequently citing the Panel's recommendations regarding fertility. They feel it is important to tell people about the Panel's findings and emphasize that the Panel's recommendations were based on testimony from patients and survivors; this helps them communicate with doctors who may not think infertility is an important concern for their patients. The Panel recommendations may carry more weight than recommendations of other groups (e.g., reproductive specialists) because the Panel does not have a financial or professional stake in this issue. Fertile Hope also cites the Panel during presentations to the oncology community, in grant applications, and on the application for the Fertility Hope Centers of Excellence Program.

Interestingly, the feasibility study survey results suggest that awareness of the Panel is low among state legislators and that the Panel is not considered an important information source for or influencer of cancer-related health policy on the state level. It may be possible for the Panel to

increase its visibility among state-level public officials by expanding its dissemination activities or other outreach efforts. Another option would be to work with organizations with similar interests to the Panel that are already considered influential at the state level (i.e., advocacy organizations, health professional organizations).

Recommendation 2

Funding for and Emphasis on Clinical and Translational Research

In 2004 and early 2005, the Panel held a series of meetings to learn more about why many basic science discoveries with apparent promise for improving outcomes of people with and at risk for cancer have yet to be developed into preventive, early detection, diagnostic, therapeutic, or supportive interventions. The resulting report, *Translating Research Into Cancer Care: Delivering on the Promise*,[17] describes numerous barriers to translation related to the culture, focus, and infrastructure of the research and healthcare delivery enterprises and offers recommendations for overcoming these barriers. A subset of these recommendations was revisited in meetings in October 2005 as part of the *Assessing Progress, Advancing Change* series.[18] One of these recommendations states:

> **Governmental and private research sponsors must place greater emphasis on and substantially increase funding for clinical and translational research. Funding mechanisms should promote collaborative science but should also include greater support through the R01 mechanism for more applied research.**[*]

For this feasibility study, evaluation of this recommendation focused on changes in emphasis on and funding for clinical and translational research by the National Cancer Institute.

Evaluation Strategy

The current evaluation focused on NCI because it is the largest source of funding for cancer research in the United States and, as a Federal agency, should be responsive to the needs of Americans. Publicly available information and personal interviews with two NCI representatives were used to assess changes in funding for and identify programmatic and/or organizational changes relative to clinical and translational research. Organizational and/or programmatic changes designed to increase efficiency or effectiveness of clinical and translational research were considered an increase in emphasis for the purposes of this evaluation.

For a more detailed description of the methods used for evaluation of this recommendation, see Appendix B.

Evaluation Results

NCI Clinical Trials and Translational Research Working Groups

NCI established two working groups relevant to this recommendation at around the time the Panel was conducting the *Translating Research* series. The Clinical Trials Working Group (CTWG) was established in January 2004 to advise the National Cancer Advisory Board (NCAB) on development, conduct, infrastructure, support, and coordination of NCI-supported

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[*] This recommendation was in a slightly altered form in the 2004-2005 report, *Translating Research Into Cancer Care: Delivering on the Promise*: Governmental and private research sponsors must place greater emphasis on and substantially increase funding for clinical research and human tissue research. Funding mechanisms should promote collaborative science and include greater support through the R01 mechanism.

clinical trials. The CTWG report, which was accepted by NCAB in June 2005, presented the Group's plan for restructuring the national cancer clinical trials enterprise.[19]

In the same month that the Panel's *Translating Research* report was released, the Translational Research Working Group (TRWG) was established to advise NCAB on the future course of NCI-supported translational research. The TRWG identified the *Translating Research* report as one of its foundational documents and modified the Panel's Translational Continuum to illustrate the scope of its efforts (TRWG report, Figure 1).[20] NCAB accepted the TRWG report in June 2007.

Several CTWG and TRWG initiatives parallel recommendations made by the Panel in the *Translating Research* report (see Appendix E), including the recommendation being addressed in this evaluation.

In response to recommendations of the CTWG and TRWG, NCI established a new organizational structure to advance its clinical and translational research enterprises. The Coordinating Center for Clinical Trials (CCCT) was created within the NCI Office of the Director to guide implementation of the CTWG and TRWG recommendations with the overarching goal of strengthening NCI-supported clinical trials and translational research. As part of its mission, CCCT manages two advisory bodies established to oversee clinical and translational science—the Clinical Trials and Translational Research Advisory Committee (CTAC) is an external committee that advises the NCI Director regarding NCI-supported clinical trials and translational research, and the Clinical and Translational Research Operations Committee (CTROC) is an internal NCI advisory committee responsible for review of ongoing and prioritization of proposed NCI-supported clinical trials, correlative science programs, and translational research. CTROC members include Directors of all NCI Divisions, Offices, and Centers that have clinical trials or translational science portfolios.

NCI Funding for Clinical Trials and Clinical Research

NCI's annual investments in clinical trials and clinical research for fiscal years 2000 through 2008 (most recent year for which complete data are available) are shown in Table 3. In 2008, NCI spent $854.4 million on clinical trials[21] and $1.6 billion on clinical research.[22] These figures include investments in both intramural and extramural research and reflect total annual funding (i.e., dollars spent on new grants and/or competitive renewals are not distinguished from those used to fund noncompeting renewals). In absolute dollars, this represents a 9.3 percent increase in clinical trials funding and a 5.6 percent decrease in clinical research funding since 2005, the year *Translating Research* was released. Funding for each of these categories failed to keep pace with the Biomedical Research and Development Price Index (BRDPI),[*] which increased by 13.4 percent between 2005 and 2008.[23]

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[*] The BRDPI measures changes in the weighted average of the prices of all inputs (e.g., personnel services, supplies, equipment) purchased with the NIH budget to support research. Theoretically, the annual change in the BRDPI indicates how much NIH expenditures would need to increase (without regard to efficiency gains or changes in government priorities) to compensate for the average increase in prices due to inflation in order to maintain NIH-funded research activity at the previous year's level.

Table 3. NCI Funding for Clinical Research and Clinical Trials (in millions of dollars)

Fiscal Year	Clinical Trials	Clinical Research	Total NCI Budget	BDRPI
2000	614	941	3311.1	3.7
2001	648.6	1045	3753.7	3.3
2002	702.1	1283	4176.7	3.3
2003	799.5	1541	4592.3	3.5
2004	800	1672	4723.9	3.7
2005	781.8	1713	4794.7	3.9
2006	822.3	1742	4747.2	4.6
2007	843.7	1770	4792.6	3.8
2008	854.4	1617	4827.6	4.4

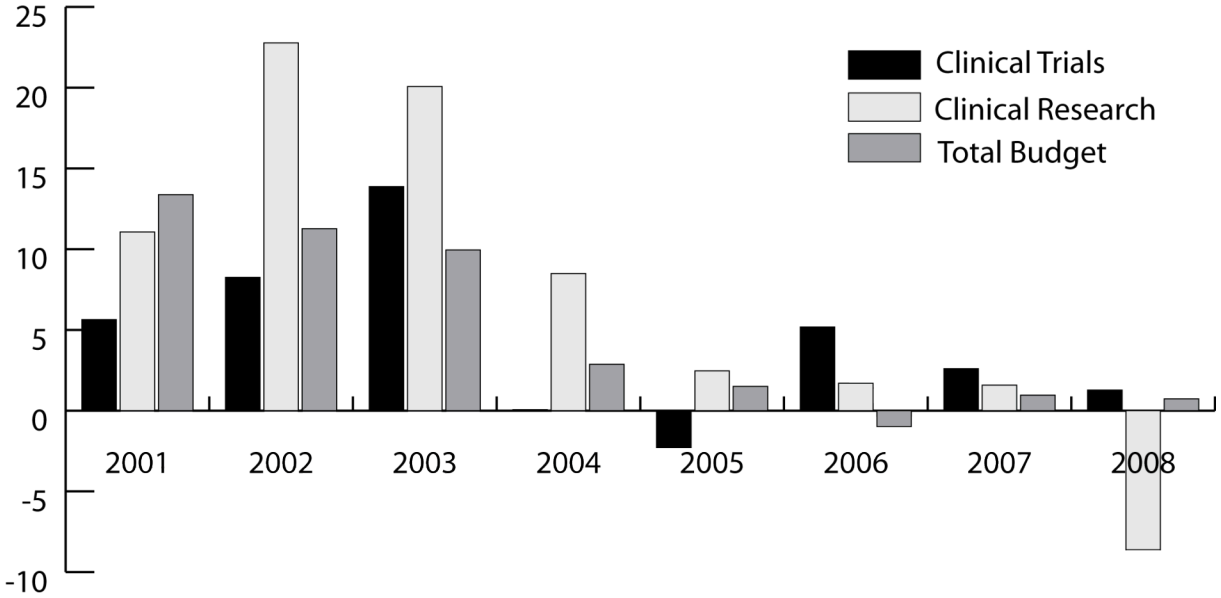
While it is informative to see how spending on clinical research has changed relative to so-called biomedical inflation, this is largely dictated by overall trends in biomedical research funding, which are driven by the President and Congress, not NCI. Insights into NCI's priorities can be gained by comparing changes in funding for clinical trials and clinical research to changes in the overall NCI budget. Figures 3A and 3B show annual changes between 2001 and 2008 in funding for clinical trials and clinical research as well as in the overall NCI budget (actual changes and BRPDI adjusted). A few salient observations are listed here:

- Robust increases in funding in all areas in 2001 through 2003 reflect increases in biomedical research funding during the final years of the doubling of the NIH budget.
- In 2005, the year *Translating Research* was released, the total NCI budget and NCI funding for clinical research increased slightly, but NCI funding for clinical trials decreased and none of these changes matched the increase in BRPDI.
- In both 2006 and 2007, changes in NCI investments in clinical research and clinical trials increased at a greater rate than the NCI budget (i.e., between 2005 and 2007, the proportion of the NCI budget devoted to clinical trials increased from 16.3 to 17.6 percent and the proportion devoted to clinical research increased from 35.7 to 36.9 percent). Thus, although NCI's overall purchasing power and the purchasing power of dollars devoted to clinical trials/research declined over 2006 and 2007, NCI increased its emphasis on clinical research and clinical trials over this time period, at least financially.
- Of note, funding for clinical research dropped precipitously in 2008 in both absolute dollars and relative to the total NCI budget. The reason for the dramatic change is unknown. Because of this, in 2008, the percentage of the NCI budget devoted to clinical research fell to 33.5 percent while the percentage spent on clinical trials continued to rise to 17.7 percent.

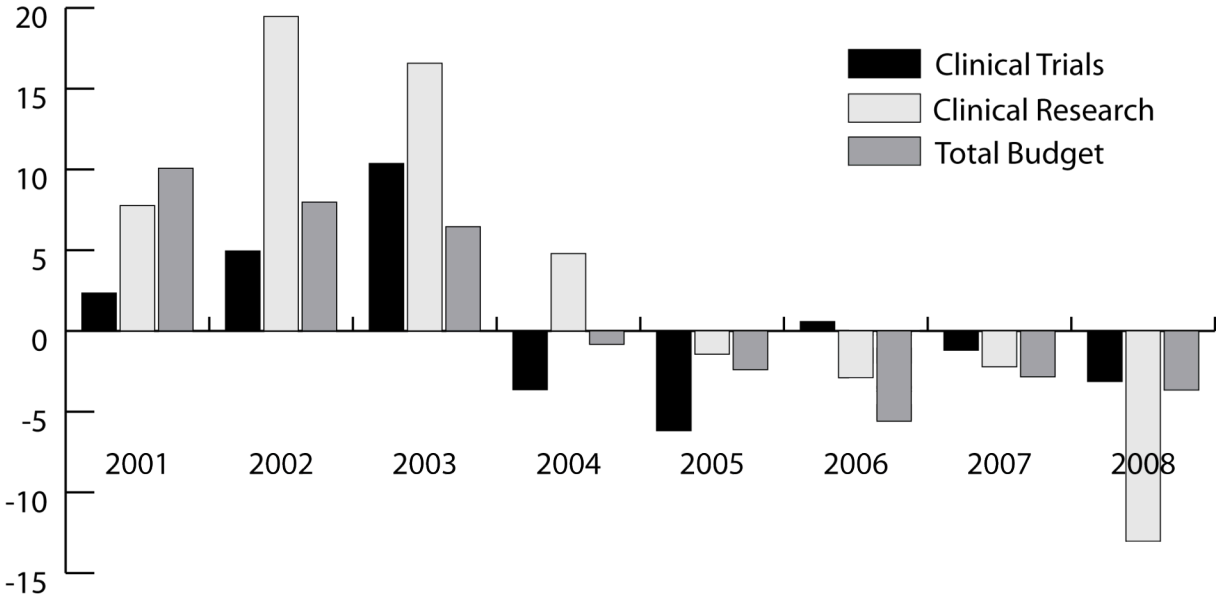
In summary, since 2005, funding for clinical trials has increased in absolute terms and as a percentage of the NCI budget. On the other hand, funding for clinical research has declined overall, despite two years of increasing investment; it remains to be seen whether this single-year decline is an anomaly that will be reversed in future years or whether this trend will continue.

Figure 3. Annual Changes in NCI Funding for Clinical and Translational Research

3A. Actual Annual Changes in Funding



3B. BRPDI-Adjusted Annual Changes in Funding



NCI Funding for Translational Research

Tracking NCI funding for translational research is more challenging. Translational research is not captured in any of the codes applied to grants (i.e., Special Interest Category or NIH Clinical Aspect [NIHCA] codes). Despite this obstacle, the TRWG wanted to quantify NCI's investment in translational research in order to inform its work. Because it was impossible to conduct an automated portfolio analysis, an *ad hoc* approach involving review of individual project abstracts was carried out to identify those with a translational component. In FY2004, a total of $1.3 billion in awards was found to fit the criteria defined for translational research (relative to a total NCI research budget of $4.4 billion), although validity tests indicated that this estimate may be high by as much as 20-40 percent.[20]

Ideally, evaluation of this Panel recommendation would involve analysis of changes in NCI's investment in translational research by conducting a portfolio analysis of fiscal years subsequent to release of this recommendation. However, a portfolio analysis of translational research was not conducted as part of this feasibility study for two primary reasons: (1) repeating the TRWG approach would be tremendously time-consuming and resource-intensive and (2) the large margin of error would make it difficult to obtain meaningful results.

Recognizing that the labor-intensive nature of the portfolio analysis was not conducive to monitoring and managing future NCI investments in translational research, the TRWG recommended that NCI "develop a set of award codes that accurately captures the nature and scope of the early translational research portfolio to enable a complete, shared understanding of NCI total investment, help identify gaps and opportunities, and demonstrate the extent of translational activity to the public."[20]

In accordance with this recommendation, CCCT has been working closely with NCI coding experts to develop a new coding system capable of capturing the extent and breadth of NCI's support for translational research. It was quickly recognized that this type of coding could not be accomplished using standard coding terms. Instead, a system comprising a series of questions is being created. The questions will determine whether a grant is translational, and, if so, identify the pathway to clinical goal* (and pathway domain) addressed by the project. An initial pilot test of 20 grants has been conducted and the system is being modified based on the results of this test. It is hoped that the system will be ready for large-scale testing by January 2010.[24] It is hoped that the ability to more robustly analyze its translational research portfolio will allow NCI to better define and monitor its overall investment in translational research as well as identify gaps in funding or focus that need to be addressed.

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* The TRWG developed a series of pathways to clinical goals, which are process diagrams that outline the steps required to advance a basic science discovery through early-phase clinical trials.* A generic pathway illustrates the activities common to most types of translational research while more detail about the steps involved in different types of translational research are depicted in six additional pathways.

NCI Emphasis on Clinical Research

As part of its efforts to implement the CTWG recommendations, NCI is undertaking a number of activities related to clinical trials and clinical research. Although not a comprehensive summary, a few of these efforts are described below, with a focus on issues that have been previously addressed by the Panel.

Promoting Team Science in Clinical Research

NCI is undertaking multiple activities to promote team science in clinical research. NCI has collaborated with ASCO to create a Cancer Clinical Investigator Team Leadership Award.[25] The first 11 recipients of this award have very recently been selected. Efforts are also under way to revise NCI program guidelines to foster collaboration among all components of the NCI clinical trials structure (e.g., Cancer Centers, SPORES, Cooperative Groups).[26]

Improving Clinical Trials

As part of its restructuring effort, NCI has created several Scientific Steering Committees (SSCs) to help guide clinical trial design and prioritization.[27] The SSCs are composed of outside cancer experts and NCI senior investigators and overseen by CTAC. A Patient Advocate Steering Committee has also been formed. This committee comprises patient advocate members of disease-specific SSCs and works to ensure that advocates are effectively and consistently integrated with the development, implementation, and monitoring of clinical trials within those groups.[27, *] Although advocates were previously involved with individual Cooperative Groups and SPOREs, this committee represents the first coordinated effort to get advocates involved in clinical trial design and prioritization across NCI.[28]

NCI has partnered with the CEO Roundtable on Cancer to develop the Standard Terms of Agreement for Research Trials (START) clauses to help decrease the time spent on contract negotiations between pharmaceutical/biotech companies and medical centers.[†,29] The START clauses are already publicly available through the NCI Web site,[30] although NCI is still in the early stages of promoting them to the research community. To date, many academic institutions have been reluctant to use them and some have even expressed displeasure that the clauses essentially "tell" pharmaceutical companies how contract negotiations tend to be settled. Changing the culture of academic legal staff will likely require pressure from academic deans (cancer center directors generally do not have enough authority over the legal staff).[28] NCI is considering development of similar clauses to facilitate Material Transfer Agreements (MTAs), which should benefit translational as well as clinical research.[28]

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[*] The formation of this committee is consistent with *Translating Research* recommendation 17: "Clinical and prevention research funders should require community participation early in protocol design and in research implementation."

[†] This advance directly relates to the Panel's *Translating Research* recommendation 12: "A task force of private, nonprofit, academic, and government stakeholders affected by current barriers to research translation due to intellectual property and patent issues should be convened to develop and reach consensus on: (1) standard language for patent exemptions for research purposes, (2) standard clauses for contracts governing collaborative research, and (3) other agreements as needed to resolve intellectual property and data-sharing issues."

Tracking and Monitoring Clinical Trials

NCI is in the process of launching a new central database—the Clinical Trials Reporting Program (CTRP)—to establish standard reporting of cancer clinical trial data. The new database was deemed necessary because existing/previous databases (e.g., NCI Physician Data Query [PDQ]) do not include all NCI-funded trials, lack information on outcomes, and are based on out-of-date information system designs.[19] To date, investigators have not been required to submit electronic reports on clinical trial progress and outcomes; thus, at the current time, there is no way for the NCI Director or anyone else to conduct comprehensive queries of the NCI clinical trials portfolio. It is hoped that the CTRP will help coordinate research efforts and avoid duplication of efforts as well as eventually facilitate prioritization of the most promising trials. Trials will be added to CTRP beginning in late 2009 and the database will eventually include all NCI-funded intervention trials that were opened to accrual on or after January 1, 2009. Observational, ancillary, and correlative studies will be added beginning in 2010.[28,31,32]

NCI Emphasis on Translational Research

Similar to the PCP, the TRWG recognized that NCI-supported translational research was not keeping pace with opportunities presented by advances in knowledge and technology. In fact, Dr. Lynn Matrisian characterized the work of the TRWG as an extension of the Panel report.[24] The TRWG proposed a series of initiatives to address this problem, and Dr. Matrisian, Chair of the Vanderbilt School of Medicine Department of Cancer Biology, was brought to NCI through a part-time Intergovernmental Personnel Act agreement to serve as Special Assistant to the NCI Director and oversee implementation of the TRWG reports.

To date, efforts to implement TRWG recommendations have focused on revising the NCI coding system (described above) and identifying ways to prioritize and accelerate translational research. With regard to the latter, NCI has developed the Process to Accelerate Translational Science (PATS), which will identify a small number of projects that are particularly "ripe" for translation and provide the necessary resource to expedite those projects to the point of early-stage clinical trials or productive failure (i.e., decision that the concept does not warrant additional investment and followup). This process is currently being pilot tested for research on use of immune response modifiers as treatments for cancer. [33] It is envisioned that the STRAPs (Special Translational Research Acceleration Projects) funded as a result of the prioritization process will be supported through a variety of existing NCI funding mechanisms, drawing from currently funded efforts with additional awards and supplements provided as necessary. It is hoped that first STRAPs for the Immune Response Modifier Pathway will be funded in FY2010.[24,34]

Conclusions for Recommendation 2

Process Evaluation

Has this recommendation and/or the reports in which it was issued been disseminated to appropriate stakeholders?

Yes. The *Translating Research* and *Assessing Progress* reports were distributed to many key stakeholders with potential to directly or indirectly increase funding for or emphasis on clinical and translational research. These include key leadership within NCI, including the Director; Division Directors; members of the NCAB, Board of Scientific Counselors, and Board of Scientific Advisors; NCI-designated cancer center Directors; and Specialized Program of

Research Excellence (SPORE) Directors. The report was also sent to other research sponsors, including the Department of Defense Congressionally Directed Medical Research Program, American Cancer Society, and Howard Hughes Medical Institute, as well as numerous academic research institutions. For a more detailed list of stakeholders relevant to this recommendation who received reports, see Appendix C.

Outcome Evaluation

Has there been increased awareness of or concurrence with this recommendation?

Yes. Those interviewed felt that overall awareness and agreement with the importance of clinical and translational research have increased over the past 5 to 10 years; however, this support is not universal—it was noted in one of the interviews that many basic/discovery research scientists are unenthusiastic about efforts to increase funding for or emphasis on clinical and translational research.

Has the recommendation been implemented?

Partially—NCI has increased its funding of clinical trials (in both absolute dollars and as a percentage of its overall budget), but funding for clinical research actually declined in 2008. Changes in NCI funding for translational research could not be accurately determined, although current efforts to update the NCI coding system should enable this type of analysis in the future.

In addition, NCI has initiated numerous activities designed to increase the efficiency of clinical trials and translational research. It is too early to ascertain whether this will lead to improvements in cancer treatment and prevention, but future evaluation of these efforts over the next five years should provide some insight.

Attribution Evaluation

Has the Panel played a role in changing awareness/concurrence or promoting implementation of this recommendation?

NCI leadership and the leadership of the TRWG were undoubtedly aware of the Panel's *Translating Research* report, although it is difficult to determine whether activities relative to clinical and translational research were influenced by this particular recommendation. As is the case with many broad recommendations, implementation actions are often the result of the collective influence of multiple voices and it can be difficult to tease out contributions of an individual organization/body.

Recommendation 3

Healthier Food Choices

In 2006 and 2007, the Panel examined how lifestyle affects cancer risk and recommended concrete actions that governments, communities, and individuals can take to reduce that risk. The third recommendation evaluated as part of this feasibility study was issued in the resulting report, *Promoting Healthy Lifestyles: Policy, Program, and Personal Recommendations for Reducing Cancer Risk*.

> **Coordinate U.S. agricultural subsidy and public health policy related to diet and nutrition to improve the food supply and help ensure that all people have access to affordable, healthy food. Specifically:**
>
> - **Structure farm supports to incentivize/encourage increased production of fruits and vegetables; limit farm subsidies that promote the production of high fructose corn syrup for use in food.**
> - **Support healthier food choices by restructuring regulations governing acceptable food choices allowed by Women, Infants, and Children; Headstart; and school lunch programs.**

Evaluation Strategy

For this feasibility study, evaluation of progress related to this recommendation focused on changes in Federal legislation. Specifically, the evaluation looked at how the most recent U.S. farm bill, the Food, Conservation, and Energy Act of 2008 (P.L. 110-246, "2008 farm bill") differs from past Federal legislation, particularly the 2002 farm bill (Farm Security and Rural Investment Act of 2002, P.L. 107-171).

For a more detailed description of the methods used for evaluation of this recommendation, see Appendix B.

Evaluation Results

The U.S. farm bill governs the majority of Federal agriculture and food policies and other related programs. This comprehensive omnibus bill is passed approximately every five years by the U.S. Congress. The 2008 farm bill is composed of 15 Titles that discuss topics from rural development to agricultural subsidies to waste water management. The total cost of the 2008 farm bill is estimated by the Congressional Budget Office to be $284 billion over FY 2008-2012 and $604 billion over FY 2008-2017. These costs represent mandatory outlays that do not require appropriations actions; costs of discretionary programs authorized in the farm bill are not included. Of this total, 67% ($189 billion) supports domestic nutrition programs and 9% ($22 billion) supports crop insurance.[35] This section of the report lists some of the changes in the 2008 farm bill that relate to the Panel recommendation.

Title I: Commodity Programs

The commodity price and income support provisions of the farm bill include direct payments unrelated to production or prices; counter-cyclical payments triggered when prices or revenue fall under established levels; and marketing assistance loans that offer interim financing and

potentially additional income support. Eligible commodities include wheat, corn, grain sorghum, barley, oats, upland cotton, rice, pulse crops (dry peas, lentils, chickpeas), soybeans and other oilseeds, and peanuts.

- The **Treatment of Farms with Limited Base Acres** provision eliminates direct and counter-cyclical subsidies to farms with fewer than 10 base acres of all crops, except for farms owned by socially disadvantaged or limited-resource farmers and ranchers. This change was meant to prevent nonfarmers from receiving government support for their agricultural activity. It does not directly relate to fruits and vegetables, as these products are not eligible for subsidy; however, there is speculation that if these small farms become ineligible for subsidies, they may increase their production of fruits and vegetables (i.e., incentive to grow non-fruit/vegetable crops is removed). On the other hand, existing fruit and vegetable growers are wary of more acres competing with their specialty crops. This provision requires that the USDA Secretary evaluate the effects of eliminating subsidies to farms with limited base acres on fruit and vegetable production.[36]
- Restrictions in the **Planting Flexibility and Restriction for Program Participants** provision, which are similar to those in past legislation, prevent farmers from growing fruits and vegetables on acres designated for federally subsidized crops, even for a limited time, without giving up the subsidy they receive. Many view this restriction as negative because it provides a disincentive for overall fruit/vegetable planting and also hinders some farmers from engaging in sustainable farming practices involving crop rotations. However, produce farmers are worried that elimination of this restriction would result in competition from growers of subsidized crops. The 2008 farm bill creates a pilot planting flexibility program for fruits and vegetables for processing; this program will allow farmers in seven Midwestern states to plant some fruits/vegetables. Although acres used for this purpose will not be eligible for subsidy during the year in which fruits/vegetables are grown, they will be eligible for subsidy the following year if used to grow program crops.[37]

Title IV: Nutrition

Food Stamp Program/Supplemental Nutrition Assistance Program

The Supplemental Nutrition Assistance Program (SNAP), previously the Food Stamp Program is the largest domestic food and nutrition assistance program for low-income Americans.[38] The name change in the 2008 farm bill indicates an increased emphasis on nutrition and healthy lifestyle choices. SNAP educates participants on the importance of consuming fruits, vegetables, whole-grains, and low-fat/fat-free milk, and maintaining an active lifestyle. The following provisions are directly related to the Panel's recommendation to ensure access to affordable, healthy food for all people:

- Provisions in the 2008 farm bill allow for income limits for SNAP **eligibility** to be annually adjusted for inflation (rounding down to the nearest $250), which will ultimately increase the number of individuals eligible to receive assistance.
- The **Nutrition Education, Promotion, and Outreach** provision recognizes that nutrition education is a key component of behavior change and should be done in conjunction with provision of food supplemental nutrition assistance. The primary goal of this provision is to reduce overweight and obesity co-morbidities among SNAP participants. Legislation allocated $20 million to conduct a pilot program that evaluates health and nutrition

promotion in SNAP, with specific emphasis placed on encouraging households to purchase fruits, vegetables, and other healthy options. There were no similar provisions in previous legislation.

Food Distribution Programs

USDA provides food and nutrition assistance to millions of Americans, with about one in five participating in at least one of these programs during a given year. The following provisions in the 2008 farm bill are directly related to the Panel's recommendation to improve food supply and help ensure that all people have access to affordable, healthy food.

- The **Food Distribution Program on Indian Reservations** allocates $5 million annually in FY 2008-2012 for the purchase and distribution of locally grown foods to American Indian reservations. The types of food distributed will be based on availability in each region; the provision requires that at least 50 percent of food distributed be produced by Native American farmers, ranchers, and producers whenever possible. Through this program, participants receive a food package monthly that contains a balanced nutritional diet. There are 70 products to choose from, including fresh fruits and vegetables in addition to canned varieties. Nutrition education is also incorporated into this program, including individual nutrition counseling, cooking demonstrations, nutrition classes, and dissemination of health education material.[39] In addition to the allocation of funds, the USDA Secretary is also required to submit to Congress a report on the food package, including a description of its dietary adequacy and appropriateness for improving health challenges faced by Native Americans. There were no similar provisions in previous legislation.
- The **Purchase of Fresh Fruits and Vegetables** provision requires the USDA Secretary to purchase fruits and vegetables through FY 2012. The new provision requires that at least $50 million be spent exclusively for fresh fruit and vegetable purchases for schools participating in school lunch and other child nutrition programs. This increase in overall funding accounts for inflation in coming years with the ultimate goal of providing healthy options for children and other qualifying individuals who may not otherwise consume a balanced diet on a regular basis.
- The **Healthy Food Education and School Gardening Pilot Program** provision provides $10 million for a five-state pilot program that makes grants available to high-poverty schools for garden initiatives. The goals of the program include promoting healthy food choices and creating projects that can be replicated in other schools. There were no similar provisions in previous legislation.
- The **Farmers' Market and Community Food Promotion** provision allows for the continuation of annual funding of $5 million for Community Food Competitive Grants through FY 2012. Previous legislation authorized annual funds up to $5 million for Community Food Competitive Grants from FY 2002-2007. This program has the goal of increasing and strengthening direct producer-to-consumer avenues for accessing fruits and vegetables. The grant money can be used to develop business plans, produce financial and marketing information, improve market access and education for consumers, organize markets, and develop other modern approaches to marketing community food programs.[40]
- The **Healthy Urban Food Enterprise Development Center** provision authorizes funding to increase underserved community access to healthy foods, including locally grown and

produced agriculture. Legislation allocated $1 million annually in FY 2009-2011 and $2 million for FY 2012. There were no similar provisions in previous legislation.

- The **Farmers' Market Nutrition Programs** allocates funding to states, U.S. territories, and federally recognized Indian Tribal governments to provide low-income seniors with coupons that can be exchanged for eligible food at farmers' markets, roadside stands, and community supported agriculture programs.[41] The 2008 farm bill increased the mandatory funding level for this program from $15 million to $20.6 million annually.
- The **Locally Produced Foods** provision encourages the purchase of locally grown and raised agricultural products by all programs receiving funds through the farm bill. This provision explicitly states that these programs may use a geographic preference when procuring unprocessed agricultural products. Previous legislation was interpreted by many as prohibiting programs from exercising geographic preference when acquiring food.

Community Food Security and Emergency Food Grants

The **Emergency Food Infrastructure Grants** provision provides funding for food banks, with the primary goal of improving the ability of the banks to handle perishable food products, identify potential providers to donate food (e.g. local farms), and support small, local family farms and ranches. Through these infrastructure changes, food banks should be able to provide food recipients with fresh food options rather than primarily canned fruits and vegetables. There were no similar provisions in previous legislation.

School Meal Issues

USDA oversees four domestic food nutrition programs that primarily serve the needs of children. These are the National School Breakfast/Lunch Program, the Child and Adult Care Food Program, the Summer Food Service Program, and the Fresh Fruit and Vegetable Program. These programs account for a quarter of USDA food and nutrition expenditures, with $14.6 billion spent in fiscal year 2008.[42] Below are provisions made in the 2008 farm bill that support healthier food choices within the school nutrition programs:

- The **Fresh Fruit and Vegetable Program** was expanded to include all 50 states, with funding increased from $9 million to $70 million a year. The Fresh Fruit and Vegetable Program started as a pilot program with the 2002 Farm Act and only included schools that voluntarily applied to participate. The program is now available to schools in each state based on need.
- The **Grain Pilot Program** was established in the 2008 farm bill to purchase whole grains and whole grain products for use in school meals. The program is allocated $4 million to determine which types of whole grain products are most often consumed and most appealing to school-aged children.
- The **Survey of School Food Purchases** will determine the types of foods purchased by schools participating in the school lunch program. This one-time allocation of $3 million will be used to periodically survey participating schools.

Title X: Horticulture and Organic Agriculture

Horticulture and Organic Agriculture, a new Title in the 2008 version of the farm bill, allocates nearly $1 billion in funding over the next ten years. Half of this funding will be used to expand

the Specialty Crop Block Grant Program, which provides funds to state agriculture departments for marketing, promotion, research, and other activities related to specialty crops (i.e., fruits, vegetables, tree nuts, dried fruits, nursery crops, and floriculture). Title X also provides mandatory funding for growth of farmers' markets and for transitioning producers to organic production. It also allocates funds for the state provision of price reporting and organic data collection.[35]

Title XII: Crop Insurance

The Federal Crop Insurance Corporation (FCIC) sets the rates and contract terms for the crop insurance policies sold and serviced by private insurance companies. The premiums and delivery costs are federally subsidized.

- The **Insurance of Organic Crops** provision requires FCIC to issue a contract for the study of organic crop production improvement. If no difference in loss history between organically grown and other crops is identified, the premium surcharge for insurance of organic crops will be eliminated. If premiums are lowered, organic crop production should increase, which may increase community access to fruits and vegetables.

Conclusions for Recommendation 3

Process Evaluation

Has this recommendation and/or the reports in which it was issued been disseminated to appropriate stakeholders?

Partially—key members of Congress were notified of the *Healthy Lifestyles* report and, as always, the White House was briefed on the Panel's findings and recommendations. In addition, some organizations known to advocate for healthier food choices were sent a copy of the report. However, according to the records reviewed, the report was not sent to USDA officials, who are instrumental in crafting farm bill language. The report was also not sent to representatives of state/local governments, who were named as key stakeholders. For a more detailed list of stakeholders relevant to this recommendation who received reports, see Appendix C.

Outcome Evaluation

Has there been increased awareness of or concurrence with this recommendation?

Possibly—awareness was not directly assessed as part of this feasibility study (i.e., the evaluation did not directly interview/survey intended implementers); however, importance of healthy food has been increasingly discussed in the popular media and by policymakers and progress relative to the recommendation in the 2008 farm bill suggests that there is increased awareness of this issue and concurrence with the Panel's call for change.

Has the recommendation been implemented?

Partially—several changes consistent with the Panel recommendations were present in the 2008 farm bill. These include changes encouraging healthier food choices for participants in Federal food distribution programs as well as those promoting increased production of fruits and vegetables. However, farm commodity programs that promote production of high fructose corn syrup were largely unchanged.

Attribution Evaluation

Has the Panel played a role in changing awareness/concurrence or promoting implementation of this recommendation?

Not likely—as part of the evaluation of this recommendation, a timeline of activities related to the development and passage of the 2008 farm bill was developed (Table 4). This revealed that although the 2008 farm bill did not become law until June 2008, nearly a year after the *Healthy Lifestyles* report was released, the bulk of the bill had been developed in the first half of 2007, before the Panel report was published. Thus, it is highly unlikely that the Panel recommendation substantially influenced the content of the farm bill. There is a possibility that the Panel report or recommendation could have influenced Congressional support for the bill, particular in the Senate, which did not vote on the farm bill until December 2007; however, this question was not assessed as part of this feasibility study.

Table 4. Timeline of Events Related to the 2008 Farm Bill

January 31, 2007	USDA Secretary submits Farm Bill proposals
July 27, 2007	U.S. House passes House version of the Farm Bill (H.R. 2419)
August 2007	President's Cancer Panel releases *Healthy Lifestyles* report
December 14, 2007	U.S. Senate passes Senate version of the Farm Bill
May 14-15, 2008	Farm Bill Conference Report (H.R. 2419) passes House and Senate
May 20, 2008	Congress sends H.R. 2419 to President Bush
May 21, 2008	President Bush vetoes H.R. 2419
May 21-22, 2008	House and Senate pass H.R. 2419 over veto
May 22, 2008	House passes H.R. 6124
June 5, 2008	Senate passes H.R. 6124
June 18, 2008	President Bush vetoes H.R. 6124
June 18, 2008	House and Senate pass H.R. 6124 over veto, H.R. 6124 becomes P.L. 110-246

Evaluation Feasibility Study Conclusions

This section summarizes insights gained through assessment of the feasibility and utility of process, outcome, and attribution evaluations of Panel activities and recommendations. The implications of these conclusions were considered in development of recommendations for future evaluations (page 36). Practical "lessons learned" through the feasibility study are described in Appendix D.

Process Evaluation

As part of the process evaluation, efforts were made to determine whether Panel reports and recommendations had been adequately disseminated. This analysis revealed that Panel reports are generally disseminated to appropriate key stakeholders and/or intended implementers, with a few exceptions.

The results of this experience indicate it is feasible to collect robust data for a process evaluation of Panel activities. Virtually all the information needed for this type of analysis can be obtained from Panel staff, contractors, or members, which makes it less resource-intensive than some other evaluation activities.

Process evaluation could be used by Panel members and staff to identify potential for improvement in the way the Panel carries out its activities (see Activities column within the Logic Model, Figure 1). Changes made based on these findings could increase the effectiveness and/or efficiency of the Panel's work.

Outcome Evaluation

The evaluation set out to determine whether desired short-term and intermediate outcomes of the selected recommendations had been achieved. These include increased awareness and concurrence with the recommendation (short-term outcomes) and changes in research priorities, funding, policy, infrastructure, etc., consistent with the recommendation (intermediate outcomes).

Implementation

It was generally feasible to gather data regarding implementation of the Panel recommendations selected for the feasibility study. Much of this information was collected from secondary data sources (e.g., legislative databases, NCI Fact Book), with supplemental primary data in some instances (e.g., interviews with NCI representatives to learn about activities not summarized in publicly available materials).

The certainty with which successful implementation could be judged depended somewhat on the nature of the recommendation. For example, it was possible to develop clear-cut, informative indicators for the concrete recommendations that costs of fertility preservation for cancer patients/survivors should be covered by health insurance (e.g., Federal or state legislation that addresses this issue) and that increased funding should be provided for clinical and translational research (e.g., increase in BRDPI-adjusted funding levels for clinical and translational research since 2005). However, it was more complicated to assess emphasis on clinical and translational research.

Importantly, because implementation of Panel recommendations involves transfer of accountability (i.e., Panel not being responsible for implementation), results of an outcome evaluation do not indicate whether the Panel has been effective/successful, which has implications for how an evaluation should be designed and how its results should be used. This type of evaluation could be used by the Panel to assess concrete progress related to issues of interest and potentially inform future Panel series or outreach efforts.

Awareness/Concurrence

Overall, it was easier to gather information about concrete implementation activities than about changes in awareness and concurrence. This is in part because of a lack of baseline data regarding these measures. It is possible to do a cross-sectional assessment of awareness and concurrence but without comparator data, determination of changes would need to be based on speculation or self-reported historical data (i.e., whether stakeholders were aware of the issue or agreed with a recommendation at some point in the past).

An additional consideration is that evaluation of awareness and concurrence often entails increased reliance on primary data collection methods (e.g., surveys, personal interviews). Some primary data collection tools can be time-consuming to develop and their effectiveness depends in part on the willingness of outside parties to participate.

The Panel could use information about changes in awareness/concurrence to gain insight into barriers to implementation.

Attribution Evaluation

In multiple instances, it was possible to draw a direct link between the Panel and activities relevant to the recommendations because a Panel report or recommendation was referenced in written materials (e.g., TRWG report, introduced Congressional resolution on cancer-related infertility). While these citations indicate Panel influence, it is difficult (perhaps impossible in some cases) to measure the extent of the Panel's role in promoting recommendation implementation. For example, assessing Panel influence poses challenges when stakeholders known to be aware of a Panel recommendation(s) engage in implementation activities. Can the Panel take any credit for promoting these activities? On the other hand, absence of a citation or public acknowledgment does not necessarily mean that a Panel recommendation has not played a role in progress.

The Panel could use attribution evaluation to identify examples of its influence on the NCP.

Recommendations for Future Evaluation Activities

> *"...good evaluation does not merely gather accurate evidence and draw valid conclusions, but produces results that are **used** to make a difference."*[1]

The evaluation design tested as part of this feasibility study included elements of process, outcome, and attribution evaluation to help determine whether and how a large-scale evaluation should be conducted to achieve the three evaluation goals articulated at the onset of the process (see page 5). In developing recommendations for future Panel evaluation(s), insights gained from the feasibility study were considered in conjunction with the CDC Framework for Program Evaluation standards that state that evaluation should be undertaken in ways that are useful, feasible, ethical, and accurate.[1]

1. Conduct a process evaluation of Panel dissemination activities.

The process analysis conducted as part of the feasibility study addressed only one indicator— whether Panel reports in which recommendations of interest were issued were disseminated to intended implementers. As discussed previously, the evaluation revealed that the Panel reports generally are thoughtfully disseminated to key stakeholders. However, through the course of gathering dissemination information, it was noted that documentation of dissemination activities is somewhat fragmented, with information stored at NOVA, Hager Sharp, and the Panel office. Improved tracking of dissemination efforts may optimize this process, enabling quality control (i.e., confirmation that all appropriate stakeholders have received or been notified of the report) and ensuring consistency over time, particularly spanning staff changes.

A more thorough process evaluation of Panel dissemination activities is recommended. One option for conducting this evaluation is outlined below.

- *Develop a logic model of dissemination activities*. Information about current dissemination processes and activities would be gathered through interviews with individuals/groups involved in these processes (e.g., Panel staff, contractor staff). At a minimum, these interviews would collect information about how dissemination activities are planned, carried out, and documented. This would be used to generate a detailed logic model of dissemination that reflects steps and parties involved. Review of a logic model draft via email or in a group meeting would help ensure that it accurately represents dissemination activities.
- *Assessment of current dissemination activities*. Using the logic model as a guide, Panel staff and contractors involved in dissemination should discuss strengths and weaknesses of the current dissemination process (e.g., Are dissemination efforts well-planned? Are they implemented as planned?). This discussion should address some of the gaps in dissemination identified through the feasibility study (e.g., USDA not being sent a copy of the report in which a recommendation about U.S. agricultural policy was issued). Ideally, this step would be done as a group via conference call or in-person meeting so that participants could respond to and build upon one another's ideas.
- *Brainstorm for ideas to improve dissemination activities.* Once strengths and weaknesses of current dissemination efforts are identified, attention should be turned to how they could be improved (could be done during the same meeting). This discussion should be broad, including thoughts on how the current dissemination process could be more efficiently

implemented and consideration of whether the scope and range of dissemination efforts could be modified to better support the goals of the Panel. One suggestion may be to ensure that each recommendation (not only the overall report theme) and its intended implementers are specifically considered when the report distribution list is being developed. Another idea that surfaced during information collection for the current feasibility study was that dissemination activities could be expanded to include outreach to key stakeholders in the NCP (e.g., use of social networking tools to interface with advocacy organizations). It may also be useful to attempt to build awareness of the Panel and the National Cancer Program among stakeholders outside of the cancer community who are in a position to influence implementation of Panel recommendations (e.g., state legislators). Brainstorming should be done as a group via conference call or in-person meeting so that participants can respond to and build upon one another's ideas.

- *Generate a framework and integrated plan for dissemination.* Based on group discussions, a framework for dissemination should be created. This could include updating the original logic model to reflect modifications to current dissemination processes. In addition, an integrated dissemination plan should be laid out in a user-friendly guidance document that can be used to plan and execute dissemination activities. At a minimum, this plan should define roles of those involved in dissemination, describe steps involved, lay out a timeline of events, and establish a system for tracking dissemination efforts. It may be beneficial to seek input on the dissemination framework and/or guidance document from people other than those directly involved in dissemination; this may include Panel members, representative(s) from the NCI Office of Communications, or others.

Some background information needed for a process evaluation of dissemination was gathered as part of the current feasibility study and is included in Appendix F of this report. This information could serve as a starting point for process evaluation activities.

Following evaluation of dissemination activities, the Panel may want to consider process evaluation of other Panel activities. This type of evaluation would generally be less resource-intensive than other types of evaluation (e.g., outcome) and has potential to increase the effectiveness and/or efficiency of the Panel's work. NCI Panel staff could identify activities that might benefit from evaluation, possibly with input from Panel members and/or contract staff.

2. Revamp the Matrix of Recommendations.

Current efforts to monitor progress related to Panel recommendations utilize the Matrix of Recommendations of the President's Cancer Panel, a table that lists Panel recommendations and provides a column to note outcome measures/progress. However, this 72-page Word document is unwieldy, which may be why updates on outcome measures/progress are not systematically or frequently added. As a result, the Matrix contains only limited information regarding NCP progress relative to Panel recommendations.

However, the Matrix could be revamped to make it an effective monitoring/evaluation tool. An upfront investment of resources to create a thoughtfully designed relational database would facilitate continuous, informal tracking/evaluation of progress relative to Panel recommendations and provide a foundation for future formal evaluation efforts.

The new Matrix would be a tool that would allow users to quickly and easily save references to or descriptions of progress-related information. These references/descriptions could then be

linked to one or more Panel recommendations or reports (the latter would be useful if information relates to issues raised in a Panel report but not explicitly mentioned in a recommendation; this function is not available using the current Matrix).

The relational database should be created by an experienced professional with extensive input from Panel staff, particularly those who would be heavy users of the database. Emphasis should be placed on usability of the database; time and effort necessary to enter data should be minimized as to not impede use. Careful consideration should be given to sources of information that will most commonly be cited so that appropriate data fields can be created and data entry forms tailored. Thought should also be given to how information will be extracted from the database; for example, a report could be designed to list all references linked to single or multiple recommendations or reports.

Panel staff should discuss procedures for adding information to the database. Decisions should be made about whether multiple people or one individual will add references/descriptions. One option would be to give Panel interns/fellows responsibility for adding and updating information. Information could be added on an *ad hoc* basis and/or an intern/fellow could be asked to look for activities related to specific recommendations.

On its own, the revamped Matrix would not provide a synthesized view of progress related to Panel recommendations. However, it would facilitate more efficient collection of information and generation of reports providing a snapshot of activities relative to select recommendations. Also, the Matrix would provide valuable preliminary data for conduct of formal evaluations.

3. Evaluate intermediate outcomes of a subset of related recommendations.

A full-scale evaluation of all Panel recommendations is not advised as it would be resource intensive and it is not clear how this information would be useful to the Panel or the NCP. More useful and practical would be targeted evaluations of subsets of related recommendations from one or more reports. This type of evaluation would be used to follow up on areas of particular interest to the Panel and could serve a number of purposes, including: (1) identification of potential issues or themes for future Panel series, (2) identification of opportunities for Panel outreach/activity (e.g., use personal communication or media to remind key stakeholders or intended implementers of the recommendation(s) and appraise them of related progress or lack thereof), and (3) collection of information that may be useful to intended implementers and other stakeholders. It should be noted that the process reaching out to stakeholders during an evaluation could promote or otherwise influence implementation (e.g., by raising awareness).

Selection of Recommendations

Recommendations could be drawn from a single report or multiple reports. The number of recommendations that should be addressed in a subset evaluation would depend in part on the complexity, scope, and interrelationships of the recommendations; however, in most cases, inclusion of more than 10 recommendations would likely be cumbersome.

Recommendations could be "flagged" for evaluation as early as during report preparation (i.e., the Panel could issue a recommendation knowing it will want to measure progress within a particular time frame). In this case, it would be possible to determine whether collecting baseline data would be warranted and special attention could be paid to monitoring relevant activities using the Matrix prior to launching the formal evaluation. Alternatively, the Panel could initiate

an evaluation based on observations made, information gathered, or events transpiring at any point following the issuance of a recommendation(s).

Evaluation Design and Methods

The evaluation design should be utilization-focused. During each step of design, careful consideration should be given to how the Panel will use results of the evaluation; this will help ensure that the correct questions are asked. In this regard, outcome indicators should be developed for the collective subset rather than for each recommendation, although it may be appropriate and helpful to link indicators to one or more recommendations. Indicators should not be constrained by phrasing of the recommendations but should reflect questions and issues currently considered important by the Panel and Panel staff.

A sequential and adaptive evaluation design should be adopted (see Figure 4). This will allow ample opportunity for the Panel to consider whether and what types of additional information are needed to guide future activities at multiple stages and avoid expending resources on evaluation components that would be minimally useful.

The first phase of the evaluation should focus on intermediate outcomes, which may include changes in research priorities, funding, policy, infrastructure, behavior, etc., relevant to the issue of interest. Based on our experiences with the current pilot study, assessing these types of concrete intermediate outcomes is more straightforward than assessing awareness and support (short-term outcomes); thus, the latter should not be addressed during the first phase of evaluation. Intermediate outcomes can largely be assessed using secondary data sources (e.g., journal articles, published reports, legislative databases) with possible input from a small number of highly informed primary sources (e.g., advocates). These types of efforts generally require less time than the development of surveys or other tools designed to collect information from a large number of primary sources; they also circumvent the need for Office of Management and Budget (OMB) data collection clearance,[*,43] which can be resource intensive and time consuming.

Based on results of the first phase of evaluation, the Panel should decide whether additional information is needed to determine why certain activities have or have not taken place. Phase II of the evaluation (Figure 4) would include attention to short-term outcomes and other potential barriers. Phase II evaluation would likely be most informative in the event that inadequate progress was documented during Phase I; however, it is also possible that the Panel may want to learn more about how successful implementation was achieved and/or explore whether implementation has resulted in long-term outcomes (i.e., a decrease in the burden of cancer). A decision may be made to follow up on only a subset of indicators identified and researched during Phase I.

A mixed methods approach should be used for Phase II evaluation. Phase IIA would include interviews with a small number of highly informed key stakeholders. These stakeholders would

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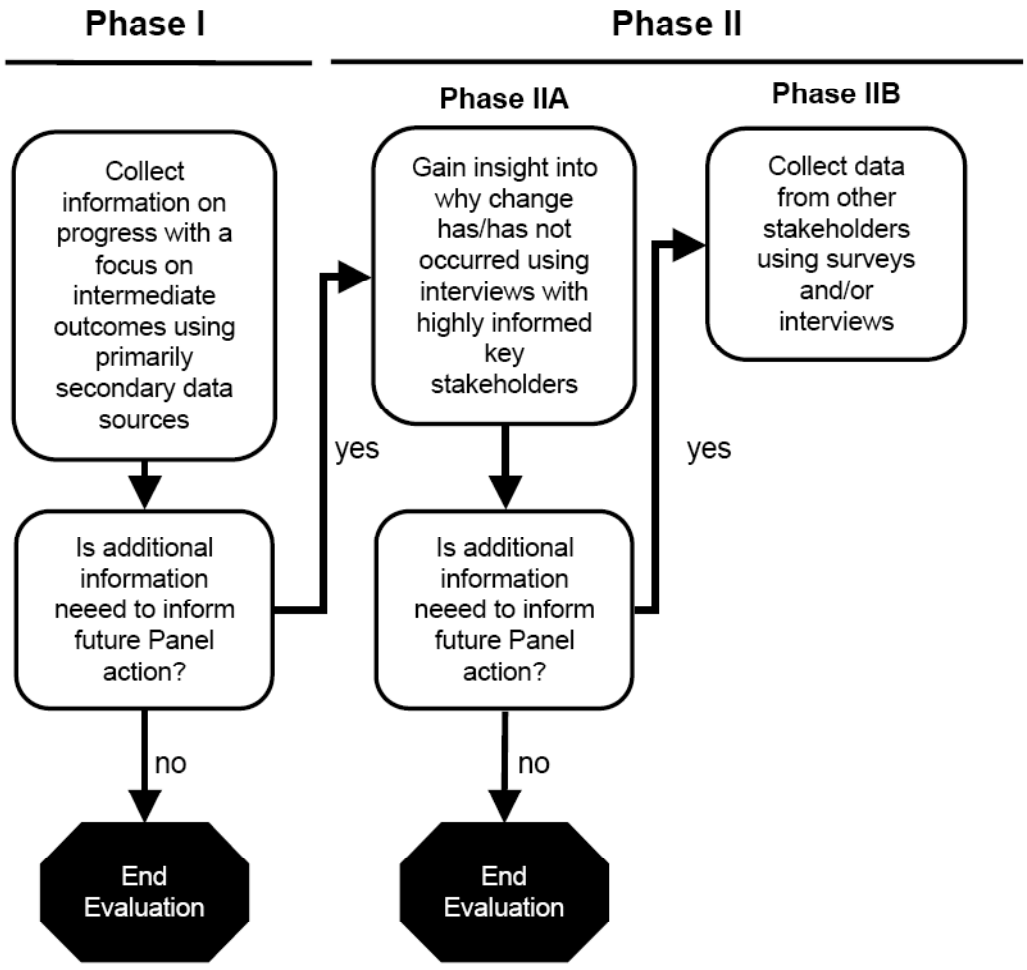
[*] OMB clearance is required whenever a Federal agency sponsors data collection by using identical questions, using identical reporting or record-keeping requirements, or asking respondents to provide the same level of information on the same subject involving 10 or more respondents in a 12-month period.

provide qualitative information and guide design of evaluation tools (e.g., surveys) for quantitative data collection in Phase IIB, if warranted. Representatives from advocacy organizations are often highly informed about "behind-the-scenes" activities in the cancer community and would likely be willing to participate in an interview for the Panel. Interviewees should be provided with a summary of Phase I findings; they will be more likely to review the summary if it is concise and easy to scan—a list of bulleted key points no longer than one page is suggested.

Informed by results of interviews with key stakeholders, the evaluation team, in collaboration with Panel staff, or Panel members if appropriate, can decide whether and what types of additional data are needed. Data collection tools for Phase IIB may include administration of a survey or a series of interviews with a broader group of stakeholders. Phase IIB data collection will likely be more quantitative in nature and may require obtaining OMB data collection clearance.

Figure 4. Sequential/Adaptive Design for Panel Evaluation



Attribution Evaluation

A formal attribution evaluation is not advised because it would be difficult to accurately and efficiently measure the Panel's contribution to progress of the NCP. This is in part because comprehensive assessment of attribution would require extensive primary data collection, which is resource intensive, and it would be difficult to rule out Panel contribution in the absence of explicit evidence. Perhaps most importantly, it is unclear how results of an attribution evaluation would be useful for guiding future activities of the Panel.

Thus, rather than focusing on attribution as a central part of an outcome evaluation, it is suggested that evaluators simply take note of instances in which Panel influence is evident when they are identified throughout the course of other evaluation activities. This would primarily occur during Phase I of the evaluation when secondary data sources are being reviewed. It may also be appropriate during Phase I or IIA interviews to ask whether the Panel name or report/recommendation has been leveraged to promote progress. However, in general, elucidating the role of the Panel should not be a focus of Phase IIB, particularly because this phase of evaluation will most likely be done on issues for which insufficient progress has been observed. Attempting to identify Panel contributions to a lack of activity can be awkward and distract from more important lines of questioning.

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Appendices

Appendix A: Evaluation Matrix

Recommendation: Fertility preservation procedures and infertility treatment services should be covered by health insurance for cancer patients/survivors whose fertility will be or has been damaged by cancer treatment

Process Evaluation

Key Questions(s) to be Addressed	Information Required	Information Source(s)	Data Collection Methods	Data Analysis Methods	Potential Limitations	Potential Conclusions from Analyses
Were intended implementers and indirect implementers sent or informed of the release of *Living Beyond Cancer: Finding a New Balance* and/or *Assessing Progress, Advancing Change*?	PCP report dissemination activities	PCP report dissemination records	Review of report dissemination records	Qualitative	Difficulty acquiring complete dissemination records	Dissemination of PCP report/recommendations is adequate/inadequate

Outcome Evaluation

Key Questions(s) to be Addressed	Information	Information	Data	Data	Potential	Potential Conclusions
Are intended implementers (i.e., state legislators) aware of this issue and/or recommendation?	List of intended implementers Knowledge/ understanding of intended implementers related to recommendation and/or issue in general	Intended implementers	Survey/ interviews	Qualitative	Difficulty contacting/getting response from appropriate legislators	Understanding of this issue is adequate/ inadequate Awareness (or lack thereof) of Panel recommendation

Key Questions(s) to be Addressed	Information Required	Information Source(s)	Data Collection Methods	Data Analysis Methods	Potential Limitations	Potential Conclusions from Analyses
Are relevant advocacy groups (or other indirect implementers) aware of this recommendation and/or issue?	List of relevant indirect implementers Knowledge and understanding of recommendation by advocacy organizations	Advocacy organizations	Interviews	Qualitative	Difficulty identifying relevant advocacy groups Difficulty securing interviews	Understanding of this issue is adequate/ inadequate Awareness (or lack thereof) of Panel recommendation
Have advocacy groups (or others) undertaken activities to make intended implementers aware of recommendation and/or issue? If so, have these activities been effective in increasing awareness among intended implementers?	Advocacy org activities	Advocacy organizations	Interviews with advocacy org reps Review of available written materials	Qualitative	Difficulty identifying relevant advocacy groups	PCP recommendations are sometimes "indirectly" disseminated PCP recommendations are used by advocacy organizations to advance issues of interest
Do intended implementers believe they could/should implement this recommendation (concurrence)?	Intended implementers concurrence with recommendation	Intended implementers	Surveys/ interviews Internet searches for policy statements, other relevant materials	Qualitative	Difficulty contacting/getting response from appropriate stakeholders	Intended implementers agree/disagree with their role in implementing the recommendation

Key Questions(s) to be Addressed	Information Required	Information Source(s)	Data Collection Methods	Data Analysis Methods	Potential Limitations	Potential Conclusions from Analyses
Have intended implementers made any changes or planned to make any changes as a result of the recommendation?	Enacted or pending legislation	Leg databases (state, Federal) Legislators/staff	Internet/ database searches Survey/ interviews	Qualitative	Difficulty gathering info on pending/planned legislation or policies Difficulty contacting/getting response from appropriate stakeholders	Intended implementers have (or have not) initiated activities to implement recommendation

Attribution Evaluation

Key Questions(s) to be Addressed	Information Required	Information Source(s)	Data Collection Methods	Data Analysis Methods	Potential Limitations	Potential Conclusions from Analyses
Have any increases in awareness and/or implementation been due to the Panel recommendation or Panel activities?	Intended implementer awareness of and/or concurrence with Panel and/or Panel recommendation	Intended implementers	Survey/ interviews Internet searches for relevant materials	Qualitative	Difficulty discerning if awareness of issue is due to PCP (many other bodies have addressed issue)	Panel has promoted change relative to this recommendation
Have advocacy groups (or other indirect implementers used the Panel recommendation to promote awareness and/or implementation of this recommendation?	Advocacy group/ indirect implementer activities	Advocacy groups/indirect implementers	Interviews Internet searches for policy statements, other relevant materials	Qualitative	Does not indicate that efforts were effective	Advocacy groups/ indirect implementers use Panel name/ recommendations

Recommendation: Governmental and private research sponsors must place greater emphasis on and substantially increase funding for clinical and translational research. Funding mechanisms should promote collaborative science but should also include greater support through the R01 mechanism for more applied research.

Process Evaluation

Key Questions(s) to be Addressed						
Were intended implementers and indirect implementers sent or informed of the release of *Assessing Progress, Advancing Change* or *Translating Research: Delivering on the Promise*?	PCP report dissemination activities	PCP report dissemination records	Review of report dissemination records	Qualitative	Difficulty acquiring complete dissemination records	Dissemination of PCP report/recommendations is adequate/inadequate

Outcomes Evaluation

Key Questions(s) to be Addressed	Information Required	Information Source(s)	Data Collection Methods	Data Analysis Methods	Potential Limitations	Potential Conclusions from Analyses
Are research sponsors (i.e., NCI) aware of this recommendation and/or issue?	Knowledge/under-standing by intended implementers related to recommendation and/or issue	Research sponsors Publicly available materials	Interviews Review of publicly available materials	Qualitative	Difficulty discerning if awareness of issue is due to PCP recommendation (many other bodies have addressed issue)	Understanding of this issue is adequate/ inadequate Awareness (or lack thereof) of Panel recommendation

Key Questions(s) to be Addressed	Information Required	Information Source(s)	Data Collection Methods	Data Analysis Methods	Potential Limitations	Potential Conclusions from Analyses
Do research sponsors believe they could/should implement this recommendation (concurrence)?	Research sponsors' concurrence with importance of clinical and translational research	Research sponsors Publicly available materials	Review of available written materials Interviews	Qualitative	Difficulty identifying/ interviewing appropriate contacts Likelihood of written materials being supportive (rather than expressing lack of support)	Intended implementers agree/disagree with their role in implementing the recommendation
Have research sponsors increased support (or planned to increase support) of clinical and/or translational research?	Changes in funding for clinical/ translational research Programmatic changes that enhance support of clinical/translational research	Sponsors' research portfolios Program staff	Internet searches NCI grant database searches Interviews with NCI staff	Qualitative	Possible inaccessibility of funding information	Research sponsors have increased funding for clinical and/or translational research
Have research sponsors increased emphasis on clinical and/or translational research?	Research sponsor activities related to clinical/translational research	Research sponsor staff Publicly available materials	Review of available materials (Web searches) Interviews with NCI staff	Qualitative	Subjective interpretation of data collected	Research sponsors have increased (or not) emphasis on clinical or translational research

Attribution Evaluation

Key Questions(s) to be Addressed	Information Required	Information Source(s)	Data Collection Methods	Data Analysis Methods	Potential Limitations	Potential Conclusions
Have any increases in funding and/or emphasis been due to the Panel recommendation or Panel activities?	Intended implementer awareness of and/or concurrence with Panel and/or Panel recommendation	Research sponsor Publicly available materials	Survey/ interviews Internet searches for relevant materials	Qualitative	Difficulty discerning if activities are due to PCP (many other bodies have addressed issue)	Panel has promoted change relative to this recommendation

Recommendation: Coordinate U.S. agricultural subsidy and public health policy related to diet and nutrition to improve the food supply and help ensure that all people have access to affordable, healthy food. Specifically:

- **Structure farm supports to incentivize/encourage increased production of fruits and vegetables; limit farm subsidies that promote the production of high fructose corn syrup for use in food.**
- **Support healthier food choices by restructuring regulations governing acceptable food choices allowed by Women, Infants, and Children; Headstart; and school lunch programs.**

Process Evaluation

Key Questions(s) to be Addressed	Information Required	Information Source(s)	Data Collection Methods	Data Analysis Methods	Potential Limitations	Potential Conclusions from Analyses
Were intended/indirect implementers sent or informed of the release of *Healthy Lifestyles*?	PCP report dissemination activities	PCP report dissemination records	Review of report dissemination records	Qualitative	Difficulty acquiring dissemination records	Dissemination of PCP report/recommendations is adequate/inadequate

Outcome Evaluation

Key Questions(s) to be Addressed	Information Required	Information Source(s)	Data Collection Methods	Data Analysis Methods	Potential Limitations	Potential Conclusions from Analyses
Were Congressional members aware of this recommendation and/or issue?	List of key members/staff Knowledge/ understanding of issue	Congressional members/staff Written materials	Interviews Review of available materials	Qualitative	Difficulty identifying/ interviewing appropriate contacts	Intended implementers are aware/unaware of this issue
Did key Congressional members believe they should implement changes put forth in this recommendation?	List of key Congressional members Congressional members' views	Congressional members Written materials	Interviews Review of available written materials	Qualitative	Difficulty identifying/ interviewing appropriate contacts	Intended implementers agree/disagree with recommendation

Key Questions(s) to be Addressed	Information Required	Information Source(s)	Data Collection Methods	Data Analysis Methods	Potential Limitations	Potential Conclusions from Analyses
Were changes consistent with this recommendation incorporated into the 2008 farm bill?	Changes in farm bill	2008 farm bill 2002 farm bill Congressional members/staff	2008 farm bill 2002 farm bill Members/staff	Qualitative		Changes consistent with Panel recommendations were/were not made in the 2008 farm bill

Attribution Evaluation

Key Questions(s) to be Addressed	Information Required	Information Source(s)	Data Collection Methods	Data Analysis Methods	Potential Limitations	Potential Conclusions from Analyses
Were changes made to the farm bill due to the Panel recommendation or Panel activities?	Intended implementer awareness of and/or concurrence with Panel and/or Panel recommendation	Congressional members/staff Publicly available materials	Survey/ interviews Internet searches	Qualitative	Difficulty discerning if activities are due to PCP	Panel has promoted change relative to this recommendation

Appendix B: Methods

Dissemination Evaluation

Information about report dissemination was extracted from FileMaker files and report distribution summaries maintained at NOVA Research Company. Information about release activities and media coverage were obtained from Hager Sharp. These data were supplemented by conversations with current and former National Cancer Institute (NCI) Special Assistants to the Panel.

Recommendation 1

Web and database searches. Internet searches using Google and other search engines were conducted to identify news articles, journal papers, Web sites, and organizations relevant to fertility preservation and cancer. The Library of Congress THOMAS Web site (http://thomas.loc.gov/) was used to search for Federal legislation using key terms "cancer and infertility, "cancer and fertility," and "fertility preservation." The NCI State Cancer Legislative Database (SCLD) Program (http://www.scld-nci.net) was utilized to obtain information on state legislation mandating coverage for the reproductive side effects of cancer treatment (e.g., sperm banking, cryopreservation). This custom search of the SCLD was conducted in September 2008 at the request of Joyce Reinecke and repeated by MayaTech Corporation in August 2009 for this feasibility study.

Interview with Fertile Hope. A telephone interview was conducted with Joyce Reinecke, Vice President of Programs for Fertile Hope. A list of interview questions was developed and sent to Ms. Reinecke prior to the call to inform her of our areas of interest and allow her time to think about her responses. Ms. Reinecke was also sent a draft of the legislator survey and a list of possible recipients prior to the call and asked to provide feedback on these items.

Survey of state legislators. A Web-based survey was created and administered using Survey Monkey (http://www.surveymonkey.com/). Potential respondents were provided with a customized Web link to the survey, which allowed us to link responses with respondent without requiring the respondent to provide personal information. A PDF version of the survey was also created for use in the event that respondents were uncomfortable or experienced trouble with the Web-based format.

The survey was sent to the offices or chairpersons of state congressional health-related committees. It was decided that the survey would be sent to no more than nine potential respondents because Office of Management and Budget clearance is required for surveys of 10 or more people. Factors considered when selecting states included geographic region, existence of legislation regarding general infertility, existence of legislation regarding insurance coverage for care related to side effects of cancer treatment, and party affiliation of committee chairperson. Contact information for chairperson or committee staff was found using Internet searches. Initial contact was made via telephone (preferred) or email (if telephone number was unavailable or attempts using the telephone were unsuccessful). Successful contact was defined as talking to or exchanging email with an individual associated with the committee; with one exception, the link to the survey was not sent until successful contact was made. Two additional "replacement" states were added to the study once it was concluded that there was not going to be successful contact with the remaining initial list of states. Evaluators were unable to make successful

contact with committees in either of these replacement states. Respondents were asked to complete the survey within two weeks, at which time a reminder email was sent or a reminder phone call placed.

Because of the small number of responses, survey data were analyzed manually and using Survey Monkey tools. In analyzing responses to questions on barriers to implementations, primary barriers were defined as those for which at least two of three respondents selected "yes" or "somewhat" when asked, "Is this a barrier?"

Recommendation 2

Web and database searches. The NCI Web site was searched extensively for information about funding for and activities related to clinical and translational research.

Funding analysis. The NCI Funded Research Portfolio (http://fundedresearch.cancer.gov/) and the annual NCI Fact Book released by the Office of Budget and Finance were used to obtain funding information. The Funded Research Portfolio contains information about research grants, contract awards, and intramural research projects funded by the Institute. Projects are classified based on their relevance to Special Interest Category (SIC) and Organ Site codes. Because of a few discrepancies and gaps in these resources, some information was gathered through direct communication with the NCI Office of Budget and Finance. Information about the Biomedical Research and Development Price Index was gathered from the NIH Office of Budget Web site.

Interviews. Telephone interviews of approximately 30 minutes each were conducted with the following NCI representatives:

- James Doroshow, M.D., Director, Division of Cancer Treatment and Diagnosis; and Chairperson, NCI Clinical Trials Working Group (ended in 2005)
- Lynn Matrisian, Ph.D., Special Assistant to the NCI Director; Co-Chair, NCI Translational Research Working Group (ended in 2007); and Chair, Department of Cancer Biology, Vanderbilt School of Medicine

In the emails that were sent requesting interviews, Drs. Doroshow and Matrisian were provided with a brief description of the project and the text of the recommendation.

Recommendation 3

Web and database searches. The primary source for this analysis was the U.S. Department of Agriculture farm bill Web site, which provides a table detailing differences between the 2008 farm bill and past legislation (http://www.ers.usda.gov/FarmBill/2008/) as well as full text of the farm bill. Internet searches using Google were conducted to find additional background information.

Appendix C: Report Dissemination Analysis

Dissemination records were analyzed to determine whether key stakeholders received the reports in which the selected recommendations were issued. *The tables below do not provide a comprehensive record of dissemination activities, but rather list key stakeholders.* Key stakeholders were defined for each recommendation and include persons or organizations with the authority to implement the recommendation or likely to influence those with authority to implement (so-called indirect implementers). See Appendix B for information on how the dissemination analysis was conducted.

Recommendation 1: Fertility Preservation for Cancer Patients and Survivors

Living Beyond Cancer: Finding a New Balance (LBC) was released through a press conference and Education Session at the 2004 American Society of Clinical Oncology (ASCO) annual meeting. Reports were distributed to over 3,000 stakeholders, ranging from government officials to the general public. *Assessing Progress, Advancing Change* (APAC) was released through an Education Session at the 2006 ASCO meeting. Reports were sent to nearly 1,000 stakeholders. For the purposes of the current report dissemination analysis, key stakeholders were defined as those with the authority to increase insurance coverage for fertility preservation for cancer patients (e.g., Federal and state government representatives, insurance companies) as well as "indirect implementers" (i.e., organizations likely to advocate for/influence change in this area).

Governmental Entities	Individual Stakeholder	LBC	APAC
White House	President of the United States	√	√
U.S. Congress	Select Members*	√	√
Department of Health and Human Services	Secretary	√	√
Centers for Medicare and Medicaid Services	Medical Officer, Special Assistant	√	
Centers for Medicare and Medicaid Services	Administrator		√

Insurance Companies/Organizations	Individual Stakeholder	LBC	APAC
American Health Insurance Plans	Membership Coordinator		√
State Farm Insurance Company	Chairman and CEO		√

* The NCI Government and Congressional Relations Office classifies congressional members using a tiered system: the first tier comprises members on the Appropriations Committee and members who sit on cancer-specific caucuses or deal with cancer legislation; tier two comprises members who have introduced cancer-specific bills; and tier three comprises all other congressional members. Legislators in tiers one and two receive emails announcing the release of all Panel reports; depending on the report topic, select members from tier three are also sent the announcement.

Advocacy Organizations	Individual Stakeholder	LBC	APAC
Fertile Hope	Founder and Executive Director	√	√
Lance Armstrong Foundation	President and CEO	√	√
Lance Armstrong Foundation	Chairman of the Board	√	√
Lance Armstrong Foundation	Director of Survivorship	√	√
Self-help Group for Women with Breast or Ovarian Cancer (SHARE)		√	√
National Partnership for Women and Families		√	
National Women's Health Network		√	
Women's Research and Education Institute		√	

Recommendation 2: Funding for and Emphasis on Clinical and Translational Research

Assessing Progress, Advancing Change was released through an Education Session at the 2006 ASCO meeting. Reports were sent to nearly 1,000 stakeholders. *Translating Research Into Cancer Care: Delivering on the Promise* (TR) was released via media teleconference in June 2005 and sent to nearly 1,000 stakeholders. For the purposes of the current dissemination analysis, key stakeholders were defined as those with the authority to influence the funding for or emphasis on clinical and translational research by research-sponsoring or -conducting institutions (e.g., Federal legislators with appropriations authority, leadership of NIH and its Institutes and Centers (particularly NCI), leadership of major research institutions). Advocacy groups likely to promote funding for and emphasis on clinical and translational research were also included.

Governmental Entities	Individual Stakeholder	APAC	TR
White House	President of the United States	√	√
U.S. Congress	Select Members*	√	√
U.S. Department of Health and Human Services	Secretary	√	√
U.S. Department of Health and Human Services	Deputy Assistant Secretary for Health	√	√
National Institutes of Health	Director	√	√
National Institutes of Health	Institute Directors	√	√
National Cancer Institute	Director	√	√
National Cancer Institute	Division Directors	√	√

* The NCI Government and Congressional Relations Office classifies Congressional members using a tiered system: the first tier comprises members on the Appropriations Committee and members who sit on cancer specific caucuses or deal with cancer legislation; tier two comprises members that have introduced cancer specific bills; and tier three comprises all other congressional members. Legislators in tier one and two receive emails announcing the release of all Panel reports; depending on the report topic, select members from tier three are also sent the announcement.

Governmental Entities	Individual Stakeholder	APAC	TR
National Cancer Institute	Director, Center for Cancer Research	√	√
National Cancer Institute	National Cancer Advisory Board	√	√
National Cancer Institute	Board of Scientific Counselors	√	√
National Cancer Institute	Board of Scientific Advisors	√	√
National Cancer Institute	SPORE Directors	√	√
National Institute of Environmental Health Sciences	Director	√	√
National Institute of Environmental Health Sciences	Associate Director, Division of Research Coordination, Planning and Translation	√	√
U.S. Department of Defense	Secretary	√	√
U.S. Department of Defense	Assistant Secretary for Health Affairs	√	√
U.S. Department of Defense	Director, Congressionally Directed Medical Research Program	√	√

NCI-designated Cancer Centers	Individual Stakeholder	APAC	TR
Abramson Cancer Center, University of Pennsylvania	Director	√	√
Arizona Cancer Center	Director	√	√
The Burnham Institute	Director	√	√
The Cancer Institute of New Jersey, Robert Wood Johnson Medical School	Director	√	√
Cancer Research Center of Hawaii	Director	√	√
Case Comprehensive Cancer Center	Director	√	√
Chao Family Comprehensive Cancer Center, University of California at Irvine	Director	√	√
City of Hope National Medical Center, Beckman Research Institute	Director	√	√
Cold Spring Harbor Laboratory	Director	√	√
Dana-Farber/Harvard Cancer Center	Director	√	√
Duke Comprehensive Cancer Center	Director	√	√
Albert Einstein Cancer Research Center	Director	√	√
Fox Chase Cancer Center	President	√	√
Fred Hutchinson/University of Washington Cancer Consortium	President & Director	√	√
Holden Comprehensive Cancer Center, The University of Iowa	Director	√	√
Huntsman Cancer Institute, University of Utah	Interim Director	√	√
Indiana University Cancer Center	Director	√	√

NCI-designated Cancer Centers	Individual Stakeholder	APAC	TR
Herbert Irving Comprehensive Cancer Center, Columbia University	Director	√	√
The Jackson Laboratory Cancer Center	Director	√	√
Jonsson Comprehensive Cancer Center, University of California Los Angeles	Director	√	√
The Barbara Ann Karmanos Cancer Institute, Wayne State University School of Medicine	President & CEO	√	√
Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University	Director	√	√
Kimmel Cancer Center, Thomas Jefferson University	Director	√	√
UNC Lineberger Comprehensive Cancer Center	Director	√	√
UNC Lineberger Comprehensive Cancer Center	Director, Center for AIDS Research	√	√
Lombardi Comprehensive Cancer Center, Georgetown University	Interim Director	√	√
Robert H. Lurie Comprehensive Cancer Center, Northwestern University	Director	√	√
Massey Cancer Center, Virginia Commonwealth University	Director	√	√
Mayo Clinic Cancer Center	Director	√	√
M.D. Anderson Cancer Center, University of Texas	President	√	√
Memorial Sloan-Kettering Cancer Center	President and CEO	√	√
MIT Center for Cancer Research	Director	√	√
H. Lee Moffitt Cancer Center and Research Institute	CEO/Center Director	√	√
Moores Cancer Center, University of California, San Diego	Director	√	√
Norris Cotton Cancer Center, Dartmouth-Hitchcock Medical Center	Director	√	√
NYU Cancer Institute	Director	√	√
The Ohio State University Comprehensive Cancer Center	Professor and Director	√	√
OHSU Cancer Institute, Oregon Health & Science University	Director	√	√
Purdue University Center for Cancer Research	Director	√	√
Roswell Park Cancer Institute	President and CEO	√	√
Salk Institute Cancer Center	Director	√	√
San Antonio Cancer Institute, University of Texas Health Science Center at San Antonio	Interim Director	√	√
Siteman Cancer Center, Washington University School of Medicine	Director	√	√
St. Jude Children's Research Hospital	Director	√	√

NCI-designated Cancer Centers	Individual Stakeholder	APAC	TR
UAB Comprehensive Cancer Center, University of Alabama at Birmingham	Acting Director	√	√
UC Davis Cancer Center	Director	√	√
UCSF Comprehensive Cancer Center	Director	√	√
University of Chicago Cancer Research Center	Director	√	√
University of Colorado Cancer Center, University of Colorado Health Sciences Center	Director	√	√
University of Michigan Comprehensive Cancer Center	Director	√	√
University of Minnesota Cancer Center	Director	√	√
University of Nebraska Medical Center/Eppley Cancer Center	Director	√	√
University of New Mexico Cancer Research & Treatment Center	Director	√	√
University of Pittsburgh Cancer Institute	Director	√	√
University of Virginia Cancer Center	Director	√	√
University of Wisconsin Comprehensive Cancer Center	Director	√	√
USC/Norris Comprehensive Cancer Center	Director	√	√
Vanderbilt-Ingram Cancer Center	Director	√	√
Vermont Cancer Center, University of Vermont	Director	√	√
Wake Forest Comprehensive Cancer Center	Director	√	√
The Wistar Institute	Director	√	√
Yale Cancer Center	Director	√	√

Other Research Organizations	Individual Stakeholder	APAC	TR
Alaska Native Tribal Health Consortium, Office of Alaska Native Health Research	Director	√	√
American Association for Cancer Research	Chief Executive Officer	√	√
American Cancer Society	Chief Executive Officer	√	
American Cancer Society	Vice President, Epidemiology and Surveillance Research		√
Broad Institute of MIT	Director	√	√
Cancer Research Foundation of America	President and Founder	√	
Cancer Research Center of Hawaii	Director	√	
Children's Hospital and Research Center at Oakland	Director of Oncology		√
Harvard Medical School, Whitehead Institute for Biomedical Research	Director	√	√
Howard Hughes Medical Institute	President	√	√
North American Primary Care Research Group	President	√	√
Pharmaceutical Research and Manufacturers Association	President/CEO	√	√

Other Research Organizations	Individual Stakeholder	APAC	TR
Translational Genomics Research Institute	Director	√	√
Translational Genomics Research Institute	President and Scientific Director	√	√
University of California Ludwig Cancer Research	Head		√
University of Chicago Cancer Research Center	Director	√	
University of Colorado at Denver and Health Sciences Center	Executive Director	√	
University of South Carolina Research Foundation	Director, Cancer Prevention and Control	√	√
Van Andel Research Institute		√	√

Advocacy Organizations/Foundations	Individual Stakeholder	APAC	TR
Association for Patient-Oriented Research	President	√	
Cancer Research Foundation of America	President and Founder	√	√
Friends of Cancer Research	President	√	√
Friends of Cancer Research	Chairperson	√	√
Friends of Cancer Research	Executive Director	√	
Multiple Myeloma Research Foundation	President	√	√
Native American Cancer Research	Executive Director	√	√
PAIR: Patient Advocates In Research	President	√	√

Recommendation 3: Healthier Food Choices

Promoting Healthy Lifestyles: Policy, Program, and Personal Recommendations for Reducing Cancer Risk was released at a Centers for Disease Control and Prevention Cancer Conference in August 2007, and was sent to over 700 stakeholders. For the purposes of the current dissemination analysis, key stakeholders were defined as those with the authority to influence public health and agricultural policy (e.g., Federal and state policymakers, leadership of Federal agencies focused on health policy [not research] and agriculture). Organizations likely to advocate for change by interacting with these intended implementers were also included.

Governmental Entities	Individual Stakeholder
White House	President of the United States
Congress	Selected Representatives*

* The NCI Government and Congressional Relations Office classifies congressional members using a tiered system: the first tier comprises members on the Appropriations Committee and members who sit on cancer-specific caucuses or deal with cancer legislation; tier two comprises members who have introduced cancer-specific bills; and tier three comprises all other congressional members. Legislators in tiers one and two receive emails announcing the release of all Panel reports; depending on the report topic, select members from tier three are also sent the announcement.

Governmental Entities	Individual Stakeholder
U.S. Department of Health and Human Services	Secretary
Food and Drug Administration	Director Commissioner Deputy Commissioner and Chief Medical Officer
Centers for Disease Control and Prevention	Director, Division of Cancer Prevention and Control Associate Director for Science, Division of Nutrition and Physical Activity Public Health Advisor, State Cancer Plan Program

Foundations and Organizations	Individual Stakeholder
American Academy of Health Behavior Department of Public and Community Health	Executive Director
American Association of Healthcare Consultants	Chairman
American Dietetic Association	Director, Scientific Affairs and Research Director of University Nutrition
American Public Health Administration	Executive Director
Association of Schools of Public Health	President and CEO

Appendix D: Evaluation Lessons Learned

Recommendation 1: Fertility Preservation

- Fertile Hope was receptive to our request to be involved in the evaluation and provided a trove of information about behind-the-scenes efforts related to this recommendation. This suggests that advocacy organizations would be an important resource for future evaluation of other recommendations. However, it was difficult to schedule an interview with a Fertile Hope representative, despite the organization's enthusiasm for the effort. Furthermore, although the interview was very informative, our contact was unable to spend significant time outside of the interview to review and offer feedback on written materials. Short, direct questions sent via email were an effective way to collect information following the interview.
- The Library of Congress THOMAS Web site (http://thomas.loc.gov) is useful for monitoring legislation and legislative activities of the U.S. Congress.
- The National Cancer Institute (NCI) State Cancer Legislative Database (SCLD) Program (http://www.scld-nci.net) is a useful resource for identifying state cancer-related legislation. SCLD draws from LexisNexis and State Net (commercial legal research services) and maintains information about state laws and resolutions addressing key topics in cancer; currently, these key topics include access to state-of-the-art cancer treatment, breast cancer, cervical cancer, colorectal cancer, health disparities, genetics, ovarian cancer, prostate cancer, skin cancer, surveillance (cancer registries), testicular cancer, tobacco, and uterine cancer. Requests for custom searches of cancer-related topics not included on this list are considered by NCI; these requests are usually approved if they are made by NCI-associated groups such as the Panel. In the event the request is not approved by SCLD, searches can be performed by The MayaTech Corporation through a purchase order (Kerri Lowrey, Director, Center for Health Policy and Legislative Analysis, The MayaTech Corporation, Email communication, August 21, 2009.).
- The availability of Web-based information about state legislative bodies, legislators, and legislation varies widely by state. Of particular relevance for this evaluation effort, contact information was not uniformly available for committees and/or committee chairs. If a large-scale survey of state legislators is conducted in the future, it may be worthwhile to consider obtaining a subscription to the National Conference of State Legislators StateConnect Directory (http://www.ncsl.org/Default.aspx?TabID=788&tabs=856,33,722#856), which contains contact information for all state legislators and also allows searches of legislators based on committee assignment(s), legislative leadership, party affiliation, and other characteristics.
- The committees contacted varied in their responsiveness to our request to complete the survey. In general, multiple personal interactions were needed before a potential respondent completed the survey. The following is a summary of the contact/response rates:
  - 54.5 percent successful contact rate (talking to or exchanging email with an individual associated with the committee)
  - 36.3 percent overall response rate (responses received/attempted contacts)
  - 66.7 percent successful contact response rate (responses received/successful contacts)

- Two respondents agreed to give feedback on the survey. Both indicated that the length of the survey was acceptable, with one reporting that it took 5 to 15 minutes to complete and the other reporting that it took 16 to 30 minutes. When asked to rank five information collection methods (Web-based survey, paper-based survey, email-based questionnaire, telephone interview, in-person interview), both respondents ranked Web-based surveys as the most preferable method. The only respondent to complete the ranking did so in the following way: Web-based survey, in-person interview, telephone interview, paper-based survey, and email-based questionnaire. All respondents declined our request for a follow-up interview to provide additional feedback on the survey.
- Survey Monkey (http://www.surveymonkey.com/) is an inexpensive and easy-to-use Web-based survey service. The platform worked well for our survey design and administration.

Recommendation 2: Clinical and Translational Research

- The NCI Web site is a valuable and easily accessible resource for identifying ongoing NCI activities. Among the most informative sites for this evaluation were the NCI Funded Research Portfolio, NCI Office of Budget and Finance, and Web sites of Federal advisory boards (e.g., National Cancer Advisory Board, Clinical Trials Advisory Committee).
- Senior NCI staff members are willing to participate in short telephone interviews and provide insight into activities that are not yet publicized.
- The NCI Funded Research Portfolio facilitates queries of NCI's investments in areas of research for which there are codes; however, it is more challenging to determine funding for areas of research not represented in the coding system. This is more likely to be the case for emerging areas of research.

Recommendation 3: Healthier Food Choices

- When evaluating legislative activity (particularly activity surrounding bills as large as the farm bill), it is important to remember that the legislative process is often drawn out and can cover several months or even more than a year. This is exceptionally important if one of the goals of the evaluation is to determine whether the Panel had a role in driving changes.
- There is extensive publicly available information regarding the farm bill, likely because activities related to this massive bill are largely carried out by the U.S. Department of Agriculture (USDA). The USDA Web site includes a link to the language of the final bill as well as the proposal for the 2008 farm bill developed by USDA. It also includes a table delineating differences between the farm bill and past legislation and information about ongoing activities related to farm bill provisions. It is possible that there are similarly rich data sources for other Federal government activities, which could be valuable for future evaluations.

Appendix E: President's Cancer Panel, Clinical Trials Working Group, and Translational Research Working Group Recommendations/Initiatives

CTWG Initiative	PCP *Translating Research* Recommendation	TRWG Initiative
Coordination New Initiative #2: Realign NCI funding, academic recognition, and other incentives to promote collaborative team science and clinical trial cooperation.	Recommendation #1: The existing culture of cancer research must be influenced to place more value on translational and clinical research. To effect this culture change, a task force representing key stakeholders in academic research should be convened to examine and modify existing reward systems (e.g., compensation, promotion/tenure, space and resource allocation, prestige) to encourage collaborative research and ensure that all contributors (including but not limited to pathologists, radiologists, and research nurses) benefit from participating in these research activities.	Initiative B1: Modify guidelines for multiproject, collaborative early translational research awards to focus research on advancing specific opportunities along a developmental pathway toward patient benefit, and to reward collaborative team science.
Coordination New Initiative #2 *(continued)*	Recommendation #2: Governmental and private research sponsors must place greater emphasis on and substantially increase funding for clinical research and human tissue research. Funding mechanisms should promote collaborative science and include greater support through the R01 mechanism.	Initiative A2: Designate a specific portion of the NCI budget for early translational research to facilitate coordinated management, long-term planning, and prioritization among opportunities and approaches as well as to demonstrate NCI's commitment to translational research.
Coordination Enhancement Initiative #2: Increase awareness of the NCI-FDA expedited concept/protocol approval process, including use of the FDA Special Protocol Assessment.	Recommendation #10: The current partnerships between the National Cancer Institute and the Food and Drug Administration to expedite cancer drug reviews and between NCI and the Centers for Medicare and Medicaid Services to generate clinical data on new interventions to support Medicare coverage decisions should be continued and strengthened.	

CTWG Initiative	PCP *Translating Research* Recommendation	TRWG Initiative
Standardization Enhancement Initiative #1: Establish commonly accepted clauses for clinical trial contracts.	Recommendation #12: A task force of private, nonprofit, academic, and government stakeholders affected by current barriers to research translation due to intellectual property and patent issues should be convened to develop and reach consensus on: (1) standard language for patent exemptions for research purposes, (2) standard clauses for contracts governing collaborative research, and (3) other agreements as needed to resolve intellectual property and data-sharing issues.	Initiative C4: Develop enhanced approaches for negotiation of intellectual property agreements and agent access to promote collaborations among industry, academia, NCI, and foundations.
Prioritization/Scientific Quality New Initiative #3: Enhance patient advocate and community oncologist involvement in clinical trial design and prioritization through representation on Steering Committees and creation of patient advocate and community oncologist focus groups.	Recommendation #17: Clinical and prevention research funders should require community participation early in protocol design and in research implementation.	Initiative C5: Increase NCI interaction and collaboration with foundations and advocacy groups to capitalize upon their complementary skills and resources for advancing early translational research.

Appendix F: Preliminary Information for Process Evaluation of Dissemination Activities

Timeline

Each year President's Cancer Panel staff, NOVA, Hagar Sharp, and the science writer discuss the release of the annual report and dissemination efforts. The science writer sets the timeline for the production of the report and the deliverable date. This determines the estimated release date. Once the estimated timeline is in place, health conferences/meetings that pertain to the specific report topic are sought out as venues for releasing the report to the public. If there are no conferences that seem relevant to the topic during the estimated release time, other avenues for releasing the report are discussed. These range from press releases to media blitzes (scheduling several media segments that promote the report).

Report Recipients

Several people/organizations receive a copy of every Panel report, including, but not limited to:

- President/White House
- U.S. Congress (key members)
- Department of Health and Human Services Secretary
- National Institutes of Health (NIH) Director
- NIH Institute/Center Directors
- National Cancer Institute (NCI)
    - Director
    - Division Directors
    - Board of Scientific Advisors
    - Board of Scientific Counselors
    - National Cancer Advisory Board

Roles

- **President's Cancer Panel Staff** - The Special Assistant to the PCP is in charge of finalizing all lists of stakeholders to receive the report release announcement email that is sent out during dissemination activities. These lists are compiled through various resources and take into account the topic of the report and those who have expressed past interest in the Panel. Dissemination lists from previous reports are also used to generate a final list by removing organizations that aren't relevant to the report topic and adding new stakeholders. These stakeholders receiving the report vary from advocacy organizations to state and Federal legislators to government agency leadership. The report always goes to the leadership of NCI and NIH. The other supporting agencies that may receive an email/copy of the report vary each year depending on the level of interest they may hold in the report topic. If specific agencies express interest for more than one report, they are automatically added to the dissemination list each year. The Panel also receives report requests from the general public

throughout the year, which are tracked within the Panel office. A list is generated of these requests and sent to NOVA to be included in the main database of stakeholders.

The Panel office is also in charge of developing marketing materials for release of the report. This includes postcards/one pagers that advertise the report and are distributed at meetings and conferences.

- **NOVA Research Company** – NOVA staff compiles and manages the final list of stakeholders and arranges shipment of hardcopy reports. They draft the form that is submitted to NCI's warehouse for mailing of the reports and coordinate efforts with Panel staff regarding report dissemination.
- **Hager Sharp** – Hager Sharp is in charge of all media relations for the President's Cancer Panel. They send out a PDF of the report to various media outlets, and book interviews with newspapers, magazines, and news stations. A report of media efforts is submitted to the Panel office and Panel members at the end of the primary dissemination period. This report includes all of the Web sites, news stations, magazines, newspapers and other media outlets that highlighted the release of the Panel report.

  Hager Sharp also arranges for the production of the marketing materials that is created by the Panel office staff.
- **NCI Government and Congressional Relations Office** – The Office compiles a list of select congressional members to receive the Panel report. They utilize a tiered system by which Congress is divided into three tiers. The first tier comprises members on the Appropriations Committee and members who sit on cancer-specific caucuses or deal with cancer legislation. Tier two comprises members who have introduced cancer-specific bills. Tier three comprises all other congressional members. Legislators in tiers one and two receive the report release email, as well as two select members from tier three based on the report topic. In the past, report release emails have not been sent to state legislators. The list of Congresspersons who receive a report is housed in the Government and Congressional Relations Office at NCI and is generally not submitted to the Panel office for record.