

Interagency Breast Cancer and Environmental Research Coordinating Committee

**Department of Health and Human Services  
National Institutes of Health  
National Institute of Environmental Health Sciences  
National Cancer Institute**

**Minutes of the Interagency Breast Cancer and Environmental Research Coordinating  
Committee Meeting**

**January 23-24, 2012**

The Interagency Breast Cancer and Environmental Research Coordinating Committee (IBCERCC) convened its fourth meeting on January 23, 2012 at the Rodbell Auditorium at NIEHS in Research Triangle Park, North Carolina. The committee chair is Michele Forman, PhD, of the University of Texas MD Anderson Cancer Center.

The meeting was open to the public on January 23, 2012 from 8:30 a.m. to 5:30 p.m. and on January 24, 2012 from 8:30 a.m. until adjournment at 2:53 p.m. The agenda for January 24, 2012 included provision for a 15-minute session devoted to public comment. Notice of the meeting was published in the *Federal Register*.

The IBCERCC is a congressionally mandated body established by the National Institute of Environmental Health Sciences (NIEHS), in collaboration with the National Cancer Institute (NCI). This Committee is comprised of 19 voting members, including representatives of Federal agencies; non-federal scientists, physicians, and other health professionals from clinical, basic, and public health sciences; and advocates for individuals with breast cancer. The Committee encompasses three subcommittees, each charged with the preparation of one section of the Committee's final product, a report to the Secretary of the Department of Health and Human Services: the State-of-the-Science (SoS) subcommittee (chaired by Dr. Forman), the Research Process (RP) subcommittee (chaired by Dr. Gould), and the Research Translation, Dissemination, and Policy Implications (RTDPI) subcommittee (chaired by Ms. Rizzo).

**Members Present**

Janice Barlow, PNP

Rachel Ballard-Barbash, MD, MPH

Beverly Canin

Ysabel Duron

Suzanne Fenton, PhD

Michele Forman, PhD, MS

Michael Gould, PhD

Sandra Haslam, PhD

Ronda Henry-Tillman, MD

Karen J. Miller

Sally Perreault-Darney, PhD

Laura Nikolaidis, MS

Marcus Plescia, MD

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Kenneth Portier, PhD  
Jeanne Rizzo, RN  
Gayle Vaday, PhD  
Cheryl Walker, PhD

**Ex Officio Members Present**

Dale Sandler, PhD  
Neeraja Sathyamoorthy, PhD

**NIH Staff Present**

Jennifer Collins, MR  
Gwen Collman, PhD  
Caroline Dilworth, PhD  
Christie Drew, PhD  
Gary Ellison, PhD, MPH  
Symma Finn, PhD  
Nonye Harvey, MPH  
Christie Kaefer, MBA, RD  
Ed Kang, NIEHS OCPL  
Les Reinlib, PhD  
Claudia Thompson, PhD  
Deborah Winn, PhD

**Other**

Kathy Brown-Huamani (by telephone)  
Connie Engel, PhD  
Ernie Hood  
Shelia Zahm, ScD

**I. Welcome and Introductions**

Dr. Forman welcomed attendees, and had everyone in the room introduce themselves. She thanked the committee members and staff for the extraordinary amount of work on the report that had taken place since the last meeting. She said that the purpose of this meeting would be to work on synthesizing the elements already in place, threading together the themes and recommendations and achieving the goal of speaking in one voice. She reiterated the importance of communicating a sense of urgency in the report, particularly since it would resonate in so many diverse communities.

**II. Opening Remarks**

Dr. Collman introduced a pre-recorded video greeting from Dr. Linda Birnbaum, Director of NIEHS and NTP, who was unable to attend the meeting in person. She thanked the members of the committee and staff for their hard work and commitment to the report project. She

particularly wished to thank Dr. Shelia Zahm for her contributions. Dr. Zahm has retired from federal service and although she is no longer able to participate as a federal representative on the committee, she has graciously agreed to assist in the efforts to finish the report. Dr. Birnbaum welcomed Dr. Ballard-Barbash of the National Cancer Institute to the committee, who is representing the NIH and filling the vacancy created when Dr. Vivian Pinn retired in 2011.

### **III. Overall Impressions of the IBCERCC Report Draft**

Dr. Forman asked each committee member to briefly summarize his or her initial thoughts in response to the following questions:

- 1) What were your **overall impressions** of the draft IBCERCC report?
- 2) Are there **significant gaps** in the draft of the IBCERCC report?
- 3) Are there **areas** in the draft report **that need greater clarity** (text or visual)?
- 4) What **audience(s)** did you anticipate that the IBCERCC report will reach/impact? Does the current draft accomplish this?
- 5) What were the **2 most important messages** that came through to you after reading the current draft of the IBCERCC report?

Ms. Harvey felt that the report was well-written. She said that some of the recommendations could be tweaked and warrant discussion. She noted some differences in the content from the subcommittees, and that uniformity of language would be important to achieve.

Dr. Sathyamoorthy said she was impressed with the document, and that it is a very comprehensive study that reflects the tremendous amount of work put in. She felt that some of the ideas in the draft could still be distilled and better focused, with overlapping themes in different sections causing redundancies.

Dr. Henry-Tillman felt that the document draft was very comprehensive, but very long, with the intended audience unclear at times. She noted that if she was not on the committee, she probably would not pick up the document and read it. She felt that the most important points included were the recommendations, but that the message of the document needs to be more concise, with a well-defined audience.

Dr. Canin felt that as it stands the document is not as bold or punchy as the committee had intended. She said it might be helpful to reconsider the order of the content. She missed a summary at the beginning with the key recommendations. She noted that the IOM report's recommendations were all targeted, but that those made by this committee were not. Looking at the original charge, she felt that the imprimatur to "reduce the burden of breast cancer" had not been addressed much in the report. She thought that the duties outlined in the legislature should be reflected in the report's content. She felt that in its current state the report is not yet a "usable

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product.” She said that the report is not bold enough in addressing disparities and inequities, and that more references to those issues should be included. She recommended consideration of different summaries to directly address different audiences. She noted the need for coordination and the formulation of a strategic plan for the future.

As a new committee member, since she had not been part of the process, Dr. Ballard-Barbash said she would limit her comments. She felt it would be useful to summarize the recommendations as well as the key evidence in the various areas of the report.

Dr. Portier said that he thought a big jump had been made from Version 19 to Version 21. He felt that the State of the Science section read much better than it previously had. As he read the document, he said, he was confused about how to integrate public health policy and regulatory recommendations. He agreed that references to disparities were insufficient; missing an opportunity to point out that there is not a lot of good research to support how public health policy and regulation are done in disparate communities. He felt the document needed a clearer storyline, with a backbone related to identified audiences. He said that the policy section needs re-organization to more clearly focus on the targets.

Ms. Miller said she was unclear about the roadmap for the project moving forward. She noted redundancies in the report draft. Answering the prepared questions, she provided her overall impressions. She noted several repeated themes, such as “precautionary principle” and “prevention.” She recommended the inclusion of more sub-headings for major themes. She liked the flexibility expressed in language about the proposed framework, acknowledging that it might change in response to new research findings. In terms of gaps in the report, she wished to see more examples of bold, out-of-the-box research included. She said it would be important to be cognizant of how the IOM report had flowed out upon its release. Responding to question #5, she said that the most important messages for her were prevention, the importance of animal models, and the need for a new health paradigm.

Dr. Gould said he was quite impressed with the most recent revision. He felt that the State-of-the-Science subcommittee had done an excellent job of reviewing the science, but that many of the facts presented still needed to be vetted by experts in the field to ensure accuracy. He endorsed the inclusion of just two or three major recommendations in the Research Process section, but felt that there may have been too many recommendations in the Research Translation, Dissemination, and Policy Implications section, and suggested that they might be consolidated. He said that the language regarding regulatory agencies should be more specific, and that use of the term “primary prevention” may be inaccurate. He felt that all of the sections will need to be looked at carefully in that one inaccuracy could threaten the impact of the report.

Dr. Perreault-Darney felt that the report was much improved, and agreed that people were unlikely to read the entire document. Thus, she said, the recommendations need to be clear and concise, with the use of sub-heads as appropriate. She recommended a clear focus on unique

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interagency initiatives. She approved of the emphasis on innovation and recommended that it be strengthened wherever possible, as well as attention to health disparities. She recommended caution regarding references to reform of the Toxic Substances Control Act (TSCA). She was struck by how many of the recommendations refer to generic needs that would apply to many diseases with an environmental linkage.

Ms. Rizzo was pleased with the current iteration of the SoS section, with the inclusion of transdisciplinary elements and animal studies. She felt that in the RP section, there should be a more direct focus on the various agencies and how they could be responsive to this effort. She noted that the report does not currently address the cost of breast cancer – the human toll and the dollar toll, which would help make the case for the imperative of addressing the disease. She felt that the word “uncertainties” had not been consistently dealt with in the report. She agreed that there were several overlaps to be addressed. In terms of audiences for the report, she stressed the importance of intermediaries, who will help disseminate it and its messages to the broader public. She noted the need for a communications plan to address multiple audiences. She agreed that the Executive Summary would be crucial, but that there will be multiple levels of response over time. She said that the report itself will be the bible that will support many other communications. She specified that policymakers and their staffs will be a major audience for the report.

Overall, Dr. Fenton felt that there were “some really solid messages” in the draft report, but that the recommendations need to be streamlined. She recommended strengthening the message that mammary glands must be included in all toxicology testing. She said that the SoS group had worked to ensure that the racial and ethnic issues and different breast cancer subtypes were addressed. She said that the placement of some of the elements designated as “some evidence” or “research gaps” may need to be reconsidered. She recommended more visuals, particularly in the last third of the document. She felt that the policymakers and agency personnel would be the major audiences for the report, as well as breast cancer advocates. She found the recommendations to be the major message, and felt that they and the table of breast cancer advances stood out nicely. She felt that the primary prevention message was not strong enough.

Dr. Walker found the report draft easy to read. She spoke about putting it into historical perspective along with the President’s report, which delineated the breast cancer problem, and the IOM report, which discussed the uncertainties related to the problem. When the IOM report was rolled out, the press desired some sense of the magnitude of the issue. Also, the message of uncertainty in the IOM report was translated by some to mean that no problem was identified, which of course is not true. Dr. Walker said that the sense of urgency, that there is a problem, is central. Thus, this report needs to have the life course perspective, and note that the quantum leaps in genetics have already been made. She felt that the report needs to be strengthened in the sense of urgency to be communicated, as well as the need for innovation and more prioritization. She felt that the RP section had too few recommendations, whereas the RTDPI section had too many. She added that the SoS section should include more discussion of epigenetics.

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Ms. Duron said she did not at first read all 147 pages of the draft, but instead went directly to the recommendations, as would members of the media and the public – anyone who would want a quick read of what the report is all about. “Everything that must be said should be said in the initial 2 or 3 pages,” she said. She also felt that the sense of urgency was lacking, and that a red flag needs to go up on certain issues, particularly lack of knowledge in this area about women of color or multicultural communities, and whether they are equally impacted by the same environmental factors. She said research needs to target these issues, and the report’s recommendations in that area were not strong enough. She added that “approaches, materials, and messaging must all be culturally and linguistically sensitive and appropriate,” and that minority researchers must be included at all stages and venues of dissemination. Also, all underserved women should be referenced, beyond just black and Hispanic women. She said that there is a critical need to share the current information across the agencies, calling for collaborations, as opposed to the work currently being done in siloes. She noted that there are fewer people in the media who are charged with reading and analyzing reports such as this, and so it is even more critical that the major messages come out clearly and strongly in the Executive Summary and the recommendations.

Dr. Haslam said she thought that the conclusions should be “right up front” in the report, as should the recommendations. She added that the terms “bold,” “innovation,” and “novel” are meaningless without context and definition. She agreed that there were redundancies to be addressed, and that better integration is needed.

Dr. Vaday disagreed that there was a lack of interagency collaborations in the past. She felt that the agencies work to complement each other. She felt that the report currently does not speak well to breast cancer researchers, but seems to be more directed at environmental researchers. She said she got lost in the last third of the report, and that it was moving too far away from the breast cancer problem itself. She reiterated the point made by several others that the sense of urgency needs to be strengthened. “Just state it up front – we need to end this disease,” she said.

Dr. Plescia said he approached reading the draft from the perspective of a researcher working in cancer who may not know as much about some of the environmental issues. He felt that the opening, talking about the scope of the problem, was good, but perhaps could be stronger and bolder. He found the SoS section quite useful, particularly the narrative about animal studies. However, as a clinician and researcher he found some of that section very hard to follow, and that it should be gone through with an eye to comprehensibility for non-researcher readers. He particularly liked the diagram on page 92, and felt there should be more visuals like it in the report. He said he still didn’t perceive a clear call to action. He was concerned about the complexity seen in the translation and dissemination sections, and felt that the policy section could be punched up to achieve more leverage and interest from the media.

Dr. Nikolaidis said that her overall sense of the report was that “we missed the mark,” and that the original vision for what it was all about had been lost. She felt that in the process the report

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had become a tool “to push an environmental agenda,” and was not the critical analysis of breast cancer research that was originally envisioned. She noted that 40,000 women per year continue to die of breast cancer, and that she has no confidence that anything in the report will change that fact. In terms of the messages, she felt that reading the report would not give anyone the sense that there are any problems in the area of breast cancer research, or that there is any lack of progress, or any lack of collaboration or innovation. She said the messages that came through to her were support for the status quo in federal research, and an aggressive push of a policy agenda on chemical exposures. She was specifically concerned about the extrapolation from animal data included in the report, particularly recommendations to develop public policy on the basis of animal data. She also expressed concern about the lack of evaluation or prioritization in the report; that everything seemed to be presented on an equal level, with no sense of what is most important or what the most important gaps are. She felt that the document will only add to the overload of information on breast cancer presented to the public, and that it will do nothing to propel efforts to save lives.

Dr. Zahm felt that the report was “very thorough and impressive.” Despite its length, she noted some gaps, particularly the minimal attention given to the exposure side of the equation. Although risk factors were discussed, there was little on the challenges or opportunities for innovation and advances in exposure assessment. For example, she said, the word “exposome” never appeared. Another gap was discussion of access to both breast tumor and normal tissue. She noted that there were several duplications to be addressed, and that some of the recommendations were too wordy. She said that the agencies were the primary audience, and not just the research funding agencies, but others such as the FDA. She felt that the most important messages were that the environment and that taking a life course approach are important.

Ms. Kaefer noted that the report is quite broad, and does include several areas that apply to multiple health issues, including other types of cancers. She said that knowing that non-scientists will be reading the report necessitates simplification of the language in several areas, sections that are presently very technical. She pointed out that the discussion of risk varied widely, denoting the fact that several different people had been working on the report, highlighting the need for more consistency. She felt there were great examples of federally funded projects included, but that it might be useful to include some information on the impact of some of the older initiatives. She approved of the discussion of the framework and national strategy in the report.

Ms. Collins thanked everyone for their hard work. She acknowledged the fact that there are many redundancies in the draft report, but said that they represent obvious areas to integrate the content. She also pointed out that there are areas where terms need to be defined, as well as some inconsistency in definitions.

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Dr. Collman said she had read the latest version of the document in the context of the original mandate contained in the legislation, to see whether the report in its current form accurately reflects the original intent. She noted that there are some elements that still need major adjustments, either because the committee has not done everything it said it would, or there is a need to revise the original intent based on what actually was done. She cited the definition of the environment as an example of her point. She noted that in some sections, answers are left to the reader, and the committee cannot afford to do that given the many and diverse audiences. The conclusions should not be made by others; the committee should draw the conclusions and make them clear. Some of those take-home messages should be in the introduction. She also suggested the inclusion of a conclusion or summary chapter different from the Executive Summary—a section to pull everything together. She noted that there had been little or no reference to radiation exposures, and felt that there was much new work that needed to be included. She also wanted to see a section in the SoS section on the mechanisms of breast cancer. She recognized that there were some mechanisms, but was unsure that all known mechanisms were captured effectively. Expanding discussion of mechanisms would allow further discussion of how they change with various exposures. That would bring the discussion back to the breast cancer researchers, as the intersection of mechanisms and exposures is the new innovative scientific arena, with opportunities for synergy, collaboration and coordination. She also mentioned that one of the original documents called for the creation of a research strategy, which has not been done. There is much background information on research in the document as it stands, but it needs to go to the next step. There should be more explicit language in the report as to how agencies should work together in the future, she said, and in the recommendation sections there is not enough substance to create a committee to address some of those needs.

Dr. Winn said that most of her thoughts had already been expressed, and that she was impressed with the nuanced discussion thus far. She felt that the most important items had been captured to support the recommendations. She agreed with Dr. Birnbaum's point that there are some things this panel can do uniquely, and is best informed to accomplish. She said that the differences with other reports should be expressed specifically. She recommended ensuring that the recommendations are explicit in terms of who will have the responsibility to carry them out.

Dr. Forman said it was time to achieve what she calls "crynthesis," or critical evaluation with synthesis. She said it would be important to put this report in context in the wake of the two other recent reports. She agreed with the suggestion to put the conclusions and recommendations up front in the report, so that even the casual reader would be exposed to them. She said that ultimately "what we want is to have this integration, we want this oversight, we want the ability for this area, breast cancer and the environment, to be not only taken seriously, but taken seriously in certain ways, and should be very strategic in the manners in which we want the issues to be handled." She felt that the report may veer off and become too environmental at times. She urged the generation of some overall, overarching

recommendations, to be included in the Executive Summary. She noted that there need to be conclusions to the individual chapters, some of which are lacking them currently.

#### **IV. Group Discussion: Overall Impressions**

The balance of the session was devoted to open discussion of the points that had been made in the individuals' comments.

Dr. Portier pointed out that while breast cancer mortality is declining, incidence of the disease is flat. Thus, with growing population, more women are developing the disease, and the only approach to reducing that incidence is primary prevention, because chemoprevention and treatment only reduce mortality. He said that statement should be made and made clearly at the very beginning of the report. He also called for some discussion of the utility of federal research in terms of assessing risk.

Dr. Henry-Tillman expressed her concern about the previous comment that the committee had missed the boat in terms of fulfilling its original mandate.

Dr. Walker asked Dr. Nikolaides to elaborate on her comments, particularly regarding an "agenda." Dr. Nikolaides reiterated her point that the report seemed to be concentrating on chemical exposures, which, although a worthy cause, was not focusing on what to do about breast cancer incidence, mortality and causes. She said that the point was to tie together the biomedical fields looking at breast cancer metabolism, initiation and such with the environmental researchers, to create an intersection of those worlds, and she did not see that occurring in the report.

Dr. Gould noted that now the discussions were real based on the existing document, as opposed to prior discussions that were more hypothetical in nature. Thus, the true gaps can now be identified. He called for an opinion in the SoS section as to whether the committee really believes that a large percentage of the etiology of breast cancer is associated with environmental chemicals and radiation, or whether those exposures are minor concerns and research should look elsewhere. In the RP section, the question should be, is the possible environmental etiology of breast cancer researched adequately and funded adequately? He recommended that the terms "primary prevention" and "prevention" be carefully defined in the report, as they are central to the call to action.

Dr. Perreault-Darney noted that several speakers had called for clarification, simplification, and strengthening of the report's message, even though the problem is complex. It should be kept in mind, she said, that many different people will read the report, and it could be dismissed if the message seemed to be yet another report calling for more money for more research in a given area.

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Ms. Canin asked Dr. Nikolaidis whether she felt that the original legislation and the mandate for the committee adequately expressed the intent. Dr. Nikolaidis noted that the original intent was to create a funded research center with advocate involvement, encouraging a collaborative, multidisciplinary look at environmental issues and breast cancer. That center never came to be, but the committee was created instead. She reiterated that the intent had been to look at how to decrease the incidence and mortality of breast cancer, not to set up an environmental agenda. Ms. Canin said she had been concerned about whether the committee had fulfilled its original mandate to reduce the burden of breast cancer. She felt that it would still be easy to focus more in the report on the breast cancer element. She said that with 60% of the causes of breast cancer still unknown, much of that would be attributable to environmental factors, and the mandate was to address breast cancer and the environment, so the approach is appropriate. Dr. Nikolaidis said that she would take a broader approach to the unknown factors to include things like lifestyle, but that the report seems to focus unduly on chemical exposures. She said she had seen no evidence to convince her that chemical exposures were causing a majority of breast cancers not explained by genetic mutations.

Dr. Haslam noted that breast cancer etiology is complex and often involves interactions beyond the initial mutation or exposure event, and that environmental factors impact those subsequent steps in the process. She felt that research really needs to get a handle on the factors known to impact the disease process. Dr. Nikolaidis noted in response that there is no relative ranking of factors in the report. She wanted to see the report looking at more global factors that will actually make a difference in terms of prevention.

Ms. Miller felt that the committee had been mandated to look at the environment and breast cancer, and so needed to generate a document and not pass the buck. She felt that the draft report does focus on the mandate, and that if some of the critiques brought up in the session are addressed, it will be an action document that will change the paradigm of health.

Dr. Fenton said she disagreed with Dr. Nikolaidis, but that she had brought up some very important points that would improve the report. She said that perhaps the SoS section had not adequately made the point that there have only been a few chemicals that have been looked at. She noted that every time a new chemical is screened, mammary gland effects should be part of the screening. Also, a limited number of risk factors have been evaluated. She felt that the risk factors actually had been ranked in the section. Dr. Haslam pointed out that the concern was not with ranking but with relative contribution. Dr. Fenton said that was the area where more research is clearly needed. “We make it very clear in the SoS that the work in humans has not been done, but we really need to pay attention to this,” she added. She noted that the research programs such as ToxCast and Tox21 were the wave of the future in this area and were referred to in the report. Dr. Collman said that it was urgent for other members of the breast cancer research community to understand the existence and value of those resources.

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Dr. Forman described the tension between what people want to hear is known by the scientific community, and the actual lack of knowledge. She also noted that carcinogenesis is today considered to be a series of multiple events that can occur across various cancers, and is not a process peculiar to any particular type or subtype, with mechanisms and pathways shared with other cancers such as colon, prostate, and others. Thus, the focus should not be on specific mechanisms of breast cancer, as that is not the state of the current science, although there could be more discussion of particular risk factors associated with subtypes. Dr. Nikolaidis said she appreciated Dr. Forman's points, but still wished to see the intersection between breast cancer and epidemiology better tied together in a meaningful way in the report.

Dr. Walker wanted to explore how the report might need to be adjusted or changed to avoid the impression of an environmental agenda mentioned by Dr. Nikolaidis.

Dr. Gould cautioned about the use of percentages to describe causes of breast cancer. He also noted that there are few oncogenes associated with breast cancer, which does render it rather unique among cancer types. He said that to prevent breast cancer, it must be thought of broadly, as there is so much endogenous etiology involved.

Dr. Plescia agreed with Dr. Nikolaidis' point that the need for a breast cancer research agenda is not as strongly expressed in the report as it should be.

Dr. Ballard-Barbash said that as the newcomer on the committee, it had been her impression from afar prior to joining that the report was intended to deal with environmental contaminants, and after reading the draft, that remained her impression. She felt that it would be disingenuous to claim that that was not the committee's focus. She added that some other related issues should be addressed in more detail in the report, such as the impact of lifestyle, social and economic environment, the dramatic decline in HRT and its impact in breast cancer incidence and mortality, and being on the cusp of major change in pharmacoepidemiology. Dr. Forman agreed that some of the factors she mentioned should be synthesized into the SoS section. Dr. Ballard-Barbash recommended the use of tabular layout to more effectively communicate some of the issues to be brought out in the synopses. Dr. Winn added that she thought the report should be clearer about why more attention is being paid to certain areas than others that may have been dealt with in more depth elsewhere.

Ms. Barlow, who had not been present for the earlier discussion, shared her overall impression of the report. She felt that the draft was too long, particularly the SoS section and the policy sections. She particularly liked the RP section. She wanted to see more emphasis on the importance of animal research. She was comfortable with the concept of the report having an environmental agenda, as a complementary report to others that are available. She found the two most important messages to be the need for a conceptual framework for how to look at breast cancer and the environment, as well as the need for interagency cooperation and coordination.

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Dr. Henry-Tillman agreed with the need to include pharmacoepidemiology, noting that in her clinical practice causes are not typically discussed with patients, with the exception of factors such as HRT.

Dr. Gould felt that the report's environmental agenda should inform a broader context, as the most important problem at this point is to understand the etiology of breast cancer. If the belief is that there are many chemical exposures associated with the development of the disease, that should be stated...or the reverse, if that is the belief. Either way, the clear expression is a service to the community, helping to define where limited resources should be utilized.

Ms. Rizzo said the report has an environmental *health* agenda, and that that was what the committee had been charged with—a drive to look at something that had not previously been given adequate attention. As a result, things will be learned that will apply more broadly and contribute to the larger field. “Our task here [is] to bring the environmental health lens to breast cancer, and approach it as broadly as it needs to be, but to recognize that the area that has not been addressed are the contaminants and the environmental factors where we haven't studied it,” she said.

Dr. Collman recommended thinking about “the hook” in a slightly different way, focusing on breast cancer as a disease that starts much earlier than previously thought, with a latency period that goes back to the grandmother, mother, and developing fetus, child, teenager and reproductive-age woman. Over that course of time, the wide variety of exposures impact differently, at different times. That spells out the complexity in a very different way, she noted, and puts prevention in a different light. “So to have that prevention theme that is bigger and broader than the breast cancer incidence of today, to have some hope that we could dramatically change, wipe out, reduce to a minimum [breast cancer] if we do all of these things that would give us a better understanding of how they all work together...and then figure out the policy actions, the medical interventions, the behavioral interventions, the consumer products, and then the testing of all of those, pre- and post-, will give us the very integrated, transdisciplinary research with answers that will put that prevention in perspective,” she said. She said that that could be the key message pulled together in the report.

Dr. Haslam discussed the fact that various pieces of new knowledge in areas such as diet or irradiation help add to understanding of the complexity of the disease, complexity that occurs over a period of time. Dr. Nikolaidis agreed with Drs. Collman and Haslam, and said she would be happier if the report reflected their remarks. She preferred to focus more on the research than on policy or translation.

Dr. Forman said she was gathering from the discussion that the committee was trying to capture the main themes and translate them to multiple audiences. She asked, “What are the major themes that we want to invest ourselves in for this major report?”

Dr. Walker suggested that one important theme should be the concept of legacy, in terms of breast cancer and the life course. Dr. Fenton added that there was a need for a visionary statement about how all of the small parts add up to understanding the disease's etiology. Dr. Walker said that we inherently understand the concept of small contributions, with cumulative effects. Dr. Collman pointed out that to thoroughly understand that concept would require an enormous amount of research, which is not there yet for many of the factors people are asking questions about.

**V. Group Discussion: Overarching Themes, Gaps, and Conclusions**

Dr. Forman asked committee members to continue excavating the themes they wanted to commit to having in the report.

Dr. Gould suggested consideration of an area of breast cancer research he considered to be underappreciated, underfunded, and under-personneled—breast cancer etiology. He said that prevention of breast cancer, whether primary, secondary or tertiary, lies in understanding the etiology of the disease. He felt that the etiology of breast cancer is unique compared to other cancer types. He said that the intersection of etiology and prevention would provide a context for everything the committee has been working on. Dr. Walker endorsed Dr. Gould's suggestion, particularly in the context of prevention. Ms. Canin asked her to define the prevention being endorsed. She said that as a molecular biologist, she saw prevention in light of the effort to identify modifiable risk factors, which could be used to prevent the disease.

Dr. Fenton suggested going back into the funding agency (RP) section of the draft, to make some bold statements and provide some recommendations. She suggested, for example, federally funded meetings for breast cancer researchers and advocates, as brainstorming sessions. She added that if the committee believes NIH peer review needs updating, it should say so in that section.

Dr. Collman felt that the encouragement of research partnerships was well-stated in the draft, and was one of the major, evolving take-home messages in the report.

Ms. Rizzo said that the RTDPI subcommittee had found itself focusing often on the concept of investment, with the idea of a long-term legacy return, as opposed to the simple expenditure of resources. Dr. Walker reported that the subcommittee had also worked on a potential acronym to illustrate the central concepts in the report, starting with Legacy, Prevention, Engagement, and Investment. Urgency was also suggested. Dr. Nikolaidis asked what was meant by Legacy of breast cancer. Ms. Rizzo explained that the idea is to do something now so that daughters do not develop breast cancer ten, twenty or more years from now. Dr. Walker added that the concept had been a friendly amendment to the subcommittee's discussion of life course.

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Dr. Forman suggested “transdisciplinary” as another overarching theme. Dr. Walker added that the term should be expanded to the inclusion of advocates in all activities, not just transdisciplinary in the scientific disciplines.

The group discovered and discussed the TULIPE acronym—Transdisciplinary, Urgency, Legacy, Investment, Prevention, and Engagement.

Suggesting the addition of an “r,” Dr. Portier said that if there is to be progress in prevention, there needs to be research that supports assessing risk. The group discussed at length the concept of risk in its many permutations, in the context of how it should be treated as an overarching theme of the report.

Dr. Gould noted the importance of drawing a distinction between population risk and individual risk, particularly in the context of recommendations.

Ms. Miller stressed the importance of dissemination as an overarching concept.

Ms. Canin recognized “framework” as an important theme. Dr. Forman agreed that it is a theme inherent to each of the chapters. Dr. Collman said that to her the framework is a way to think about and display the complexity of the research questions, and a tool to keep track of progress while being accountable. Ms. Canin suggested there might be a graphic visual to illustrate the framework concept.

Ms. Rizzo brought up the sometimes years-long lag time associated with data, wondering whether there might be a good opportunity for infrastructure investment to ameliorate that situation. Dr. Fenton pointed out a section of the SoS section that addressed that need. Dr. Portier mentioned that in some circles, the trend is actually going in the wrong direction, and the lag is increasing.

Dr. Forman described a treatment of the framework concept in three iterations: research, data, and dissemination, in cube form. She asked to return to discussion of the primary prevention concept. She felt it was important to drive the point home about the decreasing mortality of breast cancer in the face of flat incidence. She said it should be stated in the Executive Summary, the SoS section, and in each one of the chapters. This is particularly important, she said, because primary prevention does not raise money. The economic costs of not preventing the disease should be included, she added. Dr. Portier said that with cancer, disease avoidance provides a substantial return. Dr. Collman identified this area as an action item; that at least a paragraph needs to be added about the economics that frame the prevention issue. Dr. Haslam pointed out that the life course concept could also be intertwined with prevention.

Dr. Winn discussed the idea of a research pipeline that would take disparate elements of environmental and medical research and outflow them to influence regulation. She cited the example of tobacco control to illustrate the concept.

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Dr. Perreault-Darney discussed the need to link different types of databases together in order to help move the breast cancer field forward. That would include the ability to incorporate medical records and to integrate other disparate forms of data.

Dr. Fenton related another potential version of an acronym: Transdisciplinary Organization (for using a) Lifestage approach (for) Engagement (and) Accountability (for) Prevention (of Breast Cancer) i.e., TO LEAP.

Regarding the informatics side, Dr. Perreault-Darney wondered whether the RP subcommittee had found it difficult to drill into the data properly to glean the sought-after information, in terms of how projects were coded. Dr. Forman said that challenge should be addressed as an action statement, in that the transdisciplinary approach needs to be part of the paradigm of an informatics platform. As such, it would then provide dynamic data for people to assess risk at various levels, she added. Dr. Perreault-Darney reiterated her point that there are huge databases associated with environmental monitoring, chemical screening programs, and public health projects such as NHANES that all need to be linked to help understand exposures and health. That will require much transdisciplinary attention, and those skills are just being learned, she said.

Dr. Portier felt that it was important in the context of this report to identify achievable goals and recommendations, and that in this instance the goal would be to be able to look at breast cancer data as it is generated, to place it in the breast cancer framework in order to help identify research gaps in a real time setting. Dr. Gould added that in the proposed framework, each box would represent a particular area of breast cancer research and would have a code that would link to grants, publications and PIs in that area. Thus, holes where there is a lack of research would be evident. Grants are not presently coded, and this system would address that lack. Dr. Portier said it would be coding that facilitates integration.

Dr. Collman read the numbered items in the committee's charter to focus further consideration of overarching themes and the status of the report draft.

### **VI. Group Discussion: Recommendations**

Dr. Collman introduced the session, which was to focus on the recommendations previously identified by the subcommittees that are to be included in the report's Executive Summary. The recommendations had been sent out to all committee members in table form, with the opportunity for individual members to register their opinions and comfort levels with each recommendation. Members were to rate each recommendation as Green, Yellow, or Red. Green signified *I am very comfortable with the recommendation as it is currently presented. The recommendation does not need discussion, but it might require some minor editing and wordsmithing to improve clarity.* Yellow signified *I am generally comfortable with the recommendation as it is currently presented; however, it needs some discussion and refinement of content at the meeting.* Red signified *I am uncomfortable with the recommendation as it is*

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*currently presented. The recommendation needs thorough discussion at the meeting.* There was also to be provision for discussion of new recommendations, as well as “smaller” recommendations that would appear only in the individual chapters.

Dr. Collman said the discussion would be ordered according to the recommendations with the most perceived need for discussion, per the Green, Yellow and Red votes. Thus, those recommendations with the most Red votes would be discussed first. Ms. Rizzo and Dr. Gould co-facilitated the session, with each facilitating discussion of recommendations emanating from each other’s subcommittees. Discussion of each recommendation began with a brief summary of the intent of the originating subcommittee from one of the members. Discussion and the offering of “friendly amendments” followed, culminating in consensus that the recommendation had achieved acceptability for all.

- Create a new national breast cancer prevention strategy that emphasizes primary prevention, establishes deeper coordination across both research and regulatory agencies, and sets tangible goals for reducing or eliminating toxic environmental exposures implicated in cancer causation. PAGE 139 (8 Green, 4 Yellow, 4 Red)

Dr. Zahm spoke for the RTDPI subcommittee. She said the recommendation was crafted to include both research and regulatory agencies, with the emphasis on primary prevention. She said it closely mirrors text in the chapter, which highlights the need for closer coordination. She anticipated, based on discussions earlier in the day, that there might be objections to some of the individual phrases within the recommendation.

Dr. Gould said he did not understand the recommendation. He felt that “primary prevention” needed to be clarified. He was unclear about the language following that, and suggested that it might be deleted. Dr. Vaday felt that the recommendation was too broad and vague in defining the research and regulatory agencies. Dr. Haslam objected to the word “toxic.” Dr. Fenton voted Yellow, because she thought the umbrella represented by the recommendation was too big, with it being unclear how or who would create the stated strategy. Dr. Portier had voted Red, and also felt the recommendation addressed too big of an umbrella, and that it addressed policy but not federal funding for breast cancer research, with no discussion about changing the portfolio mix. Dr. Walker also voted Red, sharing the concerns of the others. Dr. Forman said there appeared to be consensus that the recommendation was too broad. She wondered if some of the pieces might be more appropriate elsewhere, and suggested flagging approval of various parts, to consider moving them. Dr. Nikolaidis took issue with the concept of a strategy, in that it implied that how to achieve primary prevention is well known, when it is not, and more research is what is needed. Ms. Rizzo, from the subcommittee, explained that the recommendation was in the context of a specific chapter, trying to address what it would take for there to be a prevention strategy across agencies.

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- Create a standing interagency breast cancer and environmental factors research coordinating committee. PAGE 89 (9 Green, 3 Yellow, 4 Red)

Dr. Portier spoke for the RP subcommittee. He said the recommendation followed considerable discussion within the subcommittee about the need to coordinate change in research related to breast cancer, with much interagency research taking place in many centers. This came following the subcommittee's recommendation of a framework, to address the question of who would own and manage the framework. He mentioned that an alternative approach might be to simply state the intentions involved but leave out the mechanism, leaving that to the Secretary to decide.

Dr. Plescia, who voted Yellow, asked whether there were any examples of a committee effectively carrying out this type of coordination role. Dr. Vaday cited the Interagency Autism Coordinating Committee (IACC) as one successful example. Ms. Canin said she voted Yellow because the recommendation did not say what the committee would be charged with. Dr. Zahm was skeptical about the idea that an external group could coordinate agencies, and was uncomfortable with the concept of creating another entity to fund breast cancer research. Dr. Ballard-Barbash also objected to that idea. Dr. Collman noted that the IACC is very involved in strategic planning and keeping the agencies accountable for making progress. Dr. Winn noted that when creating a committee, it might well live beyond its usefulness. Dr. Zahm said the recommendation should be more targeted as to who will do what. Regarding the extra funding, Dr. Portier said most of the committee was neutral on the idea, but to fill gaps, funding would be necessary. He urged retention of the idea, by offering a "carrot" to researchers to work on particular issues, which is now lacking. Ms. Rizzo summarized the discussion, saying that it appeared that it was not essential that the proposed committee have separate funding, but imperative that there is a commitment to the needed coordination, and that gap funding needs to be addressed somewhere, if not in this fashion.

Ms. Duron discussed the need to address the many groups of people who are under-researched, and suggested inclusion of language incorporating minority researchers and advocates nominated by their peers in the coordinating committee, specifically, as a way to highlight those concerns to readers of the report from minority communities. She noted that the issue of minority inclusion in general should rise to the top in the report, which it currently did not.

There was extensive further discussion of the role of strategic planning in the context of the proposed committee. The suggestion was made to strike the word "standing" to clarify that this would be a long-term committee that would work on strategic planning.

Ms. Rizzo summarized the balance of the discussion, and called for any further objections from those who had voted Yellow or Red. There being none, consensus was achieved on the recommendation.

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- Translate the findings of research related to breast cancer and the environment into recommendations for public health interventions, such as health behavior interventions, regulatory policy, and further research. PAGE 118 (10 Green, 3 Yellow, 3 Red)

Ms. Miller spoke for the RTDPI subcommittee. She said they had felt that there was sufficient relevance in the text to support the recommendation. She felt that every part of the recommendation was very important.

Dr. Vaday said she had voted Red because she did not understand the recommendation. Dr. Henry-Tillman said that the recommendation was trying to communicate the fact that there is a great deal of information available, but people don't know about it. Ms. Miller said that there needs to be something in place to provide that information to speak to individual behavior or advocacy work. Dr. Ballard-Barbash said she had voted Red due to language referring to the use of basic science to create guidelines for public policy, a concept which made her very uncomfortable. Dr. Collman made the point that some people consider epidemiological research to be basic, and the point was to use all relevant data, and that perhaps the recommendation needed some re-wording on that basis. She noted that the kernel of the recommendation was the concept of expediting communication of data from the research community and the various databases to the various stakeholders who would need it for decision-making. Dr. Nikolaidis voiced her concern about contributing to the overload of information going out to the public. Dr. Fenton said she had voted Yellow, again because the umbrella was too large. Ms. Canin suggested including allusion to who would be translating the findings. Dr. Portier said he had voted Yellow, taking some issue with the way the recommendation was worded, particularly the word "translate." He suggested replacement wording, which several members subsequently discussed: "Periodically evaluate the state of scientific knowledge on breast cancer and association with environmental and lifestyle factors, to ensure that current public health and regulatory policies and interventions are based on and consistent with best available knowledge." Members appeared to approve the replacement, although it was pointed out that who would carry out the task still needed to be specified.

- Develop a communication toolkit specifically focused on breast cancer and the environment in collaboration with advocates from diverse socioeconomic, cultural, and linguistic communities. PAGE 119-120 (8 Green, 6 Yellow, 2 Red)

Ms. Rizzo spoke for the RTDPI subcommittee. She said there were toolkits that had been developed in the different agencies to help communicate to constituents about research. The idea would be to have a template to make communication consistent and to specify the needed elements when crafting a communication strategy. She noted that the report's appendix contains more content about the toolkit.

Dr. Haslam felt that the word "toolkit" was jargon-ish, and that the elements should be spelled out more specifically. Dr. Barlow said the recommendation should include a commitment to

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keep the toolkit updated. Ms. Rizzo said that the toolkit would build on much of what had already been developed by the BCERPs and others. Dr. Collman felt that this recommendation was too small to be one of the overarching report goals, and too specific. She felt that a bigger, broader, take-home message from the report about the importance of communication would be better. Dr. Portier voted Yellow for the same reasons, he said. Dr. Fenton also voted Yellow, and said it was unclear who would develop the toolkit, or exactly who would use it.

Dr. Gould felt that the committee had achieved consensus that “toolkit” needed to be further defined, and that the recommendation should be put under a larger umbrella recommendation, including who would carry it out.

- Commit to the formation of interagency collaborations to adopt prevention-oriented guidelines for decision making that consider limitations in the current risk assessment models. PAGE 139 (8 Green, 6 Yellow, 2 Red)

Dr. Zahm spoke for the RTDPI subcommittee. She said the intent of the recommendation was to address the fact that there are many elements not being taken into account in the way risk assessment is currently conducted, such as age, life course issues, medical conditions and treatments, genetically determined differences in metabolism and repair, epigenetics, and more. The idea would be to change the current risk assessment model, which would necessitate increased interagency collaborations.

Dr. Fenton, who voted Yellow, felt that the recommendation did not address the main problem with current risk assessment—that people involved with risk assessment do not want to use mammary gland data. Dr. Zahm felt that the recommendation needed to be rewritten based on some of the other content and Dr. Fenton’s comments. Dr. Ballard-Barbash said that the recommendation should focus on enhancing the quality and relevance of risk assessment models and not be linked to the adoption of prevention-oriented guidelines, that being a separate process. Dr. Gould made the point that some of the recommendations were being taken somewhat out of context, and that by reading the full paragraph, they make more sense. Dr. Portier said he had voted Red, because it was so policy-oriented, and lacked the research component. He re-wrote it to read: “Increase the number of and resources allocated to collaborations between the NIH Centers and regulatory agencies to facilitate the identification of priority research needs, to support policy and regulation, and to increase the transfer of research findings into new policy and regulation.” He suggested that his re-write could be adjusted to include the prevention focus. He said he was focusing on the collaboration element, but Dr. Zahm pointed out that that had not been the main point of the recommendation. Dr. Collman reiterated that the idea was for agencies to use the most current and relevant data available in their risk assessment models. The committee discussed the nature of risk assessment models at some length in the context of the recommendation. Dr. Gould summarized the discussion by stating that the committee feels that breast cancer biology is not being used in risk assessment, and that the SoS has made that point and should perhaps consider raising it to the level of a sub-recommendation.

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- Develop an inter-agency dissemination model to provide a current stream of information on breast cancer and the environment. PAGE 119 (9 Green, 5 Yellow, 2 Red)

Ms. Rizzo spoke for the RTDPI subcommittee. She said the idea was similar to the toolkit recommendation, to establish a “push-pull” mechanism for dissemination of current information.

Dr. Haslam felt the recommendation was redundant, and that the envisioned component could be incorporated into the broader communication agenda. Dr. Collman felt that the recommendation was actually to provide the information, rather than just to create the model. Dr. Forman agreed, noting that it is a process, not simply a model. Dr. Winn felt that the task needed to be assigned to someone specific. Ms. Rizzo pointed out that the expectation that the funding would include a mandate for a dissemination plan is included. Dr. Portier said he had voted Yellow, also citing redundancy as his reason for doing so.

- Establish processes for the inclusion of breast cancer advocates and diverse community representatives as equity members in major research and policy efforts. PAGE 139 (9 Green, 5 Yellow, 2 Red)

Dr. Zahm explained on behalf of the RTDPI subcommittee. She said that this aspect need not be included in this place if the point is made well in the RP section.

Ms. Harvey noted that the recommendation was similar to the first RTDPI recommendation, and suggested that the point could be threaded throughout the report. Dr. Forman said she particularly liked the reference to “equity members.” Ms. Rizzo pointed out that the recommendation also addresses resources, so that advocates would be remunerated for their contributions. Dr. Vaday said she had voted Red because there are already such processes in place, suggesting a reference to existing processes or current working models. Ms. Rizzo said that that point is made in the section’s narrative. Dr. Gould suggested using another word than “establish”—perhaps “expand.”

- Support policy changes to ensure more comprehensive, validated, high-throughput pre-market screening, as well as post-marketing surveillance. PAGE 139 (9 Green, 4 Yellow, 2 Red)

Dr. Zahm spoke for the RTDPI subcommittee. She noted that the paragraph accompanying the recommendation made clear that the intent is that more testing is needed, and there should be testing that takes breast cancer factors into account. She noted that there is a similar recommendation in the SoS section.

Dr. Collman felt that the recommendation was too small and too specific to be a report-wide recommendation. She suggested, “Invest in new approaches to measure, monitor, conduct surveillance and trend analysis of environmental risk factors for breast cancer.” Dr. Portier said he had voted Red, again looking for the research component in the recommendation. Dr.

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Perreault-Darney agreed, noting that it is not the committee's job to recommend policy. She agreed that research should be prioritized to inform policy. Dr. Zahm pointed out that some of the research had already been done, but was not being incorporated into the choice of which chemicals are going into testing. Dr. Perreault-Darney said that the information should be used to inform the agencies that develop the test guidelines, with the right expertise brought to bear on the process—not setting the policies themselves. Dr. Portier felt that the recommendation should actually come under translation, as it is part of translating research into action. Dr. Fenton suggested addition of some reference to the CDC's high-throughput exposure screening processes as a way of determining what children and adolescents are being exposed to, versus adults. Dr. Collman felt that the recommendation was “old school,” and a wasted recommendation, but that the whole concept of using such innovative screening procedures could be framed as investing in new technologies and tools, which she said would be much more powerful. Ms. Rizzo noted that one reason for the recommendation was to help identify the barriers to accomplishing the stated goals. The narrative section was trying to capture the idea that policy does matter; that the policy agencies and current policies do have an impact on funding, what kind of research is conducted, what kinds of industry opposition there is, and who the advocates and stakeholders are.

- Increase interagency coordination and collaboration to reduce duplication and to enhance the conduct of research; to translate, disseminate, and communicate research results; and to improve the efficacy of regulatory activities that can protect public health and reduce the burden of breast cancer. PAGE 140 (10 Green, 4 Yellow, 2 Red)

Dr. Walker felt that this was a strategic recommendation, and others could roll into it as tactics. Dr. Zahm noted that it was a bit of a summary-type recommendation, laying out what the subcommittee would want the agencies to do. Dr. Forman agreed that it is an overarching recommendation, encompassing several of the subcommittees in its intent. She noted that it may be duplicative of some of the other recommendations. Dr. Zahm agreed that it is, but noted that it was in a sense a mission statement for the committee. Dr. Forman suggested that it might in fact be converted into a mission statement.

- Expand biologic and environmental monitoring to improve ascertainment of exposures across the life course, representation of population subgroups, including the underserved and under-researched, coverage of high production volume chemicals, inclusion of “fenceline” communities that are adjacent to high-emission industrial or military complexes, and coordination of data collection across federal programs. PAGE 139 (10 Green, 4 Yellow, 2 Red)

As Dr. Zahm explained for the RTDPI subcommittee, the recommendation addresses the need to know who is exposed to what. There has been a certain model of monitoring in place for a long time, but there needs to be strategic expansion or reconsideration, so that there can be an improved ascertainment of exposures across the life course.

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Dr. Forman recommended moving this recommendation in with the SoS recommendation on monitoring, while still clearly identifying the population subgroups who should be monitored. Dr. Haslam asked if the recommendation included only chemical exposures. Dr. Zahm said it could also include radiation. Dr. Haslam said it could also include lifestyle and other environmental factors not covered by “exposures.” The committee discussed some of the existing biomonitoring program, including one at the CDC. Dr. Collman suggested deleting the words following “under-researched,” as the recommendation is too long. She also noted the need to make such data freely available to facilitate research on breast cancer risk. Dr. Zahm said the availability issue had been mentioned in the narrative, but that it was a good idea to also include it in the recommendation. Dr. Ballard-Barbash mentioned that there has been some progress in interagency cooperation and coordination in this area, with recognition of the need for collaboration in these times of tight budgets. Dr. Portier felt that the fact that much monitoring on the exposure side is done by the regulatory agencies. He said that monitoring should be emphasized as a research tool, not just a regulatory tool. Dr. Zahm expressed concern that moving this recommendation into the SoS section may mean that many people who would need to see it would not if it was removed from the policy section. Dr. Forman mentioned that she did not see a need to remove some of the items from their specific sections, in that some level of repetition would actually be helpful. Dr. Perreault-Darney noted that EPA avoids use of the term “subgroups,” instead calling them “vulnerable groups.” Dr. Portier suggested adding “public health” after “Expand.” Dr. Zahm suggested inserting “lifestyle” instead.

- Develop a framework for breast cancer and environmental factors research. PAGE 90 (12 Green, 2 Yellow, 2 Red)

Dr. Portier explained the recommendation for the RP subcommittee. He said the subcommittee had kept its recommendations terse. The idea of the framework, he said, was to support monitoring of the state of knowledge in the area and finding gaps in understanding. Dr. Gould added that it was intended to provide a visualization tool to help with coding scientific activity in the area and identifying gaps, also allowing agencies to monitor progress in specific areas.

Dr. Winn asked what is meant by “framework,” suggesting that perhaps direct reference to the visualization tool might be clearer. Dr. Portier said the subcommittee discussed that, but that it was complex and difficult to actually envision the tool itself. Ms. Canin said she had marked this Yellow, since it seemed close to the recommendation about creation of a standing committee. Dr. Zahm said she was not in favor of the recommendation, not because she did not like the idea in general, but did not know how it would be curated or supported, and felt that past similar efforts had not had any impact on their fields. Dr. Gould replied that what Dr. Zahm was objecting to was not the intent—“We’re not trying to put Medline into a wiki,” he said. He said the intent was to provide the agencies with a tool to visualize what is going on, what they’re funding, and what results they’re getting, in one place, rather than a disorganized list. Dr. Fenton recommended adding a specific reference to coding. She was also concerned about the use of jargon-y language, such as “wiki” and “consumer.” Dr. Collman felt that the language actually

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made the idea sound more contemporary, in that it implied that the framework would be fluid, dynamic, and open to contributions from many sources. It would be a tool for interagency collaboration, accountability, and for interactive visualization, she added. She felt that the recommendation as written is “a little flat,” and suggested the use of more empowering language that would speak to the technological enhancement of a research agenda.

The committee continued to discuss the recommendation at some length. Ms. Rizzo asked how the framework would be accomplished, and who would be given the directive. Dr. Gould pointed out that originally it had been considered to be a task for the committee to be designated by the Secretary, and suggested that implementation of the recommendation was beyond this committee’s purview. He noted that this recommendation was central to the RP subcommittee’s work, in that it provides longevity and accountability. Dr. Winn noted that there are now sophisticated portfolio analysis tools available to NIH and other agencies. Dr. Forman said this might be a good area to add a timeline, to foster the sense of urgency.

Dr. Rizzo asked if anyone was still Red or Yellow on the recommendation, or whether everyone understood the changes that needed to be made. There was no response, so the committee moved on to the next recommendation.

- Improve testing of chemicals for effects on the breast, including TSCA reform, methods development, studies of mechanisms, updated websites and databases. PAGE 59 (8 Green, 7 Yellow, 1 Red)

Dr. Fenton explained the recommendation for the SoS subcommittee. She said the subcommittee had not spent enough time on its recommendations, and suggested breaking this one into two or three separate recommendations.

Dr. Portier said he had voted Red on this recommendation, because he objected to the word “testing,” and suggested that it be changed to “assessing.” He noted that the underlying intent was to increase the utility of research for risk assessment. Ms. Canin agreed with changing the wording to “assessment,” and suggested adding, “for potential health effects.” She thought that the call in the text for consistent protocols was important enough that it should be in the recommendation itself. Dr. Zahm felt that TSCA reform should not be specified, and that reference to mammary gland research should be added. Dr. Winn suggested wording to do so.

- Integrate research translation, dissemination, and communication plans early in the research process and engage multiple stakeholders. PAGE 117 (9 Green, 6 Yellow, 1 Red)

Ms. Rizzo explained for the RTDPI subcommittee. She said that the recommendation was intended to encourage researchers to consider the need for communication strategies early in the process, not waiting for publication.

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Dr. Vaday said she was the lone Red vote. She felt that the recommendation was redundant and its elements could be combined with others. She also noted that there was no action plan. Dr. Portier voted Yellow, thinking that this should be two recommendations instead of just one. He rewrote them to read: “Increase participation and effectiveness of the non-research public and stakeholders in the research decision-making process.” Also, “Make it mandatory that federal research programs have communication and dissemination plans that ensure that the non-researcher public, and especially potential beneficiaries of federally funded research, are kept informed of new research findings, their implications for breast cancer, and the state of the science.” Ms. Rizzo said the group had intentionally not distinguished between researchers and non-researchers, as there is also a need to communicate with the research community and other agencies. Dr. Portier felt that the research community keeps itself informed, unlike the non-research stakeholder community and the public. Ms. Canin and Dr. Zahm disagreed, and said that researchers tend to stay well-informed only in their own specific areas. Ms. Miller said that Dr. Portier’s version was not as bi-directional as the subcommittee had intended for this recommendation. Ms. Duron added that that bi-directional communication element was essential. Dr. Gould agreed that it should be a two-way street. Dr. Portier said he was trying to get at the forum for that communication. He felt that the engagement should occur both at the beginning and the end of the research process; thus his splitting the recommendation into two segments. Dr. Forman suggested that the recommendation be expressed more actively, with reference to early planning at the start of the text. Dr. Gould suggested adding “research prioritization” to the recommendation.

Dr. Walker said the discussion was moving her into the Red zone. She felt that it was asking too much of researchers to become good communicators and translators, it may or may not be their fortes. She said there was a need to build tools and infrastructure to help make the process happen, because the researchers will need that type of help. Ms. Rizzo pointed out that there was some support for those ideas in the narrative. Dr. Walker added that it should be kept in mind that at times innovative science is not ready for communication or translation, and the need for dissemination should not be allowed to stifle such pioneering research. Dr. Zahm agreed, adding that the funding agencies should take some of the communications burden on, as many do. Dr. Duron said that sometimes the public and advocates can be the best missionaries for the innovations, especially when they are involved early in the process.

Ms. Harvey suggested that this recommendation might be integrated into the RP section, as part of the process of having the document speak in one voice. She felt that the concept should be woven into all of the chapters. Dr. Forman agreed with that idea, as an overarching theme across the board. Dr. Barlow asked whether broad, high-level recommendations were being prepared for the Executive Summary, and whether the recommendations in each of the sections would relate to those in the Executive Summary. Dr. Forman replied that some would rise to the level of overarching, Executive Summary recommendations. Dr. Collman and Dr. Gould agreed that

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it was part of the current process. Ms. Canin felt that some of the recommendations might appear at both the Executive Summary and chapter levels.

Returning to the recommendation under consideration, Dr. Walker suggested replacing “early” with “along the research continuum,” since “early” could be misinterpreted.

- Increase collaborations with research stakeholders and advocates and provide new mechanisms for these individuals to have significant involvement in the design of research programs, in the translation of research findings into public health and regulatory actions, and in communicating research and intervention needs to a diverse American public. PAGE 92 (10 Green, 5 Yellow, 1 Red)

Dr. Portier spoke on this recommendation for the RP subcommittee. He said it was the third RP recommendation.

Ms. Duron suggested removing “American.” Ms. Canin suggested that the terms “stakeholders” and “advocates” need to be defined carefully throughout the document. Ms. Rizzo pointed out that the terms had been defined separately in the RTDPI section. Ms. Canin suggested changing the language to “stakeholders, including advocates...” Dr. Ballard-Barbash pointed out that there are existing mechanisms, and so the reference to “new mechanisms” might need to be changed. She suggested “provide and apply mechanisms...” Dr. Vaday suggested that a reference to peer review be added, as it appears in the expanded text. Dr. Walker suggested a friendly amendment to change the phrase to “design and review of research programs...”

- Increase funding of ongoing prospective longitudinal human studies that collect early life exposure and reproductive development data and that can shed light on breast cancer risk over a lifetime. PAGE 61 (9 Green, 7 Yellow, 0 Red)

Dr. Fenton explained the recommendation for the SoS subcommittee. She said that the main idea was to ensure continued and expanded funding for the described studies.

Dr. Zahm said she was totally sold on the idea, but suggested changing from “increase” to “assure adequate funding...” Dr. Forman suggested “new and ongoing...” Dr. Zahm suggested removing that phrase altogether. Dr. Ballard-Barbash felt that there were too many adjectives, which could be included in the paragraph text. Dr. Perreault-Darney felt that the recommendation was missing the concept of sustained funding and suggested “assure sustained funding.”

- Increase confirmation of *in vitro* or *in silico* findings for translation to *in vivo* situation. PAGE 61 (10 Green, 6 Yellow, 0 Red)

Dr. Haslam spoke for the SoS subcommittee. She said the idea was that as there are many ways something is studied outside the human, the data need to be made relevant to the whole animal or human. She felt that the recommendation needed to be re-stated.

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Dr. Forman noted that this was an opportunity to talk about the transdisciplinary paradigm. Ms. Canin suggested replacing “confirmation” with “validation.” Dr. Walker thought the recommendation was vague and did not say what was desired, with the primary message being unclear. Dr. Forman reiterated that the primary message was the application of the transdisciplinary paradigm. Dr. Collman suggested deleting this recommendation altogether.

- Increase and better coordinate research on environmental exposures and breast cancer across all agencies that fund breast cancer research. PAGE 139 (11 Green, 5 Yellow, 0 Red)

Several members felt initially that the recommendation was redundant, but Dr. Winn wanted to make sure of that before it was passed over, because she felt that it was tightly worded. Dr. Collman returned to the mandate, which said that they wanted to know specifically how and what strategies would be used to increase research. She suggested re-wording the recommendation to get to the crux of the charge within the mandate. Dr. Gould felt it had been stated elsewhere and better. Ms. Rizzo pointed out that there was narrative on page 138 of the draft that addressed the point and spawned this recommendation. Discussion ensued about whether to delete the recommendation. The conclusion was that if it was to be retained, it should be changed, with increased emphasis on exposure.

- Increase funding of transdisciplinary and translational studies. PAGE 60 (12 Green, 4 Yellow, 0 Red)

Dr. Fenton described the recommendation on behalf of the SoS subcommittee.

Dr. Barlow suggested “increase emphasis” instead of “increase funding.” Discussion centered on the fact that translational research was not coded within portfolio analysis, and so the need for an increase could not readily be captured. Dr. Haslam suggested that “transdisciplinary” and “translational” should be defined. Dr. Henry-Tillman felt that the recommendation should be broader in terms of funding. Dr. Winn said it should be linked directly back to breast cancer. Dr. Perreault-Darney noted that there is a pie chart in the text showing the distribution of funds within the breast cancer field, and wondered if the recommendation was aimed at changing that distribution. Ms. Canin said she was troubled by the fact that no purpose was specified in the recommendation. Dr. Walker felt that the recommendation spoke to the fact that there needs to be long-term commitment to research investments that have already been made. Dr. Forman agreed that it is important to capitalize on existing investments, and recommended that the recommendation be tweaked accordingly. Dr. Gould added that the intent was not to re-apportion money from one piece to another in the breast cancer field, but to find ways to use the funding more effectively. Dr. Portier disagreed, saying he did see the recommendation as a re-distribution and growing of the funding pie.

- Support research specifically addressing new/novel/emerging mechanisms of cancer initiation, progression, and treatment. PAGE 60 (13 Green, 3 Yellow, 0 Red)

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Dr. Fenton explained for the SoS subcommittee that the intent is to support research efforts to discover more about the etiology of breast cancer.

Dr. Portier asked whether the recommendation was intended to generate more etiology research, since there are several programs in place currently. Dr. Collman wondered if the intent was to inspire existing breast cancer researchers to explore new directions. Dr. Walker questioned the need to specifically support research on new mechanisms, since “we’re about 80% there” in terms of mechanisms contributing to breast cancer, but are only about 5% along in terms of the role of environmental factors. Dr. Gould suggested changing “initiation” to “etiology.” Dr. Vaday said that an informal analysis had shown that about 10% of breast cancer research was related to environmental factors, and that broadening the conceptual framework might help attract more researchers to the field. Dr. Fenton advocated proposing a shift in how the pot of money is spent, to suggest the most important areas for funding in the future. Ms. Rizzo described a California program that did that, and said it had worked. Dr. Collman noted that the pool of successful unsolicited funding proposals had not grown, because so much of the funding is targeted in specific areas. Dr. Ballard-Barbash felt that the recommendation was mixing concepts that did not belong together, with the treatment being particularly out of place. Dr. Portier mentioned that targeting funding should be done cautiously in that some of the researchers may not be ready to tackle research at a particular targeted level.

Dr. Forman noted that training had not been included in the draft report or recommendations—addressing the next generation of researchers, portfolio people, and policy people. She asked for a new recommendation along those lines.

The balance of the session was devoted to a recap of the tasks remaining to be completed during the meeting.

### **VII. Group Discussion: Consideration of New Recommendations**

Dr. Forman led off the session by restating her proposed new recommendation regarding training of the next generation of transdisciplinary researchers in breast cancer and the environment. Part of the proposal would involve training personnel to be program administrators and portfolio specialists within funding agencies. Also, there should be provision for training the next group of stakeholders, including clinicians, nurses, and advocates. After considerable discussion among the committee members, the recommendation read:

- Train individuals in transdisciplinary science related to breast cancer and the environment
  - Training the next generation of transdisciplinary researchers, including mid-career professionals and administrative staff
  - Training the next group of investigators who can conduct research and mount efforts within agencies; investigators to participate in activities within the agencies, help develop RFAs, etc.

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- Training the next group of stakeholders – clinicians, nurses, advocates (Page 97 definition of stakeholder)

Dr. Fenton offered a new recommendation on method development specific to breast cancer. The committee discussed several points related to the recommendation, including specific areas where new method development is needed. However, given that many of the specifics would be described in more detail in the narrative text, ultimately the committee opted to leave the recommendation fairly general:

- Identify new methods and computational tools for (transdisciplinary) research to accelerate progress in breast cancer prevention

Dr. Gould proposed a new recommendation addressing genomic research related to breast cancer. It was suggested to add a phrase regarding the life course. Following discussion of specific wording, the committee settled on:

- Expand the organ specific global genomic and proteomic analyses, such as ENCODE, to include breast tissue across the life course in humans and rodents

Dr. Walker referred to a discussion that had taken place in her subcommittee related to “reapportioning the pie,” and asked for a new recommendation related to that concept. Dr. Fenton wanted to recommend that the proportion of funding spent for prevention be increased, with a suggestion for a new way to slice the pie. Dr. Ballard-Barbash felt that that “gets us nowhere,” since it had been proposed many other times. She recommended highlighting specific areas, because the recommendation was too broad. The finished recommendation was tabled for later re-consideration. Dr. Fenton said that the SoS could contribute examples. The recommendation was:

- Increase the proportion of funding that is spent on breast cancer and the environment

Dr. Perreault-Darney, citing the fact that the report contained central messages about new directions in breast cancer work, felt that a recommendation from that regarding alignment of national resources with those emerging issues would be appropriate. The committee discussed the specific wording and elements of the recommendation at length, as it was deemed a likely overarching recommendation. With the need for further development acknowledged, the recommendation read:

- Align and realign our national resources to invest in the priorities articulated in the report. Grow these resources by leveraging federal funding with private partnerships with the goal of tripling prevention efforts. Accelerate breast cancer research and the environment (overarching recommendation).

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- Triple prevention (work on assessment of the costs involved to be able to identify a proportion or increase in funding). “Current funding is grossly disproportionate.”
- SOS

Dr. Forman, summarizing the previous discussion, noted that there seemed to be a call for the development of an investment strategy for breast cancer prevention, and suggested it might constitute another new recommendation. Dr. Zahm felt that that was taking a step backward; that the report should be delineating such a strategy. Dr. Gould said that his subcommittee’s analysis had shown that too little money was going toward breast cancer prevention—at most 10%, even with generous coding. He advocated saying to the wider community that it’s not a matter of asking for more money, but that the money be spent differently. Dr. Ballard-Barbash agreed that it is important to point out that prevention is where the opportunity is currently. Dr. Collman said that the report need not include the specific numbers involved, but that there should be support for developing the strategy and determining the money to be reallocated. Ultimately, with additional thoughts/reminders appended, the recommendation read:

- Develop an investment strategy to reach the goals of breast cancer prevention. Based on breast cancer portfolio analysis, we feel that the area of breast cancer prevention is underfunded and adequate funding requires the reallocation of funding for breast cancer prevention.
  - Summit with stakeholders
  - Articulate benefits of reallocation
  - In executive summary as part of narrative: “The research strategy calls for an investment strategy which will require an alignment and realignment of national resources for breast cancer research.”

Dr. Fenton offered another new recommendation to develop meetings of breast cancer stakeholders to foster the types of strategies and collaborations being proposed. Following committee discussion, the recommendation was to:

- Develop interagency funded cross-disciplinary problem-oriented meetings of breast cancer stakeholders to foster collaborations

Dr. Sandler noted that much of the current research is devoted to treatment and to incremental advances, but that it was important for this committee to concentrate on key opportunities to make a difference. Following committee discussion, the concept was logged as an optional recommendation.

- Key opportunities will make a difference – not incremental

Dr. Forman moved to the next item on the agenda, consideration of overarching messages to be included in the report’s Executive Summary. She emphasized that they need to be expressed in

active voice and be compelling. Discussion focused on the points presented by Dr. Forman in the slide titled “Preface.”

- We recognize the contributions of researchers, clinicians, and partners in the BC community in the progress to date.
- We recognize the complexity of BC that is several intrinsic diseases with diverse underlying profiles and prognosis.
- Our overall goal is to create a national BC prevention strategy that envisions a day when BC is a disease like polio—a disease of the past. To assure the realization of this goal, we call for a BC prevention strategy that emphasizes primary prevention, establishes deeper coordination across both research and policy agencies and investigators, and sets tangible goals for reducing or eliminating environmental exposures implicated in BC.

Dr. Fenton suggested adding a reference to “legacy,” or “changing our breast cancer legacy” to the preface. She also suggested adding an overarching recommendation that “Our analysis shows that the area of prevention of breast cancer is underfunded at the federal level.”

### **VIII. Group Discussion: Consideration of Overarching Recommendations**

Dr. Forman and Dr. Collman felt that the goal of the session should be to select the overarching recommendations from those generated to date and wordsmith them, rather than engaging in further discussion of their individual merits.

Following debate on how to proceed, the committee decided to vote on whether individual recommendations should be included in the overarching recommendations.

The committee voted in favor of the first bullet on the slide labeled Recommendation 4:

- Develop a conceptual framework (RP chapter) for breast cancer and environmental factors research

The committee voted in favor of adding the recommendation from page 139 regarding breast cancer advocates to Recommendation 3:

- Establish processes for the inclusion of breast cancer advocates and diverse community representatives as equity members in major research and policy efforts.

The committee created Recommendation 5:

- Develop an inter-agency dissemination model to provide a current stream of information on breast cancer and the environment. PAGE 119

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- Translate the findings of research related to breast cancer and the environment into recommendations for public health interventions, such as health behavior interventions, regulatory policy, and further research. PAGE 118

The committee decided that the recommendation regarding a toolkit (pages 119-120) was a tactic, and was too specific for inclusion as an overarching recommendation. Dr. Perreault-Darney made the point that the overarching recommendations should be concerned with the “what” rather than the “how.”

After rejecting several other recommendations for inclusion in the overarching category, the committee elected to make the one addressing prevention Recommendation 6:

- Create a new national breast cancer prevention strategy that emphasizes primary prevention, establishes deeper coordination across both research and regulatory agencies, and sets tangible goals for reducing or eliminating toxic environmental exposures implicated in cancer causation. PAGE 139

The committee proceeded to go through the new recommendations from the previous session, to assess their inclusion as overarching recommendations. Most were rejected. Ms. Canin pointed out that much of the material would be included in the narrative and need not be in the recommendations.

The committee decided to include the recommendation regarding an investment strategy in Recommendation 1:

- Develop an investment strategy to reach the goals of breast cancer prevention. Based on breast cancer portfolio analysis, we feel that the area of breast cancer prevention is underfunded and adequate funding requires the reallocation of funding for breast cancer prevention.
  - Summit with stakeholders
  - Articulate benefits of reallocation
  - In executive summary as part of narrative: “The research strategy calls for an investment strategy which will require an alignment and realignment of national resources for breast cancer research.”

Recommendation 1 currently retains a second bullet that is rendered redundant by the above text. The committee then assessed the new recommendation regarding “...meetings of stakeholders to foster collaborations.” Ultimately, it was decided to reword the recommendation as follows and include it as a second bullet in Recommendation 4:

- Create opportunities for synergy by holding cross-disciplinary forums with all stakeholders for key opportunities for breast cancer prevention research

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The committee considered the overarching recommendations that had been written originally by Dr. Forman. Following much discussion, they were amended to read as follows (with notes for later reference):

### RECOMMENDATION 1

- We call for the development of an integrated strategy for breast cancer prevention research, translation, applications, policy and communications. (This may be developed by a working group that has its distinct period of time.)
  - To reduce the BC burden in current and future generations (within text note women and men)
  - Close gaps in research and eliminate disproportionate BC risk (need to wordsmith) among minorities and the underserved.
  - To develop a transdisciplinary framework for breast cancer and the environment research that accelerates progress towards BC prevention.

### RECOMMENDATION 2

- We call for inter-agency federal government oversight to assure:
  - transdisciplinary research initiatives across the NIH, other government institutions and foster collaboration with entities outside the federal government;
  - the application of the life course approach to research and intervention strategies across the breast cancer control continuum; and
  - balanced contributions from researchers, clinicians, advocates and all other partners in the BC community at all stages of research and interventions.
  - research gaps among minorities and underserved populations are addressed

The committee revised Recommendation 7 to read:

- To formulate evidence-based strategies for BC and the environment across the life course to assure identification of the optimal developmental period or age or population sub group for effectiveness.
- To prevent breast cancer in future generations, new scientific opportunities exist today to focus research on early life exposures and breast cancer risk/development

The committee eventually consolidated some of the prior materials to formulate a recommendation titled “Research Agenda,” as follows:

Research agenda (preface with what we have learned/discovered)

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- We recognize the need to capitalize on innovative technologies and approaches and expand support for the development of new methodologies to assess environmental exposures.
- We envision the development of methods and computational tools .... an informatics infrastructure to merge research findings, biospecimen data bases, and environmental monitoring that fosters early discovery of adverse contaminants.
- Relate to RP framework

With the recommendations roughly in place, the committee discussed how to move forward with finalizing them. Dr. Winn volunteered to receive committee members' comments on the recommendations and attempt to consolidate the recommendations. Dr. Portier suggested considering the recommendations in the context of the proposed outline, which the committee had yet to take up.

At Dr. Fenton's request, the committee discussed the timeline for completion of the report and subsequent events. Given the current status, Dr. Collman said she hoped that the project would be delayed no more than two months, aiming for submission of the report to the Secretary by June at the latest. She asked Ms. Collins to poll the members as to their availability should another face-to-face meeting be necessary. She hoped that by the end of the federal fiscal year, September 30, communication and dissemination efforts would be in progress, with the report having been delivered and approved. She noted that the committee would need to vote to approve the report prior to its submission to the Secretary. Dr. Perreault-Darney asked whether federal agency representatives would be voting on behalf of their agencies. Dr. Plescia pointed out that each of the agencies will clear the report. Dr. Collman clarified that each individual would vote as a committee member, with their votes not constituting agency clearance. She anticipated that agency clearances would be in place prior to submission of the report to the Secretary.

### **IX. Group Discussion: Communications Plan for IBCERCC Report**

Prior to taking up the communications plan for the report, the committee considered the proposed outline that had been prepared by Dr. Portier. He briefly summarized his thoughts concerning the outline. It began with provision for both an Executive Summary and a Recommendation Summary, with the Main Document to follow. He said that the flow of chapters proposed was designed to address both gaps and the various stakeholders. Each chapter would start with a brief summary of the gaps that had been identified, followed by discussion. The last chapter would include the detailed recommendations.

Dr. Collman recommended adding an introduction to describe the imperative, the urgency of the situation. Ms. Rizzo suggested that some attention be paid in the introduction to the human and economic costs of breast cancer, to help set the tone for the report. She noted that the RTDPI

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chapters were not set up as suggested by Dr. Portier, beginning with identification of gaps, and that the subcommittee would need to look more closely at the idea.

Dr. Collman suggested including an appendix tied to the recommendations from each chapter that would delineate action plans related to the recommendations. Dr. Forman was concerned with the idea of pulling out the action plans into a separate section. Dr. Collman clarified that the appendix she was proposing would be in addition to action plan mentions in the chapter recommendations, as a guide to implementing the recommendations. Dr. Portier noted that as his proposed outline was set up, the final section of the report would be devoted to recommendations, with descriptions of accompanying action plans there. He and Dr. Forman noted that that structure would separate the recommendations from the discussions, with their compelling arguments, resulting in a disconnect.

Dr. Fenton suggested that there should be considerable cross-referencing among the chapters, as well as inclusion of a glossary of keywords, along with important definitions appearing on the same page as the defined terms.

Dr. Forman departed the meeting, and Dr. Winn assumed the chair.

The committee discussed the idea that the concept of “gaps” emphasized in the proposed outline might be too restrictive, and that another term such as “opportunities” or “issues” might be more appropriate.

Dr. Barlow said she still supported the original three sections based on the subcommittees, and was concerned that the report was getting too many sections. Dr. Collman pointed out that all of the sections in the proposed outline would not be equally balanced. She was concerned that reverting to the original structure would lose the sense of it being a breast cancer report.

Dr. Portier noted that he had intentionally constructed breast cancer risk assessment and research translation as distinct chapters, in that he felt both concepts had gotten lost in the previous structure. Ms. Canin pointed out that the terminology associated with the original three sections could be used in the narrative, and felt that the proposed outline lent needed continuity to the content.

Dr. Plescia felt that the Executive Summary was the most important part of the report, in that many readers would only look at that section.

Dr. Haslam noted that the proposed outline would require a “huge rewrite” of her section. Dr. Collman said that the idea was not to re-organize the report just to create more work, but that everyone should take a look at their individual sections and assess the workload required to conform to the proposed outline. She noted also that all of the mandates must map clearly to the sections, with allusions to them in the Executive Summary as well.

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It was left that committee members would evaluate the impact of the outline in terms of rewrites necessitated.

Ed Kang of the NIEHS Office of Communications and Public Liaison presented the institute's communications plan for the report to the committee. He said he liked what he had been hearing within the committee's discussions recognizing the importance of bold statements and emphasizing the most important points in the report.

He summarized the news coverage received by the IOM report, including more than 2000 news stories, which he characterized as outstanding success. He felt that the use of a media conference call upon release of the IOM report contributed to the wide coverage, as well as the strategic value of releasing the report at the San Antonio meeting. At the same time, other events that week may have negatively impacted coverage. He felt that the report's executive summary and Q&A sections were very well done and understandable, and that it was professionally composed and branded. Looking at many of the headlines from the news stories, it was apparent that many of them focused on women's risk, as opposed to the life course approach. The questions that arose during the media conference call were consumer-oriented.

In terms of the IBCERCC report, he emphasized the importance of focusing the message for the expected audiences. He described the proposed elements of the NIH/NIEHS communications strategy upon the report's release, which would include a news release, a press conference, and a single website where the report as well as supporting documents would be available. Also, there would be use of social media such as Twitter, Facebook and blogs, coordination with *Environmental Health Perspectives* (EHP), NIH and NIEHS newsletter articles, and podcasts by NIH and EHP.

He told the committee that the report's conclusions and recommendations should be concise and powerful for translation into the media. That will ensure broad dissemination, particularly if all involved speak with one voice. He said it is still unclear how much involvement can be expected from Dr. Sibelius or Dr. Collins. He noted that in terms of the timeline, clearance of the press materials associated with the report will also need to be considered. He added that the branding of the report will obviously be very important to the success of the communications strategy.

He concluded by sharing potential discussion points with the committee:

- How will committee members/organizations participate?
- Who will be permitted the report ahead of embargo?
- What are the opportunities for communication to the public or extension to communities/families/individuals?
- How will we coordinate with Congress?

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Ms. Miller suggested setting up round table discussions and town hall meetings in the communities upon the release of the report.

Dr. Plescia pointed out that the CDC will be holding the National Cancer Conference in Washington in August, and suggested it might be a suitable venue to launch the report.

Dr. Perreault-Darney appreciated Mr. Kang's discussion of messaging, and wondered if it would be best to emphasize the differences between the IBCERCC report and the IOM report. He replied that that would be one aspect, but that the Secretary is likely to want to see very strong, action-oriented recommendations in this committee's report.

Ms. Duron was intrigued by Dr. Plescia's idea for release of the report, in that it would be a good opportunity to introduce the concept of the environment and its association with breast cancer to the audience at the CDC, many of whom may not have considered it before. She also recommended that at least the executive summary be translated into Vietnamese, Mandarin, Spanish and Arabic as one way to encourage coverage in various ethnic press outlets. Mr. Kang endorsed the idea. Ms. Rizzo also suggested that webinars should be considered.

Dr. Barlow noted that the coverage of the IOM report did not emphasize the life course approach or periods of vulnerability, and that those are difficult messages to communicate, perhaps because people do not want to hear them. Dr. Collman felt that it was a framing issue, and that those messages had not been translated from the 365-page report to the media. She added that some education of key media contacts in those areas in advance of the report's release might help. Ms. Rizzo added that targeted, directed messages to specific audiences (e.g., "mommy bloggers") should be considered. Dr. Haslam added that it would be important to use very accessible language in messaging, so that the report's key concepts would be understood by the media. Dr. Gould noted that it would only be possible to effectively communicate one or two concepts, and that the committee should decide what those key messages would be based on its mandate.

Dr. Fenton felt that launching the report at the CDC meeting would be an excellent idea, since the CDC actually includes "prevention" in its name. She said she had not been impressed by the IOM's press release, and hoped that all committee members would make sure to issue press releases by their own organizations. Ms. Canin questioned whether the report could realistically be expected to be cleared and ready for release by August. Dr. Collman agreed that it would be a great opportunity, and mentioned that she was scheduled to speak at the CDC meeting, whether to roll out the report or not. Dr. Portier noted that there should be plans to discuss the report at several other events in the fall in addition to the roll-out. Ms. Rizzo suggested that there should also be a congressional staff briefing, as well as briefings for state legislatures.

Dr. Gould stressed the importance of a resonant message, and suggested that primary prevention might be an appropriate one.

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Ms. Rizzo suggested to Mr. Kang that B-roll video be provided to television outlets. He said he would explore the idea, but that it was uncertain where the budget for that might come from.

Dr. Portier noted that this report was trying to answer some of the uncertainties raised in the IOM report, identifying the gaps where investments need to be made to answer ongoing questions regarding breast cancer—gaps that impede progress in prevention. Ms. Canin said that the human and economic costs should be figured into the case for prevention. Dr. Sathyamoorthy wondered whether some of the content of the IOM report could be used in this report to help set the stage. Dr. Collman agreed that this report's charge should be put in context with the IOM report and the President's cancer panel. Part of that would be the idea of Dr. Birnbaum and Dr. Hertz-Picciotto, the editor of the IOM report, writing a joint editorial.

Ms. Rizzo and Mr. Kang discussed the plans for pitching the story to media outlets when the report is launched. Mr. Kang stressed the importance of coordination, and asked that all committee members contribute their media contacts.

### **X. Public Comment**

Dr. Collman asked whether there were any public comments. There being none, she called the public comment period to a close.

### **XI. Group Discussion - Outside Review Process**

Dr. Collman asked the group to discuss the idea of an outside review process for the report. It had been proposed that some external reviewers who were not involved in the process and have no stakes in it read and comment upon the report. They would be asked questions such as:

- Did we hit the mark given the legislation?
- Are the facts correct?
- “Gut-level feedback?”
- What are the two primary take-away messages?

Dr. Collman said it was still to be determined who the reviewers would be, how many there should be, and in what time frame they would be asked to turn around their reviews. She felt that it would probably take place in the very late stages of development of the report.

Ms. Canin felt that there should be reviewers, and that they should reflect the proportional representation on the committee – agency people, scientists, and advocates. Dr. Fenton said that the reviewers should be recognized, impressive experts, and should include an environmental toxicologist. The committee discussed whether the reviewers should be asked to review the entire report, or have two or three reviewers per section, more in line with the approach taken by the IOM. Dr. Collman noted that this review process was not mandatory, but would be a way for the committee to build confidence prior to submitting to the Secretary.

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Ms. Rizzo asked whether the report could be shared confidentially with some trusted experts.

Dr. Collman said that there are some agency people who have volunteered to provide a gut-level response.

Dr. Gould said he did not feel that the proposed formal review was necessary, but that a more informal, fact-checking review would be useful.

Dr. Portier preferred to have a limited number of people reading and reviewing the full report, anticipating that they would take a broad view and not attempt to rewrite the document, pointing out places where arguments might need to be tightened. He felt that typically reviewers could do that within 10 days.

Dr. Collman said the idea had been proposed to have three reviewers—a population scientist, a mammary gland scientist, and a community person. It would be close to the end of the process, and could be accomplished within a week to ten days.

Committee members suggested several individuals as possible reviewers, whose merits were discussed.

Dr. Gould returned to the question of running individual sections of the report by colleagues on an informal basis, asking whether all important references had been included. Dr. Collman said she preferred that that not take place at this time, and that the committee maintain confidentiality for now. She said that it might be useful to ask members of the other subcommittees to take a look at sections. Dr. Winn suggested calling friends to ask about ideas and references, without sharing text with them.

Ms. Duron said that vetting the report will be important, and endorsed the idea of outside review.

Dr. Collman said that there is a commitment to conducting the outside review if possible, but understand that it is not a requirement if other situations preclude it.

She added that going forward, committee members are to evaluate the new outline in terms of added workload, after which the timeline will be adjusted and new assignments doled out.

## **XII. Adjournment**

Dr. Collman thanked the committee for the considerable work accomplished at the meeting, and adjourned it at 2:53 pm January 24, 2012.

Interagency Breast Cancer and Environmental Research Coordinating Committee

**CERTIFICATION**

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

/Michele Forman/

Michele Forman, PhD

Chairperson

Interagency Breast Cancer & Environmental Research Coordinating Committee

/Gwen W. Collman/

Gwen W. Collman, PhD

Executive Secretary

Interagency Breast Cancer & Environmental Research Coordinating Committee

Proper signatures

Treat as signed, § 1.4(d)(2)