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BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED FIFTH CONGRESS

FIRST SESSION

SPECIAL HEARINGS

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WEDNESDAY, FEBRUARY 5, 1997

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington DC.

The subcommittee met at 9:25 a.m., in room SD–192, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Hutchison, and Harkin.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF RICHARD D. KLAUSNER, M.D., DIRECTOR, NATIONAL CANCER INSTITUTE

ACCOMPANIED BY WILLIAM R. HARLAN, ASSOCIATE DIRECTOR FOR DISEASE PREVENTION

U.S. PUBLIC HEALTH SERVICE

STATEMENT OF SUSAN J. BLUMENTHAL, M.D., M.P.A., DEPUTY ASSISTANT SECRETARY FOR HEALTH, ASSISTANT SURGEON GENERAL

OPENING REMARKS OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning. The hearing of the Appropriations Subcommittee on Labor, Health and Human Services, and Education will now proceed.

Our hearing today involves the issue of mammograms and on January 23 a report was issued by the National Institutes of Health Consensus Development Conference concerning breast cancer and screening for women between the ages of 40 and 49, with the essential conclusion being that there was insufficient evidence to warrant mammograms for women between 40 and 49.

That report was greeted by considerable controversy, to put it mildly. Dr. Daniel B. Kopans of the Harvard Medical School said that the committee's report was fraudulent. Dr. Bernadine Healey, former head of the National Institutes of Health said that she was very disturbed or at least was quoted as saying that she was very disturbed that a group of so-called experts challenged the notion of early detection, saying, What they are saying is that ignorance is bliss. Dr. Richard D. Klausner, Director of the National Cancer Institute characterized his response as being shocked at the finding.

It was greeted with some substantial concern in many quarters, including the U.S. Senate, which heard a resolution yesterday introduced by Senator Snowe, and many of us spoke on the floor, including my distinguished colleague from Texas, Senator Kay Bailey Hutchison. The resolution passed by a vote of 98 to 0, expressing concern about those findings.

When I took a look at the conclusions as they were reported, there was not enough evidence to conclude that women in their forties would not benefit from mammograms as a part of routine health screening, the converse question occurred to me, which is this: is there sufficient evidence to conclude that women in their forties would not benefit from mammograms as a part of their routine health screening.

If you put the burden of proof on saying that the medical evidence has to establish a benefit, as opposed to the evidence being inconclusive or in equipoise, with a very substantial body of evidence saying that the mammograms are very important, then it seems to me that we are allowing the burden of proof issue to dominate, with so much evidence, although perhaps inconclusive or perhaps even in equipoise as to whether it is a matter of benefit.

Ordinarily, we have these hearings to find the facts and to decide what to do. I would say at the outset of this hearing that I have a fixed opinion on this subject, that women in their forties ought to be tested with mammograms. Just as a personal aside, I had a situation where the doctors concluded that I should not have an MRI and I insisted on an MRI and finally got one. They found a life-threatening situation with a meningioma. I have yet to understand why, in a context when there is a noninvasive proceeding which can be accomplished, that medical experts are reluctant to undertake that test.

I think that there is over-concern about the costs affecting this ratio. The real issue is our health system whether we have enough MRI's and mammogram machines and experts to administer them to handle the people who could reasonably benefit from them. I am convinced that we do.

You might have to give an MRI in the middle of the night for $100 or for $75, instead of at 3 o'clock in the afternoon when it is convenient to the patient at $800 or whatever the cost may be. But with the experience that I have had, I am convinced that we ought to err on the side of safety.

There is a real problem of the consequence, it seems to me, of this study having been released, of discouraging many women from having mammograms. People do not like to go and get tests because they are afraid of what the tests may show. With this tremendous splurge of publicity that women cannot benefit from mammograms who don't need mammograms in the 40 to 50 age category, I think it is going to discourage a lot of women from going to get the mammograms.

Let me say just a word or two about the doctor-patient relationship. This is about as fundamental a relationship as we have in our society, and I think that sometimes we do not really focus—or the doctors do not, and I think lawyers are equally bad and judges are even worse—on the impact of their statements on people.

When I had my test and somebody told me I had a few weeks to live, it was a pretty important impact. When specialists say women do not need mammograms it may be hard to get them back on the mammogram trail.

I talked yesterday to Secretary of Health and Human Services, Donna Shalala. I had hoped she would be at this hearing today. She has just returned from overseas and she has other commitments. It may be preferable, as she said to me last night, to hear from the scientists before hearing from the policy experts.

It is my recommendation, thought, and hope that Medicare and Medicaid will cover mammograms for women in their forties. If that is done, that will be the strongest national signal about the conclusion of the public policy in the United States on this subject.

We all know that if this test comes out and is accepted as not being indicated for women in their forties, the insurance companies will not pay for it and managed care will not pay for it. Then people will not have them available.

So I think this is an area which needs to be corrected.

Let me welcome my distinguished colleague, Senator Kay Bailey Hutchison. While not a member of this subcommittee, she is always welcome.

Senator Hutchison, do you care to make an opening statement?

OPENING REMARKS OF SENATOR KAY BAILEY HUTCHISON

Senator HUTCHISON. Thank you, Mr. Chairman. Since I am new to the Appropriations Committee, this is my first hearing, and I am a new member of the subcommittee.

Senator SPECTER. May I recant? You are, indeed, a member of the committee. You just joined and you are also a member of this subcommittee. And you are, therefore, doubly welcome.

Senator HUTCHISON. I thank you. It is not your fault because we have not had a meeting yet and I am the most freshman member of the Appropriations Committee.

I am very pleased to have this opportunity and I want to thank you, Senator Specter, for having this hearing. When I saw what the advisory committee for the National Cancer Institute and other organizations did a couple of weeks ago, I was appalled, and I know every woman member of the Senate is equally appalled.

I guess 3 years ago, when we had testimony before a hearing called by Senator Mikulski, we registered that we were absolutely sick about the health care plan that was before us not requiring mammograms and having mammograms covered before the age of 50. So this is like a festering sore, frankly.

I think it is time that we speak frankly. I hope we can speak with one voice with the facts.

I think, to just recapture a little of the history, up until 1993, the National Cancer Institute did recommend mammograms for women before 50, ages 40 to 49, every 2 years, and then after 50 every year. Then a study came out in Canada that said, I think, that it was not shown to be effective. They then rescinded the guidelines.

Since then, I think other studies have come forward. In 1995, investigators found a 24-percent lower-death rate among women who received mammograms in their forties. In 1996, Swedish research-

ers in two studies found a 44-percent and a 36-percent lower-death rate among women who received mammograms in their forties.

Right now we have a mixed message. Breast cancer is the leading killer of women in our country. Of the 43,900 women estimated to die from breast cancer this year, 10,000 will have breast cancer between the ages of 40 and 49—10,000 women in this country.

Now I hope that whatever you do, you will help us send a crystal-clear message with the facts. Maybe the facts are not 100 percent. But we know that more women will be saved if they start having screening for breast cancer before the age of 50.

Most States require coverage by insurance companies for mammograms starting at the age of 35. If there are risks involved with this, say so. We do it in every medicine that I take. We do it in every other procedure that I can think of. I mean, a doctor will say: Senator Specter, we do not recommend an MRI on this, but there may be a 15-percent chance that you need one. So he knows the facts and he takes his chances.

Or a doctor will say to a women: you are 45, we don't think it is necessary for you to have this procedure, but these are the statistics. It shows an overwhelming improvement in your chances if you do. There is a 1 percent chance—or whatever it is—that you might have a better chance not to get breast cancer from having the mammography. Why not just put the facts out there with a clear message: here is what the statistics show and here is what the risks are.

I think what happened with the advisory committee is the worst of all worlds. What I worry about the most is that now that we have this mixed message from the experts, insurance companies are now going to start saying if we do not have clear scientific evidence from the experts that this needs to be done, then it is no longer in the required category and we should move it to optional with the insurance companies.

These are questions that should not be raised with a mixed message.

So I am going to ask those of you who are testifying today to help us get a clear message. Tell us what the risks are. Tell us what the advantages are. There is no question that the advantages outweigh the risks.

I cannot understand why this is treated so much more deferentially than any other disease or any other medical treatment where they tell you what the risks are and what the rewards are. And yet, now we have all of these doctors getting together on a panel and saying well, we are just not going to make a decision.

It is not acceptable. I hope that because Senator Specter has held this hearing that you will clarify what you think we ought to do, and I hope you will work with us in a positive way to have a clear message to the women of this country that the disease that is killing more of us than any other disease does have a remedy. Maybe there are a few risks, but we know we can save 9,500 lives this year if we will stick to the advice that you have given us in the past. Give us the facts. We can take the facts.

Thank you, Mr. Chairman. I look forward to hearing from the experts.

Senator SPECTER. Thank you. Thank you very much, Senator Hutchison.

The statistics on the funding provided by the Congress on breast cancer I think are worth a moment or two.

The starting figure from fiscal year 1981 was $33.9 million, and that has escalated to $419.6 million this year.

I have been a member of this subcommittee since I came to this Senate in 1981. Notwithstanding cuts in many other branches, the funding on NIH and on breast cancer has gone up exponentially.

When Senator Weichert was chairman here, he was a leader. When Senator Chiles was here, he was a leader. Senator Harkin as chairman was a leader, and we have carried that forward.

I know that Senator Harkin wanted to be here and I think will be here. There is a commitment to try to increase the NIH funding very materially.

I said on the Senate floor last week 7.5 percent, trying to raise it to $952 million more over the $12.4 billion which NIH has at the present time.

Last year in our subcommittee we eliminated some 130 programs, not that they were not good programs, but on a priority scale they were of lesser importance than research, which we think is at the top of the list, especially when you consider that last year, 184,000 women were diagnosed with breast cancer and the estimate is that some 44,000 women will die this year from breast cancer, or 1 in 9.

We will turn now to you, Dr. Klausner. Richard Klausner has been associated with the National Institutes of Health since 1979, when he began his research career at the Cancer Institute. In 1995, Dr. Klausner became the 11th Director of the NCI. He has an impressive list of credentials with training at Yale, Harvard, and Duke. I don't know why they put Yale at the head of the list, but they did, Dr. Klausner. [Laughter.]

His research has been recognized with numerous awards and honors.

Dr. Klausner, we welcome you here and look forward to your testimony.

We are going to put on a green light which will signify 5 minutes. To the extent that you can stay within that, we would appreciate it, leaving the maximum amount of time, therefore, for questions and dialog. We do have a very extensive list of witnesses to follow our two very distinguished physicians here, Dr. Klausner and Dr. Blumenthal.

Dr. Klausner, the floor is yours.

SUMMARY STATEMENT OF DR. RICHARD D. KLAUSNER

Dr. KLAUSNER. Thank you very much, Senator Specter, Senator Hutchison. I want to thank you for your interest in this important issue.

Some 2 weeks ago, a conference was held at the NIH that brought together experts from around the world in all aspects of mammography, as well as an independent consensus panel in order to address the confusing and often contentious issue, the debate that surrounds the question of the age at which a woman should begin regular screening mammography.

On behalf of the National Cancer Institute, I had asked for this conference in response to reports of new data, primarily from Sweden, that addressed the great gap in our knowledge concerning the potential benefit of population screening of women aged 40 to 49. And, as hoped, the conference successfully stimulated the bringing together of new information and the presentation of new and updated analysis.

From a scientific point of view, the value of any screening test used in a healthy population depends upon the incidence of the disease, the mortality associated with that incidence, as well as the performance characteristics, the shortcomings and risks, as you said, of the screening procedure.

A woman's risk of breast cancer does not suddenly change at any particular age, but gradually and steadily rises. It is not surprising, therefore, that the value of widespread screening follows a similar pattern of increasing value at increasing age.

There is and has been general agreement that there are benefits from regular screening mammography between the ages of 50 and 69. While breast cancer does occur in young women in their twenties and thirties, because of its low incidence in this age group, screening for all women in their twenties and thirties has not been considered warranted. So we are left with the issue of the transition of women between the ages of 40 and 49.

As a woman enters her forties, she is moving from a time where regular population screening has not been recommended to one where it is proven to be beneficial.

One of the complexities of the question is when is the line crossed. Is it at 40, 42, 44, or 50? Rather than concluding that there is only one right answer to that question, the consensus panel concluded that each woman should make an informed decision in the decade of her forties that is the right answer for her.

Despite some press accounts, I stated at the end of the conference that I agreed with the sentiment of a woman needing the information to make her own decision. But I also stated that I had concern with the balance and tone of the discussion in the panel's draft report. It is my opinion that the draft report of the panel overly minimizes the benefits of mammography and overly emphasizes the risks for that population.

I believe that a balanced and careful statement of both the pros and the cons of screening is essential for a woman to make an informed decision whether to initiate regular mammography and at what point.

Do we now have evidence that would support a woman's decision if she decides to begin screening mammography in her forties? The best data we have is from eight randomized clinical trials involving over 180,000 women, including the five most updated Swedish studies.

Few trials have enough instances of death from breast cancer to achieve statistical significance in answering that question. But analyzed all together by a procedure called meta-analysis, there is now a 15-percent statistically significant reduction in mortality for screening beginning in the forties. The meta-analysis included the eight randomized clinical trials that were conducted over 30 years in the United States, Sweden, Canada, and Great Britain.

I would be happy to discuss further the interpretation in the questioning period.

What does this mean to an individual woman? In general, a woman in her forties has a 1 in 66 chance of being diagnosed with breast cancer and a 1 in 190 chance of dying from breast cancer that develops in that decade. A 15-percent reduction would lower these odds of dying to about 1 in 220.

This year, as we heard, over 30,000 women in their forties will be diagnosed with breast cancer and a 15-percent reduction in mortality would mean over 1,600 lives saved.

Why would a woman choose not to have a mammogram? What are the limitations and downsides of mammography?

The first relates to false positives and medical procedures involved in the followup of these false positives. If women were to receive yearly mammograms for 10 years, it is currently estimated that as many as 30 percent will have an apparent abnormality detected. And up to one-fourth of these will result in a biopsy or an invasive procedure. Only one-forth of those for women in their forties would prove to be cancer.

In other words, most abnormal mammograms do not signify cancer. Beyond false positives, mammography may miss up to 25 percent of breast cancer in young women.

What about the risk of radiation? This is a theoretical concern, but it is based largely on exposure to very high doses of radiation and in much younger women. While the risks of radiation should not be completely dismissed, there is no direct evidence that exposure of women in their forties to the levels of radiation used in mammography causes breast cancer or poses any other health risk.

I would be happy to say where we should go from here, but I see the red light is on. Would you like me to just sum up?

Senator SPECTER. Take a few more minutes, if you wish, Dr. Klausner, to sum up.

Dr. KLAUSNER. Thank you.

So, where do we go from here? The presidentially appointed National Cancer Advisory Board, which is the oversight and advisory board legally constituted to advise the National Cancer Institute will and had planned to discuss the issues of screening mammography and the results of the conference, the results that included not just the consensus report but, very importantly, the stimulation and presentation of lots of new data on which we can all make decisions.

Based upon those discussions, the NCI will move forward in terms of information and education positions and the research we need to do to address this question for women at all ages.

We must provide information to every woman and her physician or care giver to ensure that such information is accurate, is current, is balanced, and is user friendly.

NCI long has had and will continue to have a vigorous program in mammography research, including new approaches, such as digital mammography and image analysis, and in nonionizing approaches to cancer imaging, such as ultrasound, MRI, optical scanning, microwaves, and others. Dr. Blumenthal will discuss this.

The NCI will continue its long-standing commitment to support research in new modalities of imaging as well as the important

area of molecular detection. We must strive to enhance the value and reduce the limitations of current mammography. The NCI, the CDC, and the Department of Defense are supporting the breast cancer surveillance consortium, a national mammographic screening and outcome data base which, by the year 2000, will include over 1.8 million screened women, 3.4 million mammograms, and 34,000 cancers, which will provide valuable data to improve the practice, the interpretation, the delivery, and the followup for mammography, as well as an invaluable research data base.

Mammography is not a cure for breast cancer. Better screening methods will not ever replace the need to find real preventions and curative therapies. Mammography has an important place in our current approach to breast cancer, but we do tend to overestimate its benefits. We must remember that 70 percent of breast cancer deaths in women over 50 will still occur, even with regular mammography.

We must not lose sight of the fact that we have to be relentless in our search for a cure.

Women deserve to be active and educated participants in their own health care decisions, and we cannot produce certainty where it does not yet exist. Physicians and scientists must be active partners with consumers to use both the best evidence as well as the best judgment to help each woman to reach a decision that is right for her.

PREPARED STATEMENT

Based on current evidence, we must inform women that there are pros to screening mammography as well as limitations for initiating screening mammography in their forties. We must be wholeheartedly committed to helping each woman weigh these pros and cons, as you said, as a critical part of her health care.

Thank you, and I am happy to answer any questions.

Senator SPECTER. Thank you very much, Dr. Klausner.

[The statement follows:]

PREPARED STATEMENT OF DR. RICHARD KLAUSNER

Good morning, Senator. I am Richard Klausner, Director of the National Cancer Institute. I am here to talk about mammography screening for women ages 40–49. I want to thank you for your interest in this important issue. Two weeks ago, a conference was held at the NIH that brought together experts in all aspects of mammography and an independent consensus panel to address the often confusing and sometimes contentious debate that surrounds the question of the age at which a woman should begin regular mammography. On behalf of the NCI, I had asked for the conference in response to reports of new data, primarily from Sweden, that addresses the great gap in our knowledge concerning the potential benefit of population screening of women age 40–49 and, as hoped, the conference successfully stimulated the presentation and discussion of new and updated data.

From a scientific point of view, the value of any screening test used in a healthy population depends on the incidence of the disease, the mortality associated with that incidence as well as on the performance characteristics, shortcomings, and risks of the screening procedure. A woman's risk of breast cancer does not suddenly change at a particular age but gradually and steadily rises. It is not surprising, therefore, that the value of widespread screening follows a similar pattern. There is general agreement that the population of women between the ages of 50–69 benefits from regular mammography While breast cancer does occur in very young women, there is general agreement that, because of its low incidence in this population, screening, for all women in their 20's or 30's is not warranted. So we are left with the issue of women age 40 to 49. As a woman enters her forties, she is

beginning to move from a time when regular population screening is not warranted to one where it is proven to be beneficial. The question is where that line is crossed. Is it age 40? Age 42? Age 46? Or Age 50?

Rather than concluding that there is only one right angrier to the question, the Panel concluded that each women should make an informed decision in the transition decade of her forties that is the right answer for her. Despite some press accounts, I stated at the end of the conference that I agreed with this conclusion of the Panel. My concern was with the balance and tone of the discussion in the Panel's draft report. It is my opinion that the draft report of the Panel overly minimizes the benefits and overly emphasizes the risks for this population. A balanced statement of the pros and cons of screening is essential for a woman to make an informed decision whether to initiate regular mammography in her forties.

Do we now have evidence that would support a woman's decision if she decides to begin screening mammography in her forties? The best data we have is from 8 randomized clinical trials involving, about 180,000 women, including the 5 Swedish studies. Few trials have enough instances of death from breast cancer to achieve statistical significance, but analyzed all together, by a procedure called meta-analysis, there is about a 15-percent reduction in mortality. The meta-analysis included eight randomized clinical trials that were conducted over the past 30 years from the United States, Sweden, Canada and Great Britain. I would be happy to discuss the interpretation of these studies in the question period. What does this mean to an individual woman? In general, a woman in her forties has a 1 in 66 chance of being diagnosed with breast cancer and about 1 chance in 190 of dying of breast cancer that develops in that decade. A 15 percent reduction would lower these odds of dying to about 1 in 220.

What does this mean? This year, over 30,000 women in their forties will be diagnosed with breast cancer and a 15 percent reduction in mortality would mean over 1,600 lives saved. This year, about 27,000 women in their fifties will be diagnosed with breast cancer and over 3,300 lives would be predicted to be saved via mammographic screening in that age group.

Why would a woman choose not to have a mammogram? What are the limitations and downsides of mammography? The first relates to false positives and the medical procedures involved in follow-up of the false positives. If women were to receive yearly mammograms for 10 years, it is estimated that as many as 30 percent of all women will have an apparent abnormality detected. An estimated one-fourth of these will result in biopsies and, for women in their 40's, only about one-fourth of these biopsies will prove to be cancer. In other words, most abnormal mammograms do not signify cancer. Beyond false positives, mammography may miss up to 25 percent of breast cancer in young women, a percentage that falls to 10–15 percent in older women (i.e., women over age 50).

What about the risks of radiation? This is a theoretical concern, but it is based largely on exposure to very high doses of radiation and in much younger women. While the risks of radiation should not be completely dismissed, there is no direct evidence that exposure of women in their 40's to the levels of radiation used in mammography causes breast cancer or poses any other health risk.

Where then do we go from here?

The National Cancer Advisory Board will discuss the issue of screening mammography of women in their forties in order to provide guidance to the NCI concerning how we move forward with information, education and research. We must provide information to every woman and her physician or caregiver and to ensure that such information is accurate, current, and user-friendly.

The NCI has long funded vigorous programs in digital mammography, in image analysis, and in non-ionizing approaches to cancer imaging such as ultrasound, MRI, optic scanning, microwaves, and other technologies. Dr. Blumenthal will describe some of these efforts in her opening statement.

The NCI will continue its long-standing commitment to support research in new modalities of imaging and molecular detection, and we must strive to enhance the value and reduce the limitations and problems of current mammography. The NCI, CDC and DOD are supporting the Breast Cancer Surveillance Consortium, a national mammographic screening and outcome data base which, by the year 2000, will include over 1.8 million screened women and provide valuable data to improve the practice, interpretation, delivery and follow-up of mammography in this country.

Mammography is not a cure for breast cancer. Better screening methods will not ever replace the need to find real preventions and curative therapies. Mammography has an important place in our current approach to breast cancer, but we tend to overestimate its benefits. We must remember that 70 percent of breast cancer deaths in women over 50 will still occur even with regular mammography. We must be relentless in our search for a cure.

Women deserve to be active and educated participants in their own health care decisions, and we cannot produce certainty where it doesn't yet exist. Physicians and scientists must be active partners with consumers to use both the best evidence and the best judgment to help each woman reach a decision that is right for her. Based on current evidence, we must inform women about the pros and cons for initiating screening in their forties. We must be wholeheartedly committed to helping each woman weigh these pros and cons as a critical part of her health care.

Thank you. I would be pleased to answer any questions.

SUMMARY STATEMENT OF SUSAN J. BLUMENTHAL, M.D.

Senator SPECTER. We are now going to hear from Dr. Susan Blumenthal before turning to the first round of questions.

We welcome Dr. Blumenthal here. The President appointed her as the country's first Deputy Assistant Secretary for Women's Health, and she also serves in the position as Assistant Surgeon General.

Dr. Blumenthal has received the highest honors of the Public Health Service for her scientific and educational contributions for the advancement of women's health. She coordinates the implementation of the national action plan on breast cancer and serves as its cochair.

Dr. Blumenthal has been a leader on imaging and took the initiative with the Central Intelligence Agency to get a special million dollar grant from CIA which was then supplemented by an additional million dollars on the proposition that if CIA could do imaging from outer space through the clouds and find out what was going on on tiny particles of ground thousands of miles away, that that imaging process could be of special benefit for the detection of breast cancer.

Almost 1 year ago, last March Dr. Blumenthal presided at a session of the Hospital of the University of Pennsylvania on the advantages of those new imaging techniques. At that time, we found that there was a need for clinical trials.

The Congress has not passed the budget, which had been due on September 30, 1995, in our continuing efficiency. So we were able, when we passed the budget in April, the next month, to get a special grant of $2 million for clinical trials. That started last September. I think we set a record for getting something done in the Federal Government bureaucracy.

Dr. Blumenthal has been in this field for a very long time.

We welcome you here this morning, Dr. Blumenthal and look forward to your testimony.

Dr. BLUMENTHAL. Thank you very much, Mr. Chairman and to you, Senator Hutchison. I want to express our gratitude to you both for your leadership in the battle against breast cancer.

I direct the United States Public Health Service's Office on Women's Health. It is the focal point for the coordination of research, service delivery, and education programs across the agencies of the Department of Health and Human Services. We work with other governmental agencies, with women's groups, consumer groups, and health care professional organizations to advance women's health in the United States and internationally.

My remarks this morning are going to address current departmental programs to improve breast cancer detection and diagnosis to ensure that today's mammography is of the highest quality and

that women have access to this life-saving technology. I then want to describe other initiatives underway, some in partnership with other Federal organizations, to bring the field of breast imaging into the 21st century, so that we will have more accurate methods to detect and diagnose this disease in all women.

I also want to provide you with a brief progress report on departmental efforts in the fight against breast cancer.

Since currently there is no cure for breast cancer or method to prevent it from occurring, the key to saving women's lives is the early detection of the disease, when treatment is the most effective and survival rates are best. That is where today's x-ray mammography has proven crucial.

Mammography is a life-saving technology that can detect breast cancer more than 1 to 2 years before a lump can be felt. When it is detected at its earliest possible stage, 5 year survival rates are 93 percent and 10 year survival is 76 percent. Early detection also means that breast sparing surgery, lumpectomy, can be performed.

But did you know that until just 2 years ago, a woman could go to a mammogram facility and not know if that machine was 20 years old, or if the person who positioned her or interpreted the mammogram had adequate experience to do so?

The Food and Drug Administration's implementation of the Mammography Quality Standards Act now ensures that women are guided to the safest and most reliable mammography in their communities. Today, it is illegal for a mammogram facility to operate without that FDA seal of approval.

Recognizing the importance of the quality of screening mammograms, the Agency for Health Care Policy and Research developed clinical practice guidelines to define the roles and responsibilities of mammography facilities, the health care provider, and women themselves to ensure quality mammograms.

Additionally, the Centers for Disease Control and Prevention Breast and Cervical Cancer Early Detection Program is providing mammograms to women nationwide at low or no cost to those who cannot afford them. To date, over 1 million low income, minority, and underserved women have been screened for breast or cervical cancer under this very important nationwide program.

Since breast cancer is primarily a disease of older women with 60 percent of cases occurring in women over the age of 65, it is important that we educate this group of women about the importance of mammography.

Recently, a screening benefit was added to Medicare, but less than two-thirds of women were using this life-saving benefit.

So 2 years ago, in direct response, the administration launched an educational campaign to encourage the use of mammography by Medicare eligible older women.

There are many barriers that keep women from using mammography, such as cost, fear, concern about pain and radiation exposure, and inadequate information about the value of early detection. In an effort to break down these barriers, the U.S. Department of Health and Human Services has undertaken educational initiatives, often in partnership with public and private sector organizations, to increase women's use of screening mammography and

to reach underserved and priority populations. The NIH and CDC are supporting many important programs in this area.

Further, the Department has made the latest information about breast cancer available to the public and to health care providers through Federal resources, such as the NCI's information line—1–800–4–CANCER, the cancer fax, and on the Internet. In October 1996, the U.S. Public Health Service's Office on Women's Health launched an Internet web site for the national action plan on breast cancer that is providing a gateway to information resources on breast cancer for the public and health care providers.

But despite these improvements in the quality and utilization of mammography, it is still a 40-year-old technology. It misses 15 to 20 percent of cancers; 80 percent of the lesions that it finds are benign, which results in unnecessary medical procedures, including surgical biopsies that can leave scars and can be somewhat disfiguring to the breast. That is why the Department has made it an urgent priority to bring a new generation of breast cancer detection technologies to the battle against this disease.

Today, studies are being supported that have the potential for revolutionizing breast cancer detection and diagnosis. Let me take a few minutes, if I might, to describe some of these technologies to you.

Senator SPECTER. The red light is on, but take a little extra time, Dr. Blumenthal.

Dr. BLUMENTHAL. Thank you.

First is breast ultrasound. Unlike other innovative imaging techniques that I will discuss, it already has an established role in the diagnosis and management of breast disease. High resolution ultrasound can determine whether many lesions are benign cysts or solid lesions, and the features of solid masses can be further analyzed with this technology to help differentiate those that are most likely to be benign from those with malignant characteristics.

Digital mammography is the most promising new technology for improved detection of breast cancer for large-scale screening programs. In sharp contrast to conventional mammography, digital mammography actually generates images directly on the computer where the image can be digitally enhanced, improving image quality and allowing radiologists to detect smaller lesions using lower radiation doses.

In addition, digital mammography opens new avenues for improved detection, including computer assisted diagnosis, where the computer actually serves as a second opinion, enhancing radiologic interpretation and improving the ability to distinguish benign from cancerous lesions. Also, digital mammography will provide opportunities for telemammography, where using telemedicine approaches breast images actually can be transmitted by computers and satellites from community clinics in remote areas to academic centers or other sites for expert radiologic consultation.

Senator SPECTER. Dr. Blumenthal, I note that you are on page 5 of an 11 page statement.

Dr. BLUMENTHAL. Let me just highlight a few remaining points.

Senator SPECTER. Your full statement will be made a part of the record. I do not want to hurry you unduly, but it is a long statement.

Dr. BLUMENTHAL. Today, we are supporting an interdisciplinary, multidisciplinary collaboration of academic centers to facilitate the implementation of digital mammography on a larger scale.

I also want to inform you that breast MRI has emerged as one of the most promising novel technologies for the detection and staging of breast cancer in women, particularly with radio dense breast tissue.

Unlike either conventional or digital mammography, MRI does not involve ionizing radiation.

Position emission tomography, the PET scan, is also an important new strategy. It produces an image of the biochemical and physiologic process in the body. This molecular imaging technology, we believe, will help us to find tumors when there are only a few cells present. PET scan can help detect primary tumors, as well as the spread of breast cancer to the lymph nodes and other regions of the body.

Finally, deeply concerned about the limitations of conventional mammography, 2½ years ago the U.S. Public Health Service's Office on Women's Health developed the new frontiers in breast cancer imaging: from missiles to mammogram project to help adapt advanced imaging technology from the defense, intelligence, and space communities to help improve the early detection of breast cancer.

After all, if we can see missiles 20,000 miles away in distant skies and with the Hubble telescope see the surface of Mars, then surely we should be able to detect small lesions in women's breasts right here on Earth.

So we reached out to the CIA and DOD and have been working with them over the past 2 years to transfer their imaging technologies used for missile and target recognition to improve the early detection of breast cancer.

We are now supporting a multisite clinical trial coordinated by the University of Pennsylvania working with other major academic centers, to explore the effectiveness of these imaging technologies to enhance the accuracy of mammography and MRI's.

Preliminary studies are showing that these technologies significantly improve in the accuracy of mammography and MRI's.

Finally, breast biopsies are being improved with new imaging technologies using the optics from the Hubble space telescope. We are able to improve image-guided stereotactic needle breast biopsy, which is a relatively noninvasive procedure with only minimal scarring. We are also searching for new technologies that will enable us to find biological markers for breast cancer in the blood, the urine, or nipple aspirates.

To facilitate the transfer of these technologies, we have established a Federal multiagency imaging consortium on women's health with representatives from all relevant agencies of the Federal Government to identify potential technology transfer opportunities from these agencies to improve the detection of breast cancer and other diseases in women.

These are just a few of the important initiatives underway to improve the accuracy of the detection of breast cancer for women of all ages. I do not have time to give you a report card on other departmental initiatives, but I want you to know that the administra-

tion has made the fight against breast cancer a top national health priority. The Department has increased funding and has a number of programs and activities underway.

PREPARED STATEMENT

In summary, Mr. Chairman, the initiatives and programs of the Department of Health and Human Services are making significant difference toward progress in the fight against breast cancer. The Department's efforts to eradicate breast cancer are being deployed on many fronts, increasing basic and clinical research, improving early detection and diagnosis, enhancing the range and effectiveness of treatments and preventive interventions, and improving access to breast cancer services.

We are grateful for your support, Mr. Chairman, and for that of the committee. We pledge to continue to work together until the war against breast cancer is won.

[The statement follows:]

PREPARED STATEMENT OF SUSAN J. BLUMENTHAL, M.D., M.P.A.

Mr. Chairman, members of the Subcommittee, thank you for the opportunity to speak before you today and for your leadership in the battle against breast cancer. I am Dr. Susan Blumenthal, Deputy Assistant Secretary for Women's Health and Assistant Surgeon General in the U.S. Department of Health and Human Services. I direct the U.S. Public Health Service's Office on Women's Health, the focal point for women's health issues in the Department that coordinates women's health research, health care services, policy and public and health care professional education across the Department, collaborating with other government organizations, and consumer and health care professional groups to advance women's health in the United States and internationally.

My remarks will address current Departmental programs to improve breast cancer detection and diagnosis to ensure that today's mammography is of the highest quality and that women have increased access to this lifesaving technology. I then will describe other initiatives underway, some in partnership with other Federal agencies, to bring the field of breast imaging into the 21st century—to develop more accurate methods to detect and diagnose this disease in all women. I also will provide you with a progress report on Departmental efforts in the fight against breast cancer.

As you know, breast cancer is one of the most complex and devastating public health problems in our country today. It is perhaps the most dreaded and feared disease in women. It has become an epidemic in our country: the number of women affected by this disease has increased from 1 in 20 over a lifetime in the 1950s to 1 in 8 today. And, while there has been good news in that the overall mortality rate from breast cancer has dropped for the first time in recent history 5 percent among women nationwide the death rate continues to increase for women of color, though at a far slower rate than ever before. It is thought that this overall positive trend is related to the increased use of screening mammography by women in this decade, coupled with improvements in treatment.

Improving conventional mammography

Since currently there is no cure for breast cancer or method to prevent it from occurring, the key to saving women's lives is the early detection of the disease, when treatment is the most effective and survival rates are best. That is where today's x-ray mammography has proven crucial. Mammography is a life-saving technology that can detect breast cancer more than 1 to 2 years before a lump can be felt. Experts agree that it can decrease mortality rates by 30 percent in women over the age of 50. And, when it is detected at its earliest stages, 5 year survival rates are 93 percent and 10 year survival is 76 percent. Early detection also means that breast sparing surgery lumpectomy can be performed.

FDA implementation of the mammography quality standards act

Until just two years ago, a woman could go to a mammography facility and not know if the machine was 20 years old or whether the person who positioned her for the test or interpreted the x-ray had adequate training. The Food and Drug Ad-

ministration's implementation of the Mammography Quality Standards Act now ensures that women are guided to the safest and most reliable mammography in their communities. Today, it is illegal for mammography facilities to operate without certification by the FDA.

Mammography guidelines

Recognizing the importance of the quality of screening mammograms in the early detection of breast cancer, the Agency for Health Care Policy and Research (AHCPR) developed Clinical Practice Guidelines—Quality Determinants of Mammography—with separate versions for mammography providers, health care professionals, and consumers. The guidelines define the areas of responsibility for each member of the health care team delivering mammograms, including women themselves.

CDC breast and cervical cancer early detection program

Additionally, the Centers for Disease Control and Prevention's Breast and Cervical Cancer Early Detection Program is providing mammograms nationwide at low or no cost to women who cannot afford them. To date, over 1 million low-income, minority and underserved women have been screened for breast or cervical cancer under this important nationwide initiative that includes all 50 states, 3 territories, the District of Columbia and 13 American Indian tribes.

Medicare initiative

Breast cancer is primarily a disease of older women, with 60 percent of cases occurring in women over the age of 65. However, nearly two-thirds of older women don't use Medicare's mammography screening benefit. In direct response, two years ago, the Administration launched an educational campaign to encourage the use of mammography by Medicare-eligible older women.

Public education

There are many barriers that keep women from using mammography, such as cost, fear, concern about pain and radiation exposure, and inadequate information about the value of early detection.

In an effort to help break down these barriers, the U.S. Department of Health and Human Services has undertaken educational initiatives, often in partnership with public and private sector organizations, to increase women's use of screening mammography.

The National Cancer Institute (NCI), for example, supports three important leadership initiatives the National Black Leadership Initiative on Cancer, the National Hispanic Leadership Initiative on Cancer, and the Appalachian Leadership Initiative on Cancer. The first two initiatives address a broad range of cancer control issues. The last program focuses specifically on improving breast and cervical cancer outreach activities.

Moreover, the Centers for Disease Control and Prevention (CDC) has developed educational collaborations at the national level with a broad range of private sector, public sector, and consumer groups, supporting programs of national organizations from the AARP to the YWCA of the USA, and from the American Indian Healthcare Association to the National Migrant Resource Program to educate their constituencies about breast and cervical cancer, to increase access to screening programs, and to develop methods to reach underserved and other priority populations.

Further, the Department has made the latest information about breast cancer available to the public and to health care providers free through Federal resources, such as the NCI's information line, 1–800–4–CANCER, by the cancer-fax, and on the Internet. And in November 1996, the Office on Women's Health launched an Internet web-site for the National Action Plan on Breast Cancer (NAPBC) that provides answers to frequently asked questions about breast cancer and serves as a gateway to information on research, organizations, advocacy groups, educational conferences and meetings, publications and other resources about breast cancer. The web-site is found at: http://www.napbc.org.

NEW FRONTIERS IN BREAST IMAGING

Despite these improvements and initiatives to improve the quality and utilization of mammography, it is nonetheless a 40-year-old technology. It misses 15 percent to 20 percent of cancers, and 80 percent of lesions found by the technology are benign, resulting in unnecessary medical procedures, including surgical biopsies. This is why the Department has made it a priority to bring a new generation of breast cancer detection technologies to the battle against this disease. A range of studies are now being supported from basic instrumentation and technology development to

preclinical and clinical evaluation that have the potential for revolutionizing breast cancer detection and diagnosis. Let me describe some of these new technologies to you.

Ultrasound

Breast ultrasound, unlike other innovative imaging techniques that I will discuss, already has an established role in the diagnosis and management of breast disease. High-resolution breast ultrasound can determine whether lesions found on clinical examination are benign cysts or solid lesions. The features of solid masses can be further analyzed with high-resolution ultrasound to help differentiate those that are most likely to be benign from those with malignant characteristics. The same technology can be used to guide procedures such as aspiration of cysts and needle biopsies of suspicious solid masses.

Digital mammography

Digital mammography is among the most promising new technologies for improved detection of breast cancer for large scale screening programs. In sharp contrast to conventional mammography, digital mammography generates images directly on a computer where the image can be digitally enhanced, improving image quality and allowing radiologists to detect smaller lesions using lower radiation doses. In addition, digital mammography opens up new avenues for improved detection, including computer assisted diagnosis, where the computer serves as a "second opinion," enhancing radiologic interpretation and improving the ability to distinguish benign from cancerous lesions and telemammography where, using telemedicine, breast images can be transmitted by computer and satellite from community clinics and remote areas to academic centers or other sites for expert radiologic consultation. As we enter the 21st century, telemammography will bring state-of-the-art academic radiologic expertise to underserved populations in our nation and internationally.

Today, an international multi-disciplinary collaboration of academic centers, and industry, supported by the NCI, is facilitating the development, validation and implementation of digital mammography.

Breast MRI

Magnetic resonance imaging (MRI) involves the creation of images from signals generated by the excitation of nuclear particles in a magnetic field. Breast MRI has emerged as one of the most promising novel technologies for the detection and staging of breast cancer in women, particularly for those with radiodense breast tissue for whom traditional or digital x-ray mammography may not be as effective. Unlike either conventional or digital mammography, MRI does not involve ionizing radiation.

Research suggests that MRI is able to pinpoint suspicious lesions camouflaged behind dense breast tissue that traditional x-ray based mammograms have been unable to penetrate sufficiently to accurately detect. Additionally, MRI appears to be unique in its ability to define the size, shape and potential spread in the breast of the tumor, critical for disease staging and treatment planning. Preliminary data suggest that this technology can detect lesions as small as 1–3 mm and that high resolution MRI can improve the differentiation of benign lumps from cancerous ones.

Positron emission tomography (PET)

The ultimate goal of new breast imaging technologies is to detect breast cancer at its earliest stages ideally when only a few cells are present, and long before conventional mammography can detect a tumor. That's where the field of molecular imaging comes in. Positron Emission Tomography the PET scan is a nuclear medicine imaging technology that produces an image of the biochemical and physiological processes in the body. PET makes it possible to detect primary tumors as well as the spread of breast cancer to the lymph nodes and other regions of the body. It is also able to image estrogen receptors and chemotherapeutic agents.

IMPORTANCE OF FEDERAL AGENCY COLLABORATIONS

The missiles to mammograms project

Deeply concerned about the limitations in conventional mammography, the U.S. Public Health Service's Office on Women's Health 2½ years ago developed the "New Frontiers in Breast Imaging: From Missiles to Mammograms" initiative to adapt advanced defense, space, and intelligence imaging technologies from the DOD, CIA and NASA—capabilities estimated to be about 10 years ahead of medical imaging—to the early and more accurate detection of breast cancer.

Medical and intelligence imaging share some common challenges. Both must scan and compare two or more large areas to detect and precisely locate small subtle changes in topography the tank that has been deployed onto a landscape and is camouflaged behind trees; the small cancerous tumor growing deep in a woman's breast, camouflaged by dense breast tissue. And, in both intelligence and medical applications, an incorrect analysis a missed cancer or a missed military target can have tragic consequences.

Using CIA-developed computer algorithms called neural networks (modeled after human brain cells), a computer "learns" the features of the terrain from surveillance photographs and can detect subtle changes in visually matched photographs taken over time, identifying the construction of new buildings or troop movements, for example, and distinguishing them from the context or "normal" landscape. Applying this CIA technology to the detection of breast cancer, a computer can be "trained" to recognize the features of an individual woman's breast including the regions of cancer deposits, such as microcalcifications, that might not be found on digital mammography. In this way, the computer acts as a "second reader." Preliminary results have found that the CIA's neural network technology improves the accuracy of mammography. This new technology is now being tested in a major multi-site clinical trial conducted by the University of Pennsylvania in collaboration with several other academic and industrial partners, supported by the U.S. Public Health Service's Office on Women's Health.

Another component of this multi-site clinical trial is the application of CIA technology used to simulate 3-dimensional missile launches to improve MRI's diagnostic capabilities, creating 3-dimensional pictures of the breast where the volume, shape and size of a tumor can be visualized. This technology is providing a new method to determine the extent and spread of cancerous growth, to improve the accuracy of biopsies, and to monitor tumor response to treatment.

Breast biopsies

Imaging technology is also being used in performing biopsies. Eighty percent of women in the United States who undergo surgical breast biopsies do not have cancer. As an alternative to surgical tissue removal, image-guided needle breast biopsy that uses the optics from the Hubble telescope developed by NASA is being studied for women with non-palpable lesions. Image-guided needle biopsy offers the potential advantages of minimized tissue damage, reduced waiting time until diagnosis, and cost savings. A multi-institutional research program is now testing the efficacy and cost-effectiveness of large-core and fine-needle biopsies compared with more extensive surgical biopsies.

Other research is developing methods to detect products of breast cancer (antigens) in blood, urine, or nipple aspirates, and to detect genetic alterations in women who are at increased risk for breast cancer. Once cancer is diagnosed, studies of these types contribute to characterization of breast tumors and can be useful in treatment planning.

Facilitating new technology transfer opportunities

To bring these and other promising new cutting-edge technologies to reality in the diagnosis and treatment of breast cancer, the U.S. Public Health Service's Office on Women's Health established the Federal Multi-Agency Consortium on Imaging Technologies to Improve Women's Health, with diverse membership across Federal agencies, (including the Department of Health and Human Services, FDA, Department of Defense, Central Intelligence Agency, Department of Energy and the Department of Commerce) to foster the identification, evaluation, and transfer of intelligence, space, energy, defense, and other relevant technologies to advance the current state-of-the-art in the early detection and diagnosis of diseases in women, including breast cancer.

DHHS BREAST CANCER INITIATIVES

These new initiatives to improve breast cancer detection and diagnosis are a critical component of the Department of Health and Human Service's all-out assault against breast cancer. Today, real financial muscle has been put behind the Administration's commitment to eradicating this major killer of American women.

HHS spending on breast cancer

HHS funding for breast cancer research, prevention and treatment has increased from approximately $276 million in fiscal year 1993 to an estimated $541 million in fiscal year 1997. The Centers for Disease Control and Prevention (CDC) are working to increase access for all women to mammography screening and follow-up services, with resources devoted to breast cancer services having increased from $42

million in fiscal year 1993, to $81 million in fiscal year 1997. Cancer research is vital to our understanding of how to prevent, detect and treat breast cancer. The Clinton Administration has intensified research efforts on breast cancer at the National Institutes of Health by increasing funding from $229 million in fiscal year 1993, to $430 million in fiscal year 1997. FDA will spend about $26 million in fiscal year 1997 to implement the Mammography Quality Standards Act. HHS also helps provide treatment for breast cancer patients through the Medicare and Medicaid programs and through the Indian Health Service.

Federal Breast Cancer Coordinating Committee

Additionally, for the first time, all agencies of government have been mobilized to join in the battle against this disease through the establishment and work of a Federal Interagency Coordinating Committee on Breast Cancer that is fostering new collaborations in the fight against this illness. A Federal inventory of breast cancer-related initiatives has been prepared that will soon be available on the world-wide web homesite of the National Action Plan on Breast Cancer.

National action plan on breast cancer

In October 1993, the National Breast Cancer Coalition presented President Clinton a petition with 2.6 million signatures urging that there be a new national strategy to fight this disease. DHHS Secretary Donna Shalala convened a conference two months later, in December 1993, followed by the establishment of the National Action Plan on Breast Cancer, an innovative public-private partnership that is catalyzing new action in research, health care service delivery, and education about the disease. The implementation of the Plan is coordinated by the Office on Women's Health.

The Plan involves public/private working groups on a number of high priority action areas, including: (1) increasing research on the causes of breast cancer, particularly the role played by environmental factors; (2) increasing participation of women in clinical trials; (3) developing national biological resource banks; (4) establishing a comprehensive plan for counseling and educating women about the newly-identified breast cancer genes; (5) using new information technologies to improve breast cancer education for consumers and health care providers; and (6) involving consumers in policy and research decisions. Many new cross-cutting initiatives have been implemented in each of these areas.

Breast cancer among the elderly

The Agency for Health Care Policy and Research (AHCPR) is currently funding a five-year Patient Outcomes Research Team study on the care, costs, and outcomes of early stage breast cancer. The study will examine three alternative treatments for early stage breast cancer in the elderly: modified radical mastectomy, breast-conserving surgery with radiotherapy, and breast-conserving surgery without radiotherapy. The project will look at quality and cost-effectiveness in these projects and will develop clear recommendations for treating early stage breast cancer in the elderly.

Office of Cancer Survivorship

Progress is being made in the battle against cancer. Today, we have an entire generation of Americans who can call themselves cancer survivors. On October 27, 1996, President Clinton unveiled the new Office of Cancer Survivorship at the National Cancer Institute. Recent success of cancer prevention, early detection, and treatment efforts has created a new need: research into the physical, psychological, and economic well-being of the growing number of cancer survivors. The Office of Cancer Survivorship will support studies covering the range of issues facing survivors of cancer, including: long term medical and psychological effects; factors that predispose survivors to second malignancies; reproductive problems following cancer treatment; and their unique insurance and employment issues.

Closing

These initiatives and programs reflect the progress that is being made in the fight against breast cancer. Both the Administration and the Congress have made it a top national health priority. The Department's efforts to eradicate this disease are deployed on many fronts: increasing basic and clinical research, improving early detection and diagnosis, and enhancing the range and effectiveness of treatments and preventive interventions and improving access to breast cancer services. We are grateful for the Committee's support and pledge to continue our work together until this war is won. I would be pleased to answer any questions you may have.

OPENING REMARKS OF SENATOR TOM HARKIN

Senator SPECTER. Thank you very much, Dr. Blumenthal.

I would now like to turn to our distinguished ranking member, Senator Harkin, who had been chairman. I have already acknowledged his outstanding work when talking about him behind his back, before he arrived.

Senator HARKIN. And I appreciate that. You can talk behind my back anytime you want if you say those things.

Senator SPECTER. The beard looks good.

Senator Harkin and I took the lead many years ago on the separate unit at the NIH for women, and he has been a fighter on these issues for many, many years.

You don't have an opening statement, do you?

Senator HARKIN. I will just put it in the record.

Senator SPECTER. No; go ahead and make an opening statement.

Senator HARKIN. OK. I apologize for being late. We always have too many things to do around here in the morning. I really apologize because this is an area of very deep concern to me, one that, as you know, Mr. Chairman, I have worked on for years with you, in concert with you.

I want to thank the witnesses who are here, Dr. Blumenthal, for your work in this area, and Dr. Klausner at NCI for all of the fine work that you do out there. I have to leave here shortly to make a presentation on a budget matter before the Rules Committee.

I want to thank Fran Visco, too. I may miss your testimony. I am going to try to get back here if I can to thank you for your leadership. I have read your testimony and I hope and know that we will all take it to heart.

I think what we have here is an area where reasonable people may have different views on how we approach this. The findings of the NCI panel in some ways are disturbing to me. But in other ways I understand that women have to make their own decisions on these things. Regarding their health, regarding their background, and with the new areas of genetic testing now where we are able to find genetic markers for breast cancer, women will have to decide this for themselves.

I think our role is to make sure that if this is the path a woman decides to go, regardless of her age, the health care support ought to be there for them to have the proper screening and the proper support mechanisms—if that is the path she decides to go down.

I think that is really what we ought to be about doing, providing throughout this country the information that women need on which to make this decision.

I feel very passionately about this. My only two sisters died of breast cancer at a very early age. Fran and I have talked about that a lot. I often think, had they had the information and the support mechanisms, how different things would have been. They did not come from money. These were relatively poor families. But if they had had the information and the support mechanism there by which they could have gotten the information, and then gotten the mammogram screening, and then taken action, I think they would have survived. I feel very confident of that.

So that is the way I approach this issue. I just hope that this NCI panel finding, Dr. Klausner, is not sending some erroneous signal out there that if you are below the age of 50, you do not have to worry. I'll tell you that if you are below 50 and you have genetic markers, you have a family history of the disease, you have to worry. You have to be concerned.

That is what worries me about this panel's finding. It's not what it says but is the echo of what it says that goes out and ripples through society.

I thank you for your leadership in this area. Again, I hope that I can get back here after a bit. I hope that we can, again, begin really focusing on getting out the information women need to make an informed decision, putting the support mechanisms in place, to make sure that no matter how poor any person is they have the knowledge and they know that if they want that mammogram screening, they are going to get it and it is not going to bust them financially to get it; and if they have problems and need followup, that that insurance coverage is going to be there, too, whether it is for Medicare, Medicaid, or private insurance. It has to be there.

Thank you very much.

DRAFT REPORT OF PANEL

Senator SPECTER. We will now proceed with 5-minute rounds of questioning from members of the subcommittee panel.

Dr. Klausner, in your statement you say, "It is my opinion that the draft report of the panel overly minimizes the benefits and overly emphasizes the risks for this population." Aren't you flatly saying they are wrong?

Dr. KLAUSNER. I'm saying that the balance of the data and the evidence that they presented, the tone of the report, in my opinion was not reflective of the balance of evidence we now have, largely because I thought it minimized the evidence that there is benefit and it over-emphasized certain risks, such as radiation risk, which, as I said, I think is quite a theoretical one.

Senator SPECTER. Isn't that an elongated way of saying, again, that they are wrong?

Dr. KLAUSNER. No; I do think that there is a difference between sort of evidence in the verdict you reach and the way you present it. We look at multiple pieces of evidence and we weigh them in order then to reach a conclusion. I felt that the conclusion was very defensible, that women need to be informed to make a decision. But in order to be informed to make an informed and educated decision, we have to be very clear and not about whether there are pros—and I believe there are—but what are the limitations. And there are limitations. Or else we cannot expect women with the support of their physicians, with the support of NCI, to be able to make that sort of informed decision.

Senator SPECTER. Dr. Klausner, either I hear you saying for a third time that they are wrong or I hear you saying something candidly which is unintelligible.

The women in America in the age category of 40 to 49 need to know in unequivocal terms whether a mammogram would be helpful to them in detecting breast cancer. Yes or no?

Dr. KLAUSNER. And as I said, I hope—I have been trying to be very clear—that the evidence is, as far as I can read, that there is a statistically significant benefit in terms of reduction of mortality over long periods of time from initiating screening at some time in your forties. I think I have been very clear with that.

As I said, I disagree with that aspect of the report of the panel.

Senator SPECTER. I take that as a yes.

Dr. Klausner, as a threshold question, how close are we to a cure for breast cancer? The financing has been very extensive. We are prepared to do what it takes. Congressman Porter, who chairs the subcommittee on the House side, Senator Harkin and I, and our predecessors, have been willing to put in whatever money it takes if there is some realistic promise of curing breast cancer.

You are the scientist. What is your evaluation of that?

Dr. KLAUSNER. My evaluation is that I cannot say how close we are to a cure for breast cancer or, indeed, whether there ever will be one, single cure.

Breast cancer is probably multiple different diseases. That has been one of the problems, not being able to distinguish one from the other and treating them all the same.

Breast cancers, individual breast cancers, can be cured and have been cured, and I think we will continue through the types of discovery we are doing to learn what we need to find truly effective treatments for breast cancer.

Senator SPECTER. Is the current funding for breast cancer adequate?

Dr. KLAUSNER. I think there are many opportunities, really good opportunities, that we cannot fund with the current level of funding.

Senator SPECTER. What level of funding would be adequate?

Dr. KLAUSNER. I don't know the exact number to give you for that.

Senator SPECTER. Well, we would be interested in your number.

Dr. KLAUSNER. Sure.

[The information follows:]

NCI BYPASS BUDGET

The NCI Bypass Budget identifies several extraordinary investment opportunities that will advance our knowledge of cancer in general, and will greatly enhance our ability to prevent, diagnose, and treat breast cancer in particular. These investment opportunities include research in cancer genetics, the development of better detection and imaging technologies, new preclinical research models, and increased funding for investigator-initiated research. The increase needed to fund these investments is $269.5 million.

DRAFT REPORT

Senator SPECTER. Dr. Klausner, the report issued by the consensus panel was denominated: draft-draft-draft.

Dr. KLAUSNER. Yes.

Senator SPECTER. A question in my mind—and I know that you are going to convene the National Cancer Advisory Board on February 25 and 26—is why issue a draft report which has so many open questions.

I think it may be worth just 1 minute because a lot of people will focus on this dialog as to the import of what doctors say as they

reach their patients' ears, or they reach the ears of people who are concerned about the particular problem.

I referred in a very personal way to my own experience of somebody looking at my MRI with a snap of the finger saying "weeks to live"—an erroneous reading of my MRI, thankfully. As Senator Harkin points out, the message has gone out to a lot of women don't do it.

Dr. Blumenthal testifies about a variety of factors, fear, concern of radiation, et cetera. If there is any reason not to go to the doctor, let's not go, let's not get the test. The concern is for what the test may show.

This has received enormous publicity. I do not know that you can ever put the genie back in the bottle.

My question to you is, "Why release a draft report which is not final and is not the ultimate word."

Dr. KLAUSNER. That is a very good question.

Let me correct something. This is not an NCI report, nor an NCI panel, nor an NCI advisory body.

Senator SPECTER. Well, didn't you appoint them?

Dr. KLAUSNER. No. No.

Senator SPECTER. Then how did they come into existence?

Dr. KLAUSNER. Let me explain. For about 20 years there has been an independent jury type mechanism for consensus conferences at the NIH. In order not to in any way be viewed as prejudicing the outcome of a discussion about mammography, I discussed this with Dr. Varmus and we went to an office at the NIH that is separate from the NCI to ask them to convene this independent panel. It is the panel's report, and that panel report will be useful to us as we, then, proceed.

Senator SPECTER. So this is not NCI, not the National Cancer Institute? It is the National Institutes of Health?

Dr. KLAUSNER. No; the report actually is the report of this independent panel. It is convened by the Office of Medical Applications of Research within the office of the Director of NIH, and I was not involved with choosing the panel. I met the panel for the first time at the beginning of the meeting.

Senator SPECTER. Well, the document says, in addition to draft-draft-draft, National Institutes of Health consensus development statement.

Should I be asking Dr. Varmus this very good question?

Dr. KLAUSNER. Let me just say that we have been discussing the very good question about whether the process by which a draft report is released so quickly after a very complex conference.

Senator SPECTER. Well, who is responsible for releasing the draft report, which has all the indications of being a premature release?

Dr. KLAUSNER. This particular process is the current process of the NIH consensus process in the Office of Medical Applications of Research. And, based upon this experience, we are, in fact, discussing, and I have been discussing it with the head of that office, with the person responsible for that, as well as Dr. Varmus.

Senator SPECTER. Who is responsible for releasing the draft report?

Dr. KLAUSNER. The process is set up by this Office of Medical Applications of Research and it is the report of the consortium.

Senator SPECTER. Is there a person there?

Dr. KLAUSNER. Yes.

Dr. Harlan is the Associate Director who oversees this.

Senator SPECTER. And is he responsible for releasing the draft report?

Dr. HARLAN. Yes.

Senator SPECTER. Would you identify yourself, please? Please step up to the microphone, Dr. Harlan.

This is an important point as to why a draft report is released.

You are Dr. William R. Harlan, Associate Director for Disease Prevention of the National Institutes of Health.

The question is why release a draft report which causes such concern before it is in its final form?

Dr. HARLAN. The draft report was released for public comment and for comment by the scientists who attended the conference. The panel intended to take that comment and will be taking that comment into consideration as it comes to a final report.

We have been doing this, as Dr. Klausner mentioned, for about 20 years, and it has always worked reasonably well because we will make changes in it from that draft report.

But it has given the public and other public outside of the panel a chance to comment on the report.

Senator SPECTER. Thank you.

Senator Harkin.

Senator HARKIN. Thank you, Mr. Chairman. I must admit to you that I have mixed feelings about this report. On the one hand, it does say to women that you should make your own decisions. It says that you should be empowered to look at your own health background and that you should be empowered to make these decisions yourself. I like that. People ought to be empowered to make those decisions.

On the other hand, I am concerned if the report, as echoes of this report gets out, that somehow insurance companies and other coverers will begin to rescind, deny, or to cut back on coverage for women who do make that decision, who are in their forties and maybe even earlier, but who, because of a family history or their own particular situation, want to have the mammogram. I am concerned that the coverage will not be there for them.

I guess if I had a bottom line, as we always say around here, my bottom line is sort of what I alluded to in my opening statement. It is that we have to ensure that women have the power to make these decisions themselves, and the insurance coverage ought to be there for them, regardless at what age they want to have this screening.

That is sort of how I am weighing this report. It is good on the one hand and perhaps bad on the other hand if it sends out the wrong signal.

I would ask you that it was not in any way your intention or at all to send out any signal, or that you would deny that there should be anything read into that to insurance companies that they could in any way cut back on coverage for women in their thirties, their twenties—I don't care—if they, in fact, want this screening for themselves.

Dr. KLAUSNER. Right. From my reading of the clear intention of the panel, they did not intend that message at all.

Senator HARKIN. I think that is an important message to send out, very important.

Dr. BLUMENTHAL. I think, too, actually in the consensus panel report it recommended that women who choose to have mammograms during this age period would receive reimbursement for it. That was the panel's recommendation.

Senator HARKIN. Go ahead, Doctor.

Dr. KLAUSNER. Let me say one other thing. There is also a difference between population screening, addressing all women, and the issues that you raised of women with, for example, a particular family history or a medical condition, or a particular reason that would lead her to decide that at the age of 30 or 35 it was medically appropriate, specifically, not as a population screening but of her own decision.

Senator HARKIN. Individually.

Dr. KLAUSNER. As an individual test, and that is a very different issue.

Senator HARKIN. I guess the other thing that I am concerned about is this. When it gets to that age, I agree that it ought to be the individual making her decision, but the coverage ought to be there fully.

I am also concerned about where there is no dispute about the benefit of mammography for women over the age of 60, 62, or 65—and I forget just what that age is.

Dr. KLAUSNER. It's 50.

Senator HARKIN. Age 50? I thought there was no dispute over age 60, but some dispute at age 50, and then it gets less and less because of age factors.

But what I am concerned about then, if it is 50, is what can we do if less than 50 percent—I understand—less than 50 percent of the women in that age group are, in fact, getting mammograms, and there is no dispute about the benefit of that. What can we do to raise up that 50 percent level?

Dr. Blumenthal.

Dr. BLUMENTHAL. As I mentioned in my testimony, there are a number of educational programs underway. The NIH and the CDC have programs where they are working in partnership with other public and private sector organizations, from the YWCA to the Association of Retired Persons, to reach priority and underserved populations, to educate and, using community education methods, to motivate them to use this life-saving technology, mammography.

Additionally, the Centers for Disease Control and Prevention has a program, in all 50 States, that provides low cost or free mammography to women who cannot afford them. This has increased the utilization of this important procedure.

Senator HARKIN. I'm sorry, but I have to go. You have been very kind with the time, Mr. Chairman. But I just cannot leave, however, without saying that this is all well and good and we have to focus on this. But the chairman and I are working together, again, to try to get increased funding for research.

This is what we have to focus on. A few years ago, I was able to do a torpedo shot. We doubled the funding because I got some

money from star wars for it, for breast cancer research, out of the Department of Defense. We have had modest increases at NIH of 4 percent. That is fine, but that is not where it is.

Senator Specter and I are going to be proposing, again, an approach where we can really get the funding up, not only for this research but for all research at NIH. That is where we have to focus our attention, on that research.

Dr. BLUMENTHAL. Senator Harkin, it is really unacceptable that in 1997 we do not have a more accurate technology to detect breast cancer for all women. We pledge to work to intensify our efforts, as we have been already, to discover more accurate, earlier detection methods for all women.

Senator HARKIN. That is where we need more research money. Thank you very much.

Thank you, Mr. Chairman.

Senator SPECTER. Thank you, Senator Harkin.

Senator Hutchison.

Senator HUTCHISON. Thank you, Mr. Chairman.

I want to say that I will work with the chairman and the ranking member for more funding, but I am not going to take it from our missile defense systems. I think it should come from other programs that are lesser in priority.

I have this question for you, Dr. Klausner.

I believe that you agree with us that there has been a bad, erroneous signal sent through the baffling draft report of this advisory committee. But this advisory committee is not your council. It is not the one that will decide if you are going to issue guidelines or if you are going to issue statements of scientific fact.

My question to you is what are you going to recommend to the panel that will come out of the National Cancer Institute, which is the lead Government organization, as a recommendation? Are you going to suggest that we go back to clear guidelines that state what the potential risks might be? Or are you going to let this report, with which I think you have said you disagree, continue to muddy the water?

Dr. KLAUSNER. We do not want to muddy the water. I think we are going to work very hard to be as clear as absolutely possible.

I have promised the National Cancer Advisory Board that I will work, that the whole institute will work very closely with them in formulating exactly our position. I feel it would actually be unfair to them to prefigure what I think they should conclude. That is going to be an important process, an important discussion which we will have, which we will have openly, and together we will come to a position as to guidelines or not guidelines as to information, as to educational products, as to the whole range of things that the NCI needs to do to be very clear about information concerning mammography.

Senator HUTCHISON. What would be the timetable of the action of the panel so that NCI would have a position, which you do not now have—or which you have, but have changed and now we are hoping you are going to be a little more clear?

Dr. KLAUSNER. The meeting of the National Cancer Advisory Board is on February 25 and 26. I think it is going to very much

depend upon what is agreed to there, what work needs to be done to craft our positions.

We will move as quickly as we can. That is what we promise.

A number of organizations are now in the process with new information, with evolving information. I think the American Cancer Society is planning a March meeting to reexamine their guidelines.

So this is a time in which, with new information coming out, new analyses, we need to take the time. We need to do it as quickly as possible, but we need to make sure that what we do, we do right, we do clearly, and we do well.

Senator HUTCHISON. Let me ask this question.

You testified that we have about a 25-percent miss as a percentage in mammogram technology and accuracy. Dr. Blumenthal named several new types of technology that seemed to be better.

Are we going to be able to get a better rate of accuracy fairly quickly? And with the research dollars, are you going to see that we target the technology to get better accuracy for detection?

Obviously, I guess you have to make the decision are we going to go for detection or cure and how do you spend the dollars most wisely.

What is your suggestion?

Dr. KLAUSNER. Well, the reality is we need to do both. I mean, we can't put all of our eggs in one basket. We are working on cure. We're working on early detection. We are putting a lot of money into many different projects that are ongoing now to answer exactly those questions.

We think new image analysis can bring us a long way to better use of mammography, whether it is film based or digital mammography.

Dr. Blumenthal talked about magnetic resonance imaging. That is a very interesting approach. It seems to see more abnormalities, but it has much more trouble right now than mammography telling whether it is a cancer or a normal tissue. That is being worked on very intensively.

All of these techniques take development. The investments are being made.

We have a new task force at the NCI headed by Dr. David Bragg, a very well known and eminent radiologist. It is a new task force that is an ongoing think tank to provide perspectives on where we need to go in detection technologies. That is beginning now.

Senator HUTCHISON. Can we do better than 75 percent accuracy pretty fast?

Dr. KLAUSNER. I think we can. I don't know exactly how much we can get that down.

Mammography is clearly changing. One of the limitations of the studies we are talking about is some of them are 30 years old using outdated mammographic technology. Mammography, while it is an old technology, has gotten better. Reading has gotten better. Film has gotten better.

There is no question. It is continuing to get better. I would imagine that those numbers will go down.

But I suspect the way that they are going to go down much more dramatically is by the development of some new aspects of imaging technology.

Senator HUTCHISON. Thank you, Mr. Chairman. My time is up.

I do have a second round for this panel when my time comes back.

Senator SPECTER. We are going to have a second round.

Senator HUTCHISON. Thank you.

Senator SPECTER. On the issue of the MRI's and the multi-institutional testing which is being undertaken, coordinated at the Hospital of the University of Pennsylvania, it has been my understanding that there has not been quite the emphasis on funding there that there might be.

Dr. Blumenthal, I would appreciate it if you would address the expectation as to what the MRI could do by way of improving the detection rate that Senator Hutchison talks about and the issue of the adequacy of funding on that multi-institutional MRI testing.

Dr. BLUMENTHAL. That study I believe has been approved but not funded yet by the NCI.

Senator SPECTER. Why hasn't it been funded?

Dr. BLUMENTHAL. I cannot address that. I think Dr. Klausner would need to do that.

Senator SPECTER. Dr. Klausner, why hasn't it been funded?

Dr. KLAUSNER. I must say that I do not know. I am not aware that that study has not been funded.

Dr. BLUMENTHAL. We will request that NCI look into the status of the funding for the multi-institutional MRI study.

[The information follows:]

MRI IN BREAST CANCER

In April 1996, NCI issued a Request for Applications [RFA] entitled "Multi-Institutional Cooperative Agreements for Clinical Evaluation of Magnetic Resonance Imaging in Breast Cancer." The applications submitted in response to this RFA have been peer reviewed and are awaiting second level review by the National Cancer Advisory Board. Once reviewed, NCI staff will develop a recommendation for funding.

BREAST CANCER DIAGNOSIS

Dr. BLUMENTHAL. But several studies have been conducted on the effectiveness of MRI in breast cancer diagnosis. Again, preliminary evidence suggests that it is able to significantly increase the accuracy of differentiating between benign and cancerous tumors.

Senator SPECTER. How good can it get? What are the prospects for eliminating the area of error?

Dr. BLUMENTHAL. Right now MRI is seen as a diagnostic technology rather than a screening technology. We need to study MRI in many academic sites with many patients to evaluate its effectiveness so that we can get definitive evidence.

Additionally, you mentioned about improving the accuracy of conventional mammography through our missiles to mammograms project using very inexpensive computer algorithms from the intelligence community to improve breast cancer detection. Some of our scientists who have been working for 10 years to better improve detection on mammography of microcalcifications—which are the deposits that many cancers produce—report that accuracy has increased two-fold.

Senator SPECTER. Dr. Blumenthal, I want to shift gears here. These subjects all would warrant a great deal of examination but

there is limited time. I want to focus for a moment or two on the issue of gene detection.

Now the results on gene detection have been absolutely phenomenal. We compliment the research which has been done by the scientists across America in so many fields. There is nothing more important than health, and that is why the Congress has tried to put the funding into NIH.

There are some 27,000 research applications which were granted and there are many more which are needed. Frankly, I am disturbed to hear that NIH has not funded the multi-institutional MRI studies because I know what an MRI can do.

Then we have the accomplishments and advances on gene detection. If there is a determination through the genes about a proclivity for breast cancer, that can be determined at a very early stage.

Now there is not a protection for privacy on that kind of a determination. The law of the insurance companies is that if you do not make a full disclosure as to your situation, the lawyers will call it fraud in the inducement, and the insurance does not cover it. So if somebody knows they have a gene which gives them a predisposition—Fran Visco is nodding; she is both a lawyer and a breast cancer expert—it does not cover it.

We can legislate in the field, and I think we have been derelict in not moving ahead. But the question for you, Dr. Blumenthal, which I would like you to address is what can the gene therapy show us in terms of a predisposition to breast cancer? How can that be helpful to the treatment for breast cancer, whatever can follow up from it, and what needs to be done?

We can legislate on this federally to protect privacy and to change the insurance laws so that if a woman can benefit from having that determination made, she should not be disallowed insurance coverage because if she had not done it, she would be allowed insurance coverage.

Ignorance is not bliss, as Dr. Healy said.

So how can we address the gene issue and what are the potential benefits for women's health if we make that determination on an individual basis?

Dr. BLUMENTHAL. The national action plan on breast cancer has had a working group on hereditary susceptibility genes and the legal and ethical issues surrounding their discovery.

These genes offer the promise of developing new treatment strategies and one day the hope, perhaps, of repairing the gene so the disease does not develop in the first place.

However, it has also opened up a Pandora's box of very daunting legal and ethical issues, such as you mentioned.

Senator SPECTER. If we found a gene in a woman and knew the predisposition, how would that help you, Dr. Blumenthal, in caring for the woman?

Dr. BLUMENTHAL. Right now, two genes, BRCA–1 and –2, that have been identified that are associated with high risk for breast cancer. There is a blood test available today to test for these genes.

However, currently we recommend that this be used only in a research setting because we are extremely concerned about work, life and health insurance discrimination based on genetic information, and because we do not have a way of preventing the disease, and

there are unclear recommendations about what a woman can do in terms of intervention strategies.

So we are working on this right now. I think it is a very important area. It is a promising area, but it is also associated with a number of problematic issues.

One of the things that some of these new diagnostic technologies may offer, such as MRI, is no exposure ionizing radiation. This may be a better method to monitor women at high risk of breast cancer who carry the gene, because there is some theoretical concern that radiation exposure may be damaging to women who carry this gene.

Again, I want to underscore that it is a theoretical concern. But some of these new technologies may offer a promising way of following women and detecting the disease in women who are at high risk for breast cancer, especially those who have a genetic predisposition.

Senator SPECTER. Before yielding to Senator Hutchison, I would just like to ask you, Dr. Blumenthal and your department, and you, Dr. Klausner, to supplement—because we cannot go into the details now—as to what is doable on the gene line, how it can be helpful in the treatment of women, and what kind of Federal legislation you need to protect privacy so that we can move ahead medically.

[The information follows:]

UNDERSTANDING THE ORIGIN OF A DISEASE

Once a gene has been identified, scientists have an essential key to understanding the origin of a disease. While treatments for such diseases take time to be developed, isolating a gene can quickly lead to the development of a diagnostic test. Such test can readily be used to determine whether or not an individual carries an alteration in that gene. Thus, within a short time after a gene is isolated, individuals can be told whether or not they have an alteration in their copy of this gene. Often, however, they cannot be told at first what that information means to them in terms of their future health or what strategies might be available to reduce their risk of developing a particular disease.

Recently two genes that cause breast cancer (BRCA–1 and BRCA–2) were isolated. Much debate has occurred as a result of this discovery and the advisability of offering a test for alterations in these genes to women. While those who test positive have an increased risk of breast and ovarian cancer, the actual risk to develop these diseases outside high-risk families remains unknown. Even in high-risk families the risk is not 100 percent. Those who test negative may still get breast or ovarian cancer due to environmental factors or other, as yet unknown, genes. While increased cancer surveillance and prevention options can be offered to those found to have alterations in their genes, the effectiveness of these interventions remains uncertain. Furthermore, those who test positive are at increased risk of discrimination in insurance or employment. While the discovery of a gene and the development of a genetic test may be viewed as a great scientific advance, it may not result in an immediate benefit to the persons who undergo testing. This interim phase, when testing is possible but interventions are of uncertain benefit, raises questions about the appropriate use of genetic technologies and information.

The NCI is also establishing a Cancer Genetics Network, which will serve as a dynamic informatics and research infrastructure linking institutions that test individuals for hereditary cancer suseptibility as well as provide counseling and interventions to prevent cancer in these individuals.

The NHGRI has identified four areas which have high priority for the Ethical, Legal and Social Issues (ELSI) program. These priority areas, listed below, form the basis of a recently released, revised Program Announcement, which will serve to further focus future program activities.

Privacy and fairness in the use and interpretation of genetic information.—This area includes studies of the meaning of genetic information and how to minimize

or prevent its misinterpretation or misuse. Of particular concern is genetic discrimination in health insurance and employment.

Clinical integration or new genetic technologies.—This includes an examination of the impact of genetic testing and counseling on individuals, families, and society and the development of policy options related to the clinical use of genetic technologies.

Issues surrounding genetics research.—Informed consent, privacy, and other ethics issues related to the design, conduct, and reporting of genetics research are included here.

Public and professional education.—Activities in this area included the development and evaluation of alternative means of providing education about genetics and related ELSI issues to health professionals, policy makers, and the public.

The ELSI Working Group has formed a Task Force on Genetic Testing which is examining the current state of genetic testing in the U.S. to make recommendations that will ensure the development and delivery of safe and effective genetic tests. Specific issues being addressed are the scientific validation of new genetic tests; laboratory quality assurance; and education, counseling, and delivery of genetic tests. Several federal agencies including the Food and Drug Administration, Health Care Financing Administration, national Centers for Disease Control and Prevention, and Agency for Health Care Policy Research, professional societies, as well as the biotechnology industry, insurers and consumers are participating in the Task Force. In March 1996, the Task Force released a set of draft Interim Principles for public comment. The final Principles and Recommendations of the Task Force are expected to be released in the Spring of 1997.

On October 4, 1996, the National Action Plan on Breast Cancer and the ELSI Working Group held a workshop on genetic information and employment discrimination. It is anticipated that the recommendations from the workshop will provide meaningful information to policy makers as they discuss the need for additional legislative protections. The recommendations from the workshop will be published and widely disseminated to policy makers, consumer advocates, and other stake-holders.

DIFFERENT BREAST CANCERS

Senator SPECTER. Senator Hutchison.

Senator HUTCHISON. Thank you, Mr. Chairman.

Let me ask one question to either of you. Is it true that breast cancer, once it is there, whether detected or not, grows faster in younger women, before the age of 50?

Dr. KLAUSNER. There is mixed evidence about that. Probably, overall, cancer in younger women is somewhat more aggressive. But, as I said, I think the problem is lumping together lots of different diseases.

There are many different breast cancers, some of which grow slowly, some of which spread when they are still so small that that is probably why mammography could not work, even if it saw it when it was small, if it had already spread.

Those differences mean that breast cancer is different diseases, and those different diseases will be spread probably differentially across different ages. That is really important, that we shift our focus to making sure that we are treating and approaching the right disease with the right treatment. We cannot lump all breast cancers together. Some grow slowly, some grow rapidly, some spread very poorly, and some spread very rapidly and very early. They are different diseases.

Senator HUTCHISON. I understand that and I know that if it is a different type of strain it might be a slow grower or a fast grower.

Dr. KLAUSNER. There is some evidence that breast cancer on the whole is somewhat more aggressive in younger women than in older women. But this difference is not very dramatic.

Senator HUTCHISON. I understand that, but I do think that it also emphasizes the need to err on the side of doing the most that we can for a group that, with some reservations, nevertheless, is mostly going to be affected.

Let me move to another subject.

Dr. Blumenthal, the breast cancer action plan got $14.75 million from this committee for the 1997 budget. The NAPB steering committee, as I understand it, voted to use $5 million on the plan and to send the rest to NCI for more scientific research.

Do you agree with that allocation? Is the money better spent for the research at NCI? What is the $5 million in the breast cancer action plan being used for? Is that the right allocation of the funds?

Dr. BLUMENTHAL. The action plan right now has six high priority working groups. I mentioned the one on genetic susceptibility and on the legal and ethical issues surrounding these genetic discoveries. Another working group is focusing on stimulating more research on the etiology of breast cancer, particularly on environmental factors—what is it in our diets, in our workplaces, in our homes, radiation exposure in the environment, atmospheric pollutants, pesticides that may be contributing to the increased risk of breast cancer in our lifetimes. This working group is also looking at why breast cancer may have a higher incidence in certain geographic areas of the country.

Another working group is examining how to decrease barriers to women participating in clinical trials. Other priority areas for the plan include involving consumers in research and policy decisions and improving information dissemination to women and their health care providers using new information technologies.

The plan has included a number of important activities that are underway. We would be happy to provide you with a progress report on them.

As you said, the committee did make a recommendation to provide funding for more research at NIH.

This is a recommendation that will go forward to the Secretary, and she will make decisions about the funding allocations.

Senator HUTCHISON. Do you think that it is better used in the actual scientific research? Is that the right allocation, in your opinion?

Dr. BLUMENTHAL. Senator, it is not my decision. We are fighting a war against breast cancer on many fronts. For the first time, we have mobilized all agencies of government, working with the private sector, to fight this disease.

As Dr. Klausner said, we have a lot to do in terms of finding the cure and a way to prevent breast cancer. But we also have to improve early detection of the disease, improve access and education. So we need to put our investment in many different avenues when we are talking about all moneys available in the fight against breast cancer.

Senator HUTCHISON. Do you work with the Susan Komen Foundation for education and outreach to try to help women know that they can do something about early detection and the seminars that they have put together?

Dr. BLUMENTHAL. We have had the privilege of working with the Komen Foundation, with Nancy Brinker and Susan Braun, the new

executive director. We commend their efforts in terms of raising awareness about breast cancer through the Race for the Cure and also for their support of research.

We feel that they have been a very powerful force in our country in the fight against this disease, as has the National Breast Cancer Coalition and many other groups. We work with them very closely to advance knowledge, to improve detection and access to breast cancer services. It is a pleasure to work with them.

Senator HUTCHISON. I would just say that both Susan Komen and Nancy Brinker were tragically diagnosed with breast cancer before the age of 40. So I think we just have to focus on this issue and be more clear.

Thank you, and thank you, Mr. Chairman.

Senator SPECTER. Thank you very much, Senator Hutchison.

We are going to have to move on to the next panel. But I do want to make a brief comment about the question which you have just raised.

The administration came back and asked for the figure of somewhat in excess of $14 million on the action plan. There are a number of items which are included there. The subcommittee recommended that and it was approved by the full Congress and signed by the President.

There are quite a number of items there which the subcommittee and I personally think are very important—these clinical trials which are being undertaken now, coordinated by the Hospital of the University of Pennsylvania, this genetic issue which is very important, the environmental issue, the diet and the workplace issue. If you take $5 million out of $14 million and put $9 million back and more into research, the question is what is the impact there when you have a research budget of $419.6 million?

That is why I ask you the question as to what you really need on research. When you are talking about the action plan and those important items, I would not like to sacrifice them unless we know that those marginal dollars really mean something significant. Then there is the question about whether we ought to have more funding.

We have $1.6 trillion in our Federal budget, and we have not done an adequate job on assessing priorities. There is not a higher priority than breast cancer. Since this action plan has these important items, I don't want to see them eliminated. If it is more money for research, let us know. Let us see what we can do.

Fran Visco and I have corresponded on that. That is a matter of great concern and it could take a whole separate hearing. Perhaps we will have a hearing on it.

But I would like your evaluation, too, Dr. Klausner on the benefits of these other lines.

Dr. KLAUSNER. Absolutely. Thank you.

[The information follows:]

SCIENTIFIC INVESTIGATIONS INTO BREAST CANCER

NCI holds scientific investigations into breast cancer as one of its highest priorities. In 1997, 184,200 new cases of breast cancer will be diagnosed and 44,190 women are expected to die of the disease. The NCI breast cancer research portfolio currently includes the full breadth of research on breast cancer including risk fac-

tors, screening, diagnostics, therapeutics, novel clinical approaches, prevention, and quality-of-life issues.

One aspect of the NCI's efforts in this area is the tracking of incidence and mortality data related to breast cancer. For the first time since such records have been compiled, the breast cancer death rate fell between 1991 and 1995. The decline in cancer mortality rates was 6.3 percent with a larger decline (9.3 percent) in women under the age of 65. The NCI is convinced that these gains reflect the success of both early detection via mammography screening and more effective therapeutic interventions such as adjuvant chemotherapy and hormone therapy. The newest statistics also reveal very significant and positive trends in the breast cancer mortality rates in African American women. In black women, the breast cancer death rate dropped 1.6 percent between 1991 and 1995 compared to an increase of 20.3 percent in the period from 1971 to 1990.

To optimize our efforts in breast cancer, NCI has established a Progress Review Group, to assess research opportunities in breast cancer and the activities of the NCI in the context of these opportunities. It along with the Prostate Cancer Progress Review Group represent the first use of this mechanism. The Breast Cancer Progress Review Group will work with NCI staff in conducting an in-depth evaluation of the current state-of-knowledge regarding this area, survey the literature and related fields of science, and recommend to the NCI, through the National Cancer Advisory Board and the Board of Scientific Advisors, how the Institute can optimally respond to and stimulate research opportunities related to breast cancer. This exercise will help set the NCI's research agenda in breast cancer by identifying and prioritizing those scientific opportunities that are most likely to expand our knowledge base and that will ultimately reduce the burden of this cancer. An important feature of the Progress Review Group is its linking of planning at NCI with a comprehensive program analysis and with all of the institute's program implementation mechanisms.

The NCI has begun the Cancer Genome Anatomy Project (CGAP). The first two goals of CGAP are designed to build an infrastructure of resources, information, and technologies that will provide a platform for the establishment of an index of all genes that are expressed in tumors and support development of new technologies that will allow high throughput analysis of gene and protein expression as well as mutation detection. An early component of CGAP is the preparation of tumor samples for generation of cDNA libraries. During the first year of CGAP libraries will be produced from tissue derived from breast tumors (as well as from prostate, colon, lung, and ovarian tumors) and from corresponding non-tumor tissue samples. This project is aimed at accelerating our ability to develop new markers for breast cancer and to provide accurate and predictive diagnostic tests. Breast cancer is not one disease, and the CGAP is intended to identify the molecular characteristics that distinguish one breast cancer from another in ways that will guide future approaches to the design and choice of effective interventions.

The NAPBC's desire to identify research gaps and needs in breast cancer etiology serves as the impetus for the compilation of an inventory of research projects on breast cancer etiology that is being conducted by the NCI on behalf of NAPBC. A "Breast Cancer Core Questionnaire Project" is also being conducted under NCI scientific leadership and coordination for the NAPBC. This project is intended to improve the availability, quality, and comparability of data on risk factors for breast cancer.

Screening and early detection are important components of reducing the burden of breast cancer. The National Cancer Institute funds numerous research projects to improve conventional mammography and develop alternative imaging technologies to detect and characterize breast tumors. Efforts to improve conventional mammography center on refinements of the technology and quality assurance in the administration and interpretation of the x-ray films. To advance the technology, NCI is funding research to reduce the already low radiation dosage; enhance image quality; develop digital mammography as an improvement over the conventional, film-based technique; develop statistical techniques for computer-assisted interpretation of digitized images; and enable long-distance image transmission technology for clinical consultations.

OUTSTANDING WORK

Senator SPECTER. OK. Thank you very much, Dr. Klausner and Dr. Blumenthal. We appreciate your outstanding work in the field.

Dr. BLUMENTHAL. Thank you very much.

Senator SPECTER. Dr. Klausner, your board is meeting on February 25 and 26?

Dr. KLAUSNER. Yes; it is.

Senator SPECTER. We are going to schedule Secretary Shalala in soon thereafter. Do you think you will have a conclusion after that weekend so that we can start talking about policy and Medicaid and Medicare, and where the Federal money is going to go?

Dr. KLAUSNER. I certainly would be happy to report to you on what happens at that board, but I cannot speak for the board as to when they will complete what they decide to do.

Senator SPECTER. All right. I'm going to take that as a "yes" answer, too.

Thank you, Dr. Klausner.

We are going to defer panel 2 and move right now to panel 3.

The schedules are incredibly complicated around here. Senator Harkin had to go to another session. We all have commitments. I know that the entire subcommittee would like to be here.

I am due before the Rules Committee and am scheduled for 10:45, which is why we moved the hearing up to 9:15 from 9:30. Then I have another commitment. We are announcing the special counsel on the veteran's gulf syndrome issue at 11:45. So there may have to be some interruptions in our hearing.

NONDEPARTMENTAL WITNESSES

STATEMENTS OF:

FRANCES M. VISCO, ESQ., PRESIDENT, NATIONAL BREAST CANCER COALITION, PHILADELPHIA, PA

SUSAN BRAWN, PRESIDENT AND CEO, SUSAN G. KOMEN BREAST CANCER FOUNDATION, DALLAS, TX

DIANA ROWDEN, CHAIR, SUSAN G. KOMEN BREAST CANCER FOUNDATION

ANN MARILYN LEITCH, M.D., ASSOCIATE PROFESSOR OF SURGERY, THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL SCHOOL, DALLAS, TX

BARBARA MONSEES, M.D., ASSOCIATE PROFESSOR OF RADIOLOGY, CHIEF BREAST IMAGING SECTION, MALLINCKRODT INSTITUTE OF RADIOLOGY, WASHINGTON UNIVERSITY SCHOOL OF MEDICINE, ST. LOUIS, MO

DAVID G. HOEL, Ph.D., MEMBER, CONSENSUS DEVELOPMENT PANEL, PROFESSOR AND CHAIRMAN, DEPARTMENT OF BIOMETRY AND EPIDEMIOLOGY, ASSOCIATE DIRECTOR, HOLLINGS CANCER CENTER, MEDICAL UNIVERSITY OF SOUTH CAROLINA, CHARLESTON, SC

SUMMARY STATEMENT OF FRANCES VISCO

Senator SPECTER. I would like to call now the next panel: Ms. Frances M. Visco, Ms. Susan Braun, Ms. Diana Rowden, Dr. Ann Marilyn Leitch, and Dr. Barbara Monsees.

Let us begin with a fellow Philadelphian, Ms. Frances M. Visco, first president of the National Breast Cancer Coalition and a member of its board of directors. She serves on the board of directors of the Linda Krieg Breast Cancer Foundation and was appointed by the President as one of three members of the President's cancer panel.

She also sits on the Department of Defense Breast Cancer Program integration panel, which reviews Department of the Army research programs, and she cochairs the national action plan on breast cancer.

Your statement, as well as all the statements will be made a part of the record. To the extent we can summarize, it will be appreciated. We are going to have to observe the time limits a little more circumspectly here.

We welcome you all here. Ms. Visco, the floor is yours. Our prepared comments do not include the fact that you are a lawyer, but you are a lawyer as well.

Ms. VISCO. Thank you, Senator Specter.

I would like to start by answering a question that you asked Dr. Klausner, and that is how much money we need this year for breast cancer research. The National Breast Cancer Coalition will be asking for $595 million in the National Cancer Institute budget and $150 million for the Department of Defense Peer Reviewed

Breast Cancer Research Program. We will be talking to you about that in great detail.

Senator SPECTER. Is that enough?

Ms. VISCO. Probably not. If we can agree on more, I would be happy to do that.

Senator SPECTER. Ms. Visco, I ask that question very seriously to try to get an estimate. What is enough? How many applications are there out there? If you can, quantify what is enough. As I say, we have $1.6 trillion. It is up to us in the Congress and in this Appropriations Committee and subcommittee to make the determination.

Ms. VISCO. Yes; we will continue to work with you to come up with that number.

I want to take Senator Hutchison's invitation to speak frankly and with the facts, and also with some emotion.

Senator SPECTER. Ms. Visco, I have just been informed that I am due at the Rules Committee. I have to be a witness myself.

So I am going to have to recess this hearing. But I will be back as soon as I can. We may have another recess, but we are going to get it all done.

[A brief recess was taken.]

Senator SPECTER. We will reconvene the subcommittee hearing.

We were in the midst of Ms. Visco's testimony when I had to recess for a few minutes. To explain why I was gone, it was to the Rules Committee where I was presenting a budget for the Veterans' Affairs Committee. We are going to proceed now for 30 minutes and then I will have to excuse myself for a few minutes more. But we will proceed and finish our business today.

I regret the interruptions, but that is just a necessity as our schedules work out here.

Fran, you were on and we are going to start the clock again. So you will get your full time.

Ms. VISCO. Thank you.

I want to thank you, Senator Specter, and the members of your committee for holding these public hearings to further the public's education about the facts behind mammography screening.

My name is Fran Visco. I am a breast cancer survivor, an attorney. I am president of the National Breast Cancer Coalition.

I was diagnosed with breast cancer in September 1987, when I was 39 years old. My breast cancer was diagnosed through a mammogram. I had a lumpectomy, radiation, and chemotherapy. But I am here personally to speak in support of the findings of the consensus panel.

I look around the room and I am impressed with the turnout. I have been following the coverage of the consensus panel in the papers and on television since shortly before the panel convened. I am amazed at the attention we are all giving to the question, and, frankly, I am somewhat appalled at the resources many continue to devote to this question and at the outrage that met the panel's conclusions.

Over the past 2 weeks, I have lost two very close friends and great activists to breast cancer. They were both younger than 50 when they died. A mammogram did not save their lives.

We need outrage over that fact. We cannot act as though this issue, whether to recommend population screening of women age 40 to 49, is the most important question in breast cancer. We have to save our outrage for the fact that we do not know how to prevent the disease, how to cure it, how to detect it truly early, or what to do for an individual woman once we do find it.

There is the fact that we know so little about minority women and breast cancer. Let's save our outrage, resources, energy, and time for the 44,000 women who die each year, for the tens of thousands of women who have no access to health care.

I am thrilled to hear, Senator Specter, that you are outraged about the underfunding of breast cancer research and are committed to making sure that is increased.

What happened here? Specifically, the consensus panel looked at the data. They looked at the scientific data, from trials not designed to answer the question we are asking and trials that do not ask any questions about minority women, and saw that a meta-analysis of the eight trials shows, I thought, a 17 percent, but Dr. Klausner says a 15-percent decrease mortality for women under 50. But the decrease does not begin to show up for 10 years, raising the question, among others, of whether the women who are now in their fifties are actually benefiting from mammography at that age.

We don't know. The data are unclear.

This is nothing new. But we keep asking the question. I don't think that some members of the scientific and medical community are really looking for the answer anymore. I think they are chasing after statistical significance, and we are going to get it no matter what—if we have to play with confidence intervals, wait a long enough time, throw out the trials that do not fit our preconceived notions, get lost in the details.

But the big picture does not change. We all admit the numbers are not overwhelming. Whatever benefit may exist is small.

The issue here is population screening. It is not treatment. It is not the issue that the panel came up with as to whether individual women should get these facts and then make a determination. It is whether we should recommend to the population of women 40 to 49 to get a mammogram every year.

Some seem to argue that the small benefit or those issues should not matter, that public policy should be driven by the fear that we will confuse women. Well, I have more faith in women's ability to understand the truth, as do you, Senator Specter, and you, Senator Hutchison, because what you talked about earlier was the need for women to get the facts, to weigh the risks and benefits, to get the pros and cons. That is what we are asking for.

What is our goal here? A simple message is less confusing. But in this situation, the simple message is wrong. We all want it to be simple. We want mammography to work in all women. It doesn't. We want to reduce breast cancer to a sound byte. It cannot be. We cannot continue to sell women false hope simply because we do not want them to be confused.

We should be devoting our resources to designing mechanisms to get the message out to women; to get them to understand the risks, the benefits, the pros, the cons, so they can make a decision; to get

the message out to women over 50 that women over 50 should get a mammogram every year.

We know that those messages will make a difference. Let us focus our resources and energy on making certain these women have access to quality mammography, to follow-up treatment if needed.

You have the power to enact legislation that will require insurance companies and third party payers to pay for the mammograms when the women in their forties get all of the facts and decide that that is what they want to do.

Again, I am glad that you want to fund the research that we ask for. We need to focus our outrage, our energy, our commitment on guaranteeing access to quality health care for all women and their families. There is no dispute that that public policy will save many lives.

Senator, you have been a leader in Congress on issues of breast cancer. I know I and the coalition have come to you many times and asked you to support policy that is not popular but is right. I know you look carefully at all of the information, at the data. I hope you will do so now.

PREPARED STATEMENT

We cannot continue to give women false hope. If we tell women in their forties to get a mammogram every year, we are saying ignorance is bliss. What we need to tell them is that there are pros and cons, there are risks and benefits. That is the information they need to get. Then let them decide the course of their own care.

Thank you.

Senator SPECTER. Thank you very much, Ms. Visco.

[The statement follows:]

PREPARED STATEMENT OF FRANCES M. VISCO

Thank you, Mr. Chairman and members of the Committee. I am Fran Visco, President of the National Breast Cancer Coalition and a breast cancer survivor. A mammogram detected my breast cancer in September 1987, when I was 39 years old. Yet, the Coalition and I support the findings of the NIH Consensus Conference on Mammography. I am pleased to be here today to explain why.

As you know, the National Breast Cancer Coalition (NBCC) seeks to increase the influence of breast cancer survivors and other activists over research, clinical trials, and public policy and to ensure access to quality health care for all women. NBCC is dedicated to the eradication of breast cancer through action and advocacy.

The early detection of breast cancer is among NBCC's goals. There is currently no screening method that detects this disease truly early. Mammography is the only tool we have and it is far from perfect. Let's be clear, screening mammograms for women under 50 are not the answer to the eradication of breast cancer. No matter how frequently used, or highly advanced, mammograms will never prevent breast cancer, or provide a cure. Making a difference in the fight against breast cancer means making a commitment to research efforts focused on unraveling the fundamental mysteries of this disease.

Of course we all wish there was a screening device that worked for all women and provided "early" detection. But we must not let our desire for an answer propel us to form policy that is contrary to the facts. Even in women over 50, mammography reduces mortality by 30 percent, not 100 percent. For women under 50, the data are just not clear and simply do not support a policy of population-wide mammography screening. Therefore, the National Breast Cancer Coalition continues to support randomized national clinical trials that will compare a variety of screening methods, and their appropriate timing—to truly determine what is in the best interest of women's health.

The Consensus Panel brought together a well regarded and diverse group of experts, scientists, doctors and consumers to consider the data in a thorough and open forum. They reached their conclusions without bias or interference—and I see no reason to dismiss their thoughtful findings. I am very disturbed by the process I have witnessed. The Consensus Panel was brought together to consider the science because we trusted their expertise and judgment. We should not refuse to honor their finding because we would prefer a different outcome based on different science.

Rather than arguing about the Panel and its conclusions, let us turn our collective energies to the questions that remain as identified by the panel. Let's harness our resources into research for prevention, truly early detection and a cure. Let's focus on making sure that all women over 50 have access to quality mammograms, and that all women have the health care they need. Then, we can provide true leadership on behalf of all women who have breast cancer, and all women who live in fear of this disease.

SUMMARY STATEMENT OF SUSAN BRAUN

Senator SPECTER. We now turn to Ms. Susan Braun, who serves as chief executive officer of the Susan G. Komen Breast Cancer Foundation, recently named president of that organization. Prior to joining the foundation, Ms. Braun served in various positions within the Oncology and Immunology Division of Bristol-Myers Squibb.

Welcome and we look forward to your testimony, Ms. Braun.

Ms. BRAUN. Thank you, Senator. Before I get started, I would like to thank you for your leadership role certainly in this issue and other women's issues, and what you have done through the years for breast cancer, and to Senator Hutchison, as well, for being in the trenches back when, I think when people did not even talk about breast cancer in public. We are delighted to see your support for this issue as well. Thank you.

As Senator Specter said, I am Susan Braun, and I am the president and CEO of the Susan G. Komen Breast Cancer Foundation. I am here representing our staff but also the 78 affiliates that we have in 38 States, who we polled prior to coming here about their opinion on this issue as well, so that we could be speaking with their voices as well as just a single voice or two.

Our mission, the mission of the Komen Foundation, is to eradicate breast cancer as a life threatening disease through the advancement of research, education, screening, and treatment.

We do fund millions of dollars of grants each year into basic and clinical research, as well as into community educational programs and screening programs because we do believe and would reflect what Dr. Klausner said earlier, that a cure or cures—and there probably are many forms of breast cancer—are possible and they are increasingly possible with the new research advancements that have been made. But we also recognize and serve the needs of women today as a part of what we do as an organization.

We believe that one of these needs is screening for breast cancer.

I am sure that most people here are very aware that when breast cancer is detected in its earliest stages before it has become invasive, there is about a 95 percent chance of survival for 5 years; whereas after the disease has metastasized to distant parts of the body, that chance is reduced to about 20 percent.

So we do know, and I know there are a lot of data on both sides, as to which kinds of cancer we are talking about. But there are very firm data that early detection is absolutely associated with longevity in breast cancer.

We are also very aware that mammography is anything but a perfect tool. It is old. Its accuracy can vary for a number of different reasons.

The consensus panel reviewed those reasons. Among them are issues such as breast tissue density, even the techniques and skills of the screening technician as well as the screening radiologist or the one who reads the report. There are absolutely false positives and there are false negative readings, and those can be associated with both psychosocial and economic consequences. It is far from perfect.

But it does extend life, and that is, really, where our position derives its basis.

As you know, the consensus panel was charged with examining the data that presently exist on breast cancer screening for women in their forties. Fran is correct that those data, in many cases, were not designed to address the issue of screening for women in their forties. As Rick Klausner said, there are many old studies within that body of evidence, and, clearly, the panel had a very difficult task before them.

We do believe, though, in having reviewed these studies and having reviewed the public literature that they did weigh benefit far more lightly than they weighed risk in their assessment; that the studies that they looked at in determining the benefit which was primarily the end-point of mortality—and there would be other surrogate end-points to look at—but that they weighed those data more lightly relatively than they did weigh the information and/or data which are light about risks. For this reason, we feel that they failed to make a definitive statement about mammography screening for women in their forties.

We think, too, that clear guidelines of all of the available data, properly weighed, would send a very strong public health message and that is that mammograms should be considered an essential part of the health and medical screening of women in this country.

We are concerned and have heard voices of that concern, particularly in the past couple of weeks, that a statement that inappropriately sends a message that mammography is of equivocal value truly can undermine the public health policy and particularly for those individuals and health care providers who are disincentivized to recommend screening or to have screening.

Again, as Senator Harkin pointed out earlier, a minority of women are screened through mammography now, and we would hate to see what would happen if that number were to diminish even further.

So we believe that women deserve this clarity, that all members of society deserve this clarity, and we absolutely believe that women should be able to make their own choices in this matter, but that, clearly, the message that we send will have an impact on the coverage of mammography, as well as on the likelihood for those who may otherwise think they need not be screened to have a better excuse not to.

But we also believe that those most knowledgeable about the implications of this issue can best iterate the current national position on mammography. So the Komen Foundation has requested

that our chair, Diana Rowden, who is sitting to my left, also be asked to speak at this hearing.

PREPARED STATEMENT

Diana is a 44-year-old survivor, and I believe she speaks very eloquently for not only the members of our affiliates, again 78 affiliates in 38 States, and throughout the country, but also for perhaps those 34,000 women in their forties who will be diagnosed this year with breast cancer.

Thank you again for the opportunity for us to present our operations.

[The statement follows:]

PREPARED STATEMENT OF SUSAN BRAUN

My name is Susan Braun, and I am President and CEO of the Susan G. Komen Breast Cancer Foundation. I am here representing the staff members and the thousands of volunteers of the Komen Foundation, which has affiliates in 38 states across the country. Our mission is to eradicate breast cancer as a life-threatening disease through the advancement of research, education, screening, and treatment.

Although the Komen Foundation funds millions of dollars in grants each year for research dedicated solely to breast cancer, with a belief that a cure or cures will be found, we also recognize and serve the needs of women today. One of these needs is to have access to screening for breast cancer.

When breast cancer is found in its earliest stages, the likelihood of five-year survival is over 95 percent. When found after the cancer has metastasized (or spread to other parts of the body), the likelihood of five-year survival drops to 20 percent. Clearly, early detection is a key to longevity for those afflicted with breast cancer.

Mammography is far from a perfect tool for early detection. It is old. Its accuracy can vary because of such diverse factors as breast tissue density and the experience of the technician and reading radiologist. There are false positive readings. There are false negative readings. Each of these can lead to psychosocial and economic consequences. Mammography is far from perfect. Nevertheless, it does extend life.

The consensus panel charged with examining data on breast cancer screening for women aged 40 to 49 had a difficult task. We believe they acted in good faith, with a strong desire to avoid harm to the public health. We also believe that this concern for avoiding harm caused them to weigh risks more heavily than benefits. For this reason, they failed to make a definitive statement about mammography screening for women in their 40s.

Komen representatives have reviewed the key benefit and risk data published in the literature and as presented to the panel in the two days that preceded the issuance of their consensus statement. Our assessment is that the data demonstrating risk are very weak when compared to the data demonstrating benefit. One could further argue that the risks associated with mammography (such as anxiety associated with a false positive reading or even an essentially non-existent radiation risk) pale in comparison to the benefits (such as early detection of breast cancer and a significantly higher longevity).

The current Komen Foundation guidelines for mammography screening are that a woman should have a baseline mammogram by age 40, be screened every one to two years between ages 40 and 49, and be screened annually thereafter. We are now considering revisions for those guidelines, because the data indicate not only that there are benefits which outweigh the risks of screening for women in their 40s, but that once each year is the appropriate screening interval.

Clear guidelines reflective of all available data, properly weighted, send a strong public health message: that mammograms should be considered an essential element in the annual health and medical routines of women. Unclear guidelines, or a statement that inappropriately sends the message that mammography is of equivocal value, can undermine public health policy by creating confusion, undue concern, and avoidance excuses for disinclined individuals, healthcare professionals, and—perhaps most critically—healthcare insurers. We believe that women, and all of society, deserve this clarity.

We also believe that those most knowledgeable of the implications of this issue can best iterate the current national position on mammography. Therefore, the Komen Foundation has also requested that our Board Chair, Diana Rowden, speak at this hearing. Diana is a 44-year old survivor. She speaks for thousands of Komen

constituents, and perhaps, too, for the 34,000 women in their 40s who will be diagnosed with breast cancer this year.

SUMMARY STATEMENT OF DIANA ROWDEN

Senator SPECTER. Thank you very much, Ms. Braun. You have taken over my function as chairman. You have introduced Ms. Diane Rowden. [Laughter.]

Ms. BRAUN. Oh, I'm terribly sorry.

Senator SPECTER. That's OK. I will do it, anyway.

She is the chairman of the board of the Susan G. Komen Breast Cancer Foundation. She has actively been involved in the fight against breast cancer since she was diagnosed with the disease in 1991.

In addition to her position at the Komen Foundation, Ms. Rowden serves on the steering committee of the National Surgical Breast and Bowel Project Cancer Prevention Trial.

Welcome, Ms. Rowden. The floor is yours.

Ms. ROWDEN. Thank you, Senator Specter, and thank you, Senator Hutchison.

I had my first screening mammogram when I was 35 years old. At that time, the screening guidelines recommended that a woman have her first screening mammogram between the ages of 35 and 40; 3½ years later, I was diagnosed with breast cancer.

That screening mammogram did play a key role in my diagnosis, and I do know in my heart that that screening mammogram probably saved my life.

Because of this, I have committed myself in my volunteer work with the Susan G. Komen Foundation to educate as many women as I can about breast cancer. I know that mammography is not a perfect tool. So I try to explain this to women. I try to help them understand what they need to know about mammography and other screening options, and I encourage women to do breast self-exam and also to ask their doctors for a clinical breast exam every year because mammography alone is not the answer.

My biggest concern about the latest commotion over screening women in their forties is that we are sending a message to these women that they need not be concerned about breast cancer. Nothing could be further from the truth.

As Susan mentioned, some 34,000 women in their forties will be diagnosed with this disease this year.

I also have a concern about women being told to make their own decision. Yes; I think women should have a voice in their health care. I think women of all ages, regardless of whether they are 30, 40, 50, or 70, should be able to choose whether or not to go through a screening.

However, the information that they are given has a lot of impact on whether or not they choose to have screening. Many women are under the impression that if they have no family history of breast cancer, they do not need to be worried about this disease. I had no family history of breast cancer, and the truth is only 5 to 10 percent of women who are diagnosed with this disease have hereditary breast cancer.

So there are many risk factors that we do not understand that factor into a decision that even the doctors cannot always guide a woman in her decision.

I am also concerned about studies that look only at mortality as an end-point. There are many other issues of concern: issues such as quality of life, issues about whether or not a woman loses her breast to this disease, issues about whether or not a woman has to have chemotherapy to save her life. Because my cancer was found before it had spread to my lymph nodes, I did not need to have chemotherapy. I did not have that prolonged recovery, and it saved dollars, too. The truth is it saved money.

PREPARED STATEMENT

I want more than anything to find a cure for this disease. But until we find a cure, I think that all women over the age of 40 should have access to the best possible screening technology, and I think that all women of all ages deserve better technology, better screening, better imaging, and perhaps some technology that we have not yet thought of that will find this disease before it takes a woman's life.

Thank you.

Senator SPECTER. Thank you very much, Ms. Rowden. Having been involved yourself, your testimony and Ms. Visco's testimony is especially powerful.

[The statement follows:]

PREPARED STATEMENT OF DIANA ROWDEN

My name is Diana Rowden, and I am Chairman of the Board of the Komen Foundation. When I was 35, I had my first screening mammogram. Although there was no breast cancer in my family, I followed the screening guidelines, which at that time recommended a woman have her first mammogram between the ages of 35 and 40. Three and a half years later, I was diagnosed with breast cancer. That screening mammogram played a key role in the detection of my cancer.

My tumor did not show up on any mammograms nor could any of my doctors feel a lump. But a radiologist who was very skilled in reading mammograms did detect a change. This led to a biopsy and the diagnosis of an invasive breast cancer. Fortunately, the cancer had not spread to my lymph nodes, and I did not need chemotherapy. Had the cancer already spread to my nodes, I would have had chemotherapy, which would have meant prolonged recovery and significantly higher cost for my treatment.

I started volunteering with the Susan G. Komen Breast Cancer Foundation because I wanted to help educate women about breast cancer. I know firsthand that screening mammography can save lives. When telling my story to other women, I explain that all women are at risk for breast cancer. I also tell them that mammography is not a perfect tool, but that it can be of benefit when combined with clinical breast exams and monthly breast self-exam.

Compliance with screening guidelines among all age groups is well below the level needed, and ambiguous screening guidelines compound the problem. They make it that much easier for women to doubt the need for any kind of breast cancer screening.

I'm particularly frustrated by current government guidelines. They send the message that women in their forties need not worry about breast cancer. But nothing could be further from the truth. It is estimated that in 1996, women in their forties would account for 18.1 percent of newly diagnosed invasive breast cancers. Women in their fifties were estimated to make up 16.8 percent of the new cases.[1]

Much has been said about the "harms" of screening women in their forties: false negatives, false positives, over-treatment, and anxiety. But these harms, or risks, are not the exclusive domain of women in their forties. Women of all ages experi-

[1] Source, American Cancer Society Surveillance Research, 1995.

ence anxiety when called back for a diagnostic work-up. And mammography produces false negatives and false positives in women of all ages.

Doctors and screening centers should explain the limitations of mammography and the risks associated with any screening. Women do not need to be discouraged from breast cancer screening, but they do need informed consent.

The randomized clinical trials, which are being used as a basis for determining whether to screen women in their forties, use mortality as the end point: did the women die or not? I urge you to consider other outcomes, which are also valid. Women who have early diagnosis often have more surgical options and less aggressive therapy. New research is leading to even less invasive surgery, which will result in fewer complications and shorter recoveries. This means savings in health care costs as well as improved quality of life.

I am urging the government to change its guidelines to include mammography screening for women in their forties. Until we have a cure for this disease, ALL women over forty need access to the best screening currently available. The government needs to support better screening technology: ALL women, including those under forty, deserve improved imaging or some other method to detect breast cancer at its most treatable stage.

SUMMARY STATEMENT OF DR. ANN MARILYN LEITCH

Senator SPECTER. I would like to turn now to Dr. Ann Marilyn Leitch, associate professor of surgery and the medical director of breast disease programs at the University of Texas Southwestern Medical School in Dallas. She was the president of the American Cancer Society, Texas division, from 1995 through 1996, and presently serves on that division's board of directors and as medical director at large.

Welcome, Dr. Leitch. The floor is yours.

Dr. LEITCH. Thank you very much, Senator Specter and Senator Hutchison, for allowing us to discuss an issue that is very critical to the American Cancer Society.

You asked us in your invitation to discuss the findings of the NIH Consensus Development Conference. We believe that the conclusions reached by the panel were at variance with the data that was presented and, therefore, did not offer women or their physicians the best guidance.

Since the early 1980's, the American Cancer Society has recommended mammographic screening for women in their forties. In 1989, 11 other medical organizations, including the National Cancer Institute, joined us in reviewing the data and issuing a consensus statement that women in their forties should have mammographic screening.

As you know, in 1993 the National Cancer Institute withdrew their support of that recommendation citing a review of the clinical data from trials and stating: "Randomized clinical trials have not shown a statistically significant reduction in mortality for women under the age of 50."

Today, this statement is no longer true. From data that was presented at the consensus panel we have seen that two Swedish trials have shown statistically significant reductions in breast cancer mortality of 36 percent and 44 percent for women invited to be screened with mammography.

In these trials, the benefit was observed after a longer followup of 7 to 10 years. In addition, a meta-analysis, which compiles the results from all eight clinical trials, has also shown significant mortality reduction, and the numbers we have had cited here are variable, but it is at least 16 percent. When Dr. Klausner estimated

that 1,600 lives would be saved with mammography in this age group, if one takes the reduction in mortality of 44 percent, which was reported in one of these trials, we would see nearly 4,500 lives saved.

These studies provide a solid epidemiological evidence that routine screening mammography is effective in reducing breast cancer mortality.

The efficacy of mammography for women in their forties has met the same scientific criteria that has existed for women over the age of 50.

In 1993, when this data was reviewed, the observed benefits of mammography were not considered to be statistically significant. Now that more time has elapsed and further analysis of these trials has been conducted, the benefits of mammography have statistically been established according to the criteria that are demanded.

I would like to touch a bit on the issue of risks that were raised by the panel. The American Cancer Society believes that in addition to downplaying the benefits of mammography, the panel placed undue emphasis on the potential risk of mammography, including the risk of a radiation-induced breast cancer and the problems that arise from false positive or false negative results.

We certainly believe these issues are important, and we have devoted a lot of efforts to improving mammography quality and interpretation. We have been in the forefront of that fight.

But we fear that the unintended and unfortunate consequences of this current debate will be to cause widespread confusion among women and their physicians. This confusion will not be confined to women that are 40 to 49. I am afraid it will be conveyed to other women as well.

We are also concerned that the mixed messages that were delivered by the panel may influence the health insurance industry unduly to limit coverage for mammography for women in this age group.

More importantly, what about the women who do not have any third party carrier to provide for mammography and who depend on public programs? What will our response be?

The American Cancer Society over the years has made tremendous strides in educating women about the values of mammography. We have broken down barriers of financial problems, physical and psychological barriers. What we do not want to happen now is that women will turn away from mammography which, today, is the only tool that we have available to detect a cancer early and reduce a woman's chance of dying of breast cancer.

I take care of women every day. If a woman asks me what can I do in my forties to prevent me from dying of breast cancer, I tell her the first thing she can do is have a mammogram, be examined by her physician, and practice breast self-exam on a monthly basis.

The real or perceived risks of mammographic screening are really very small. The risk of a radiation induced cancer is really a theoretical risk and is far outweighed by the benefits of mammography.

We know that a woman who has a tumor caught when it is less than the size of a dime has a 90-percent chance of being alive 20

years after that diagnosis, and that is without chemotherapy. That is with surgical treatment of breast cancer.

False positives and false negatives occur in any medical test that is performed. We believe that emphasis should be placed on improving mammography technology and interpretation, rather than focusing on its shortcomings and throwing it out as an appropriate modality for screening.

Breast cancer is one of the greatest health concerns of women in the United States. And 1 in 64 women in their forties will be diagnosed with this disease. It accounts for 18 percent of the cancers that occur in women. Breast cancers that occur in women occur in women in their forties.

It represents 12 to 15 percent of the cause of death for women ages 30 to 59.

We do not believe it is good science or good public health policy to limit screening for women ages 40 to 49 to those who reportedly have a high risk. What we know is that most women diagnosed with breast cancer in this age are not identified ahead of time as having high risk. Thus, they would be deprived of the benefit of early detection.

The American Cancer Society, despite the findings of the panel, stands by its current guidelines for mammographic screening. We believe that women in their forties should have access to screening every 1 to 2 years and after age 50 on an annual basis.

In early March, the American Cancer Society will convene an expert panel to address these very issues. We are going to review all of our current guidelines for mammographic screening with all age groups.

PREPARED STATEMENT

We will review the data that was presented to the NIH conference. Of particular importance to us is the issue of the interval of screening. The data seem to suggest that for women in their forties, the interval of 1 year may provide a greater reduction in mortality than the current recommendation we have of every 1 to 2 years.

We appreciate this opportunity to talk with you and the attention that you have paid to this issue.

Senator SPECTER. Thank you very much, Dr. Leitch.

[The statement follows:]

PREPARED STATEMENT OF MARILYN LEITCH, M.D.

Mr. Chairman and members of the committee, I am grateful for the privilege to be here today. The American Cancer Society commends you for your concern about the impact of medical guidelines on health practice and for calling upon our expertise on issues related to reducing suffering and death from cancer.

The American Cancer Society (ACS) is the nationwide, community-based voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives from cancer, and reducing suffering from cancer, through research, education, advocacy, and service.

Mr. Chairman, in your invitation to the American Cancer Society, you asked us to discuss the findings of the NIH Consensus Development Conference on Breast Cancer Screening in Women ages 40–49. We believe that the conclusions reached by the Panel were at variance with the data presented, and therefore did not offer women and their physicians the best guidance. Despite the review of a meta-analysis, two separate reports of clinical trials, and numerous presentations of clinical data, which have all demonstrated a decrease in breast-cancer mortality and im-

proved prognoses due to mammography in women ages 40 to 49, the Panel concluded "that the available data do not warrant a single recommendation for mammography for all women in their forties." This conclusion was surprising in light of the data presented by European and U.S. investigators.

Since 1983, the American Cancer Society has recommended that women ages 40 to 49 get regular mammograms. Due to inherent limitations in the existing eight randomized controlled trials, the scientific basis for this recommendation has not been as strong as that for women ages 50 and older. However, breast cancer is a serious health problem for this age group, and this has led the ACS and other organizations to carefully evaluate these and other data sources, and to periodically review new data related to breast cancer detection in this age group. When we first issued this guideline, we were confident that evidence of benefit was sufficiently compelling to recommend regular mammograms to women in their forties. It was the best advice. In 1989, 11 organizations, including the National Cancer Institute (NCI), reviewed the data and joined together to issue a consensus recommendation that women in their forties have regular mammograms. We reaffirmed that position in a subsequent review of the evidence in 1992.

In 1993, following an international meeting to review recent data on screening in women aged 40 to 49, the NCI withdrew its recommendation for regular screening for women in their forties on the basis that "* * * randomized clinical trials have not shown a statistically significant reduction in mortality for women under the age of 50." Today this statement is no longer true. With the release of two Swedish studies and a meta-analysis of all of the studies, we now have solid epidemiological and clinical evidence that routine mammography screening is effective in reducing breast cancer modality, efficacy of mammography for women in their forties has met the same scientific criteria as has existed for women over the age of 50.

Mr. Chairman the limitations of existing data have contributed to the controversy over breast cancer screening for women in their forties. Of the eight studies, only one was specifically designed to evaluate the question of benefit for women ages 40 to 49, and the conduct and results of that study have been controversial. The others, the first of which began in the early 1960's, were designed to evaluate the benefits of mammography in a wide age group of women, generally women 40 to 70 years of age. In 1993, experts convened to discuss the intermediate findings of the studies and acknowledged the data limitations. Of particular concern was the small number of women in their forties in each of the trials. The seemingly-observed benefits of mammography were not statistically significant, that is, chance could not be ruled out as an explanation for the observed benefit. Now that more time has elapsed, and further analysis has been conducted, the benefits of mammography have been statistically established according to conventional criteria.

Since 1993, we have learned a great deal about breast cancer detection in women in their forties. In fact, the genesis for the recent NIH meeting held in Falun, Sweden in March 1996. Updated analyses of individual and combined trial data, mathematical modeling, and reports from community-based screening programs provide very strong evidence of the benefit of screening. These findings led the NCI to announce in late Spring that it would hold a consensus conference to review the recent evidence. The Panel received an update on the clinical trials on the efficacy of mammography. Two Swedish trials now show statistically significant reductions in mortality of 36 percent and 44 percent for groups invited to be screened. In these trials, the benefits were observed after 7-to-10 years of follow-up. A meta-analysis, or statistical compilation, of all seven population-based clinical trials, or all eight clinical trials, has shown a significant mortality reduction due to mammography. These studies provide clear evidence that thousands of women's lives may be saved each year through the availability of mammography for women ages 40 to 49. Indeed, widespread participation in mammography by women in this age group has already contributed to lives saved that otherwise would be lost, according to a report in the Journal of the National Cancer Institute in November 1996.

We acknowledge that we do not know the ultimate degree to which mammography screening of women in their forties will reduce the risk of breast cancer death, but it is probably higher than what has been observed in the trials to date. Further, we have made significant progress in the quality of mammography over the past several decades, and in the United States all mammography facilities are required to meet minimum standards and to be certified under the Mammography Quality Standards Assurance Act.

In addition to the disappointing final recommendation of the Consensus Development Conference, the American Cancer Society believes the Panel placed undue emphasis on several issues related to the risks of mammography. Though the issues of risk are important and should not be ignored, we fear that an unintended and unfortunate side effect of the current debate will be to cause widespread confusion

and concern among women and physicians, and that mixed messages might unduly influence health insurance companies' coverage decisions. Over the years. we have made superb strides in educating women about mammography by breaking down financial, physical, and psychological barriers to women seeking mammography screening based on our once-universal guidelines. We fear that existing barriers and negative attitudes towards mammography might be reinforced by this negative attention, and women of all ages might turn away from mammography as today's most important means of fighting breast cancer.

Risk of radiation-induced cancer

The risk of radiation-induced breast cancer from low-dose mammographic exposures is a theoretical possibility, but no scientific studies have ever observed carcinogenesis at such low doses. We believe the known benefits of mammography outweigh any hypothetical risk for future breast cancer due to radiation.

False positives and false negatives

False positives and false negatives are inherent to all medical tests. We believe emphasis should be placed on improving mammography, not identifying its shortcomings and abandoning the screening method altogether. Strategies to manage or reduce anxiety, to the extent that it exists, requires greater attention and further research.

Breast cancer is one of women's greatest health concerns, and for good reason. One in sixty-four women in their forties will be diagnosed with this disease. Breast cancer deaths represent 12-to-15 percent of deaths for women ages 30 to 59. We believe it is not good science or good public health to say that the needs of women ages 40 to 49 will be met if guidelines are established to screen only those who fall into certain risk categories. We know that such provisions will leave the majority of women diagnosed with breast cancer in their forties unprotected.

The economics of health care are another important and undeniable aspect of this debate. Policy makers are struggling with the issue of the cost-effectiveness of mammography. Because of the comparatively-lower incidence rate of breast cancer in women under age 50 and the higher ratio of benign to malignant biopsies in this age group, the costs of detecting cancer for women in their forties is higher. However, these costs must be weighed against the cost of more extensive care due to treating an advanced case, and more importantly, the cost of the loss of life.

The American Cancer Society believes that women should have access to breast cancer screening every one-to-two years for women in their forties and annually for women age 50 and over. We believe that women should talk with their providers and be given all of the evidence in order to reach an informed decision. The American Cancer Society will continue to provide information designed to inform women of the benefits and limitations of mammography screening. We are confident that armed with information, women and their health care providers will see mammography as the best current strategy to reduce death from this disease.

In early March, the American Cancer Society will convene an expert panel to review the Society's current guidelines for breast cancer screening for women of all age groups and will include the new data that were presented at the NIH Conference. Of particular importance is the issue of screening intervals; existing data that were presented suggest that the mortality benefit might be even greater if women ages 40 to 49 are screened annually, rather than at the Society's current recommendation of every one-to-two years.

Thank you.

SUMMARY STATEMENT OF DR. BARBARA MONSEES

Senator SPECTER. We now turn to Dr. Barbara Monsees, who has served as associate professor of radiology at the Mallinckrodt Institute of Radiology at Washington University School of Medicine since 1990. She was appointed as chief of the breast imaging section of the institute in 1993 and also serves on the cancer information center medical advisory board.

Welcome, Dr. Monsees. The floor is yours.

Dr. MONSEES. Thank you. Thank you for focusing attention on this issue, which I think is so important. I would like to reiterate some points that were just made.

I am going to focus my remarks primarily on the NIH consensus conference process, as I was asked to do. Let me say from the start

that I believe that we do now have clear scientific proof that mammography screening for women ages 40 to 49 can substantially reduce the death rate from breast cancer.

At the conference, as just stated, updated information was presented by investigators from the five major population based screening programs in Sweden. Their most recent data shows a statistically significant mortality reduction in two of the clinical trials—as stated, 44 and 35 percent mortality reductions.

These findings are very compelling because they show even greater mortality reduction than the two earlier trials which everybody uses and has demonstrated benefit for women over age 50—an age group which everybody acknowledges we should screen.

Also presented were meta-analyses, multiple different meta-analyses. Whether or not the Canadian trials were included, all of them were statistically significant. They ranged from 15- to 24-percent mortality benefit.

It is very important to note at this point in time that randomized, controlled trials inherently underestimate the actual benefit of screening, which is likely to be substantially greater than measured in these trials.

In brief, I believe that if screened annually, using today's improved mammographic equipment and techniques, breast cancer deaths in women could be reduced in women of all ages by 40 percent or more.

In 1993, the NCI set statistically significant mortality reduction as the requirement for accepting screening for women in their forties. This requirement has now been met. These new data should have been a key factor in the panel's recommendation for supporting screening of women age 40 to 49. Unfortunately, for as yet unexplained reasons, the consensus panel chose to ignore the recent data presented and based their statement on old data analyzed at the 1993 NCI meeting.

Senator SPECTER. Would you repeat what you think the consensus panel ignored, please, Dr. Monsees?

Dr. MONSEES. The consensus panel did not comment on the Swedish trials that showed a 44-percent and a 36-percent result. Each trial alone was statistically significant. They gave an upper bounds of estimate of benefit of 30 percent.

Whatever the reason the panel chose to do this, I think it is critical that we keep the scientific question of proof of benefit as the basis for determining guidelines.

The issue of whether we should assign health care dollars to screening should be kept separate from this process. That is in your ball park.

If the purpose of this consensus conference was to analyze the new data, the panel should have either accepted the new data as proof enough to recommend routine screening for all women over 40 or they should have refuted it. They did not.

In ignoring the new data, the panel's report reflects an unbalanced presentation of the facts and has, unfortunately, a surprising preoccupation with risks which are not unique to women age 40 to 49.

Clearly, the 1993 NCI policy reversal created serious controversy and substantial confusion among American women on this issue.

This situation was summarized in a report by the U.S. House of Representatives Committee on Government Operations entitled: "Misused Science, the National Cancer Institute's Elimination of Mammography Guidelines for Women in Their Forties."

The 1994 report concluded that the NCI failed to examine objectively all the scientific evidence and excluded the presentation of favorable information. This seems to have happened again.

Given the controversial history and complexity of the issue, I would like to pose a few questions for your consideration that need to be carefully examined. Could this issue have taxed the NIH consensus development model beyond its intended purpose? Were the panelists given adequate time, information, and instruction regarding the rules of evidence in order to formulate the report?

As an observer in the audience, I can surely attest that there was inadequate opportunity for comments from those with opposing views. What were the roles of NCI staff in the selection of exclusion of panelists, speakers, and topics?

One can only wonder how the influence of those involved in the 1993 NCI policy reversal played out in the formulation of the new panel and their report. Meanwhile, the panel's report has only deepened the controversy and the public's confusion on this important subject.

In conclusion, I hope the National Cancer Advisory Board will reexamine all the evidence in an unbiased fashion and conclude that mammography screening for women age 40 to 49 does save lives.

I believe that the data are compelling and should be accurately communicated to women who, ultimately, must decide for themselves whether they want to be screened.

Separate from this issue, I believe that funding for research must be a continued priority and one I hope, Mr. Chairman, that the subcommittee will again vigorously support.

PREPARED STATEMENT

While it is certainly important that we continue to search for new methods of prevention and for cure for breast cancer, I do not think we should ignore this evidence that we now have and the means already available to save women's lives today.

Thank you for the opportunity. I would be happy to answer any questions.

[The statement follows:]

PREPARED STATEMENT OF BARBARA MONSEES, M.D.

My name is Barbara Monsees. I am a physician practicing at Barnes-Jewish Hospital and I am the Chief of the Breast Imaging Section at the Mallinckrodt Institute of Radiology at the Washington University School of Medicine in St. Louis, Missouri.

Thank you, Mr. Chairman, for inviting me to present the following statement on the recent NIH Consensus Development Conference. I would like to share my perspectives both as a medical professional and as a woman who is a survivor of early breast cancer detected by a mammogram.

PURPOSE OF CONSENSUS CONFERENCE

This consensus conference was convened to examine new breast cancer data for screening women ages 40 to 49 that has become available with longer follow-up periods since the 1993 decision by the National Cancer Institute (NCI) to remove its support for screening women in this age group. The purpose of the conference was to determine the answers to these basic scientific questions. Does breast cancer

screening for women aged 40–49 save lives? If so, how large is the benefit? How do these change with age? What are the other benefits? What are the risks? I think it is critical that we keep these questions separate from the issue often debated by health policy makers of whether or not we should assign health care dollars for screening these women.

NEW EVIDENCE FOR WOMEN 40–49 YEARS OLD

Let me say from the start, I believe there is now clear scientific proof that mammography screening for women ages 40–49 can substantially reduce the death rate from breast cancer. At the conference, updated information was presented by investigators from the five major, population-based, screening programs in Sweden. Their most recent data shows a statistically significant mortality reduction in two of the clinical trials of 44 percent and 35 percent, respectively. These findings are compelling because they show even greater mortality reduction than the two earlier trials demonstrating benefit for women ages 50 and over an age group for which the benefits of mammography screening are widely accepted. Also presented was an overview meta-analysis of all five Swedish trials which revealed a 23 percent mortality reduction. Adding the other clinical trials performed in Edinburgh and the Health Insurance Plan (HIP) of Greater New York to this meta-analysis maintain the 23 percent reduction. All of these analyses are statistically significant. Two other meta-analyses of the seven population-based randomized trials, have shown a 24 percent mortality reduction for women aged 40–49. These meta-analyses have been published in peer-reviewed medical literature in 1995 and 1996.

In addition, randomized controlled trials (RCTs) inherently underestimate the actual benefit of screening which is likely to be substantially greater than that measured in trials. In RCTs, breast cancer deaths are compared between two groups. The study group is invited to be screened, but not all women accept; their compliance with screening has varied in the different trials. The other group, the control group, is not invited to screening and they get their usual health care. Some of these women have mammograms anyway and "contaminate" the control group. Both noncompliance by the study group women and contamination by the control group women diminish the measured benefit. Therefore, the actual benefit to women who partake in screening is likely to be of a greater magnitude than indicated by trial results. Furthermore, only one of the trials screened women in their 40's on an annual basis, (screening intervals for these trials varied from 18 to 28 months). Before the most recent data was known, it had been estimated that if women in the two-county Swedish trial had been screened annually, mortality reduction for women would have been at least 35 percent.

Finally, mammographic equipment and technique has improved remarkably since the 1980's when these clinical trials began. Standard use of two mammographic views per breast improves the sensitivity and specificity of mammography when compared to the one view per breast exam used in some of the trials. In brief, if screened annually, using today's improved mammographic equipment and techniques, breast cancer deaths in women could be reduced by 40 percent or more.

RELATED ISSUES

The quality of mammography for American women continues to improve through the accreditation programs of the American College of Radiology (ACR) and their publications for physicians, physicists and technologists, as well as national implementation of the Mammography Quality Standards Act (MQSA) of 1992 through the Food and Drug Administration (FDA).

Because of doubts about the validity of the results from the National Breast Screening Study of Canada (NBSS) trials, there has been much debate about whether their results should be considered in current medical decision making although this trial was the basis for convening the 1993 conference. Even if results from this trial are included in the meta-analyses, there is an 18 percent reduction (still statistically significant) in breast cancer deaths for women screened in their 40's. Yet, substantial differences in its design as well as its widely criticized deficiencies set the NBSS trials apart. All the other RCTs were population based, while the NBSS was volunteer based. In addition, significant bias was probably introduced into the trial since women with obvious cancers were allowed to participate. The randomization in the NBSS has been subject to much criticism and is the most likely explanation for the excessive late-stage fatal cancers in the study group. This methodological flaw likely resulted in a lack of demonstrable mortality reduction in the NBSS. In addition, the quality of the mammography in the NBSS was widely criticized. As noted by the reference physicist, it was "far below state of the art, even for that time (early 1980's)."

ORIGINS OF THE CONTROVERSY

In 1993, NCI set statistically significant mortality reduction as the requirement for accepting screening for women in their 40s. This requirement has now been confirmed by the new Swedish data referenced. This new data presented at the consensus conference should have been a key factor in the panel's recommendation for supporting screening of women aged 40–49. Unfortunately, for as yet unexplained reasons, the consensus panel chose to ignore the recent data and based their statement on old data analyzed at the 1993 NCI meeting. This was the same follow-up data used by the NCI to explain its withdrawal of support for screening at that time.

If the purpose of the consensus conference was to analyze the new data, the Panel should have either accepted the new data as proof enough to recommend routine screening for all women over 40, or they should have refuted it. In ignoring the new data, the Panel's report reflects an unbalanced presentation of the facts and has a surprising preoccupation with risks not unique to women aged 40–49.

Clearly, the 1993 NCI policy reversal created serious controversy and substantial confusion among American women on this issue. This situation was summarized in a report by the U.S. House of Representatives Committee on Government Operations entitled "Misused Science: The National Cancer Institute's Elimination of Mammography Guidelines for Women in Their Forties". The 1994 report concluded that the "NCI failed to examine objectively all of the scientific evidence on mammography" and that the NCI "excluded the presentation of favorable information on mammography screening". This seems to have happened again. I think it is pertinent to point out that the current NIH consensus process was overseen by a number of the same NCI staffers who were criticized in this congressional report, some of whom are known to oppose screening for women of this age group. Early in the formulation of this conference, a number of my colleagues expressed serious reservations about the selection of panelists, speakers and agenda for the conference. All involved knew that this would be a hotly debated issue and that the consensus conference would need to be fair and credible.

I would like to note a few examples in the Panel's statement that are factually inaccurate or misleading. Specifically, the Panel's statement:

—Reports that the studies may show a benefit that is as great as 30 percent. However, the data provided from the Gothenburg RCT shows a 44 percent decrease in deaths for these women.

—Suggests that the benefit in the new data could have been the result of clinical breast examination (CBE) among the screened women. This is completely unfounded in that CBE was not part of the Swedish RCTs. This statement underscores the apparent discordance between the scientific data presented during the meeting and the conclusions drawn in the Panel's statement.

—Cites estimates only for women in their 40's without any frame of reference with respect to women of other age groups. One of the charges to the Panel was to provide information about how risks and benefits of screening "change with age". So that the public can put this information in the appropriate context, comparable statistics should have been given for screening women aged 50–59 and 60–69, where screening is widely accepted.

—Dwelt on screening harms, while dismissing data showing that the recall rates and biopsy recommended rates are nearly the same regardless of age. The statement that "10 percent of all screening mammograms are read as abnormal" will likely mislead women to believe that "abnormal" directly translates to unnecessary biopsies. In most cases, this means a few extra mammographic views or an ultrasound. Only 0.5 percent (one-half percent) of women between 40–49 who are screened will need to be biopsied based on the results from a routine mammogram.

Given the controversial history and complexity of this issue, I would like to pose a few questions for your consideration. Could this issue have taxed the NIH consensus development model beyond its intended purpose? Were the panelists given adequate time, information and instruction regarding the rules of evidence in order to formulate their report? As an observer in the audience, I can attest that there was inadequate opportunity for questions and comments from those with opposing views. Perhaps the Panel was unwilling to look at the new data because of these evidentiary rules. What were the roles of NCI staff in the selection or exclusion of panelists, speakers and topics? One can only wonder how the influence of those involved in the 1993 NCI policy reversal played out in the formulation of the new panel and their report. These are questions I cannot answer here today, but I believe should be examined in the near future. Meanwhile, the Panel's report has only deepened the controversy and the public's confusion on this important subject. It has left women of all ages wondering about the benefits and risks of mammography screen-

ing, creating doubt, aniexty and resentment. We can only hope that it has not raised new barriers to screening which will translate into lost lives.

WHERE SHOULD WE GO FROM HERE?

In conclusion, I hope the National Cancer Advisory Board (NCAB) will re-examine all the evidence in an unbiased fashion and conclude that mammography screening for women aged 40 to 49 does save lives. I believe that the new data is compelling and should be accurately communicated to the women of this nation who ultimately must decide for themselves whether to be screened.

Separate from this issue, I believe that funding for research must be a continued priority and one I hope, Mr. Chairman, the Subcommittee would again vigorously support. While it is certainly important that we continue to search for new methods of prevention and cure for breast cancer, we should not ignore this evidence and the means already available to save women's lives today.

A BREAKPOINT IN INCIDENCE—AGE 40

Senator SPECTER. Thank you very much, Dr. Monsees. I am going to have to excuse myself for a few minutes in a moment or two. But I would like to raise one question about the magic of age 40 with Dr. Leitch and Dr. Monsees.

Why 40? Why not 39, or 38? Why do you have a break point there?

My own sense, from the experience I had, would be to do it at an early stage, if there is any concern, and there is reason for concern by just about everybody. You do not necessarily have to act on what you have found with the biopsies, et cetera. But what is the magic about age 40, Dr. Monsees?

Dr. MONSEES. There is no magic about 40. That is a good point.

What we do is we look at age-specific incidence. In other words, if you took women all in their forties and compared them to women in their fifties, and compared them to women in their sixties, and you look at in each decade of life how many women get breast cancer, it goes up with age.

Senator SPECTER. Would you select the age of 40 if you had the job of selecting an age?

Dr. MONSEES. That is a good question. I probably would, right around that time, I would say.

Senator SPECTER. How about you, Dr. Leitch?

Dr. LEITCH. Yes; I think it represents a breakpoint in the incidence; 5 percent of the cases of breast cancer occur below that age, and then you go from a little more than 4.5 percent in the thirties to 18 percent in the forties.

So I think that that represents a reasonable breakpoint.

What I think has been confused a bit here is the issue of someone who has identified high risk, for example, a strong family history that suggests genetic predisposition, and the breast cancer in their family members occurred in an early age. That is a woman who really falls outside of what we consider average risk for screening guidelines.

And so, that woman may well need to be screened in her thirties.

Senator SPECTER. I am going to pick this up when I return. We have a previously scheduled announcement of chief counsel for our Veteran's Affairs Committee on Gulf Syndrome.

I am going to ask Senator Hutchison to proceed.

You may have a very long round, Senator Hutchison. I will be back as soon as I can. If you run out of questions, put us in recess and I will be back as soon as I can.

Senator HUTCHISON. Thank you, Mr. Chairman. I probably will not be able to stay until you come back because I have another appointment, as well. But I will do my round.

Senator SPECTER. OK. Then we can be in recess, and I will return as soon as I can.

Senator HUTCHISON [presiding]. Thank you.

Let me ask the question of where we can best use the Federal dollars. There was the issue, and I think Ms. Visco was in on the decision, to target the money more toward the scientific research than the breast cancer awareness action project—the breast cancer action plan, I should say.

I would like to know from Ms. Visco on that issue and also from the rest of you who would like to respond where you think we can do the most good. That we are relying on two Swedish studies as our best effort gives me some concern. With the millions that we are putting into breast cancer research, it seems that we ought to have at least some statistics of our own and trials of our own that would have been well developed enough to have shown statistics by this point.

But if we do not, what do we need to do to get the best use of our Federal dollars toward the cure or toward the technology for better detection? I would start with Ms. Visco and then go to any of the others of you who have an opinion on the bigger question, but first on the targeted question of the breast cancer action plan money.

Ms. VISCO. Well, the National Breast Cancer Coalition has been a voice here on Capitol Hill since 1991, demanding more money for breast cancer research. As you have heard of the history of the increase in funding, with our partnerships in Congress we have been very successful. We all recognize, as I am happy to hear, and the Senate does also, that it is not enough and we need to continue that. You have heard all of the questions that we do not have an answer to. In fact, the consensus plan identified a number of questions that we really need to research, that we do not have answers to those questions.

So we need to increase money, without question, into research, both basic and applied research, clinical trials in this area.

We also need to increase our efforts in outreach. Outreach is done to a great extent in the private community. There are many organizations like the Komen Foundation, Why Me? many organizations, such as the Breast Cancer Resource Group, many organizations that do outreach, get the word out, and try to educate women.

In addition, the Federal Government places a great emphasis on that and has a number of programs doing that.

Now all of those questions are pretty much aside from what the steering committee of the national action plan on breast cancer decided to do. The plan is a narrowly focused, well-defined effort, and I will give you outside of the hearing as much information as I can. I would be happy to sit down and talk to you about it.

The steering committee, the plan identified six priorities. The plan is a public-private partnership. It is an unusual public/private partnership. We truly are equal partners in this effort.

The Komen Foundation, the American Cancer Society, the coalition—a number of outside organizations sit on that steering committee in addition to various government representatives.

We developed a plan within six priorities. We have working groups within those six priorities that are across the country. Membership from each of those working groups is from the scientific/medical consumer, from all of the players that should be at the table designing strategies.

Our intent is to design strategies where we see gaps, and then to encourage those strategies to encourage the Government, to encourage private, to encourage the scientific community, everyone, to implement those strategies.

What we never wanted to do was institute a new bureaucracy, a new funding mechanism.

Now this is the way the plan has worked. We came to the determination that in order to do what the plan is supposed to do, we needed about $4 million.

When the appropriation came for more than $4 million, we said to the Congress—and we thought in a very responsible way—that we really do not want to waste these resources, this is the amount of money that this public/private partnership determined unanimously that we need to spend. We believe that the rest of the money should stay in the National Cancer Institute budget, where it is now, to fund what we all agree is underfunded resource into breast cancer.

Senator HUTCHISON. Thank you.

I would like now to open it to the panel on the bigger question of where we can do the most good with our Federal resources. Dr. Leitch.

Dr. LEITCH. I think that I have a perspective on that which may be a little bit different from some people here. Our teaching hospital is a county hospital in Dallas. We see a large number of minority women. In fact, they account for about 75 percent of the women that we see in our screening program.

So, in this population we have been able to see the costs of taking care of women who are diagnosed late with breast cancer. In our population in the 1980's, and really up until the early 1990's, about 40 percent of our patients were diagnosed with stage 3 or 4 disease, had never had screening mammography, had never had any introduction to what was involved, never entered the health care system prior to that time.

When you have to take care of a woman with that stage of disease, the cost to the system and whether that is Federal dollars, State dollars, or county dollars, is tremendous. Not only do those women have the cost of their care, many of them are young women who have children. They have jobs that require physical labor. They quit their jobs. They request disability. There is public assistance that is required.

When they die, if their children are still minors, there is the support of those children that remains.

Those types of costs are very hard to get into the record in terms of estimate. In my view, when I am looking at the dollars I would want to spend in our county hospital, I would say I would rather spend the dollars to detect the cancer early when I can treat it less aggressively, save money for the system, than to let people wander in with tumors growing out of their breast, which they do—I mean, we see this every week—and then have to deal with that tragic consequence.

That is the way I would do it.

On the issue of research dollars going into mammography versus going into understanding the nature of breast cancer and how it develops, I do not think that we need to, say, do another trial in the United States, for example, which may be what you were referring to. I think it may be very hard to do here because I think there is a lot of public sentiment that women should be screened in this age group.

But what we do need to do is to take advantage of information we already have about screening in the United States. Dr. Klausner mentioned the NCI Breast Cancer Surveillance Consortium, which puts together a data base of mammographic data in the United States and would give us a picture of that. That particular project needs more funding so that we can really look at what goes on in quality programs of mammography in the United States. What is the cost of it, what is the false negative rate, what can we do to improve techniques?

That would be very helpful, I think.

Senator HUTCHISON. Is that on the drawing boards for Federal funding?

Dr. LEITCH. I believe it is on for funding but is not completely funded. It is for a continued funding request.

Senator HUTCHISON. I am very glad that you brought up the perspective that you have from the county hospital, the Parkland Hospital, and how early detection can become a priority. Probably I think you have made a very good case for it saving as many lives as research in the other direction. So I am glad to have that perspective. It also calls for more outreach. There is no question there.

Dr. LEITCH. I would point out that when we implemented a mammographic screening program in our hospital, the cases that were diagnosed of breast cancer in those women were far weighed to stage zero or 1, whereas the women who were not involved in that screening program continued to come in with these very advanced cancers.

Senator HUTCHISON. Dr. Monsees.

Dr. MONSEES. I would like to share the same viewpoint, and that is that I think we need to move now from validation of screening mammography, which I think we have already done—we know there is a mortality benefit—to implementation of programs for the underserved. The population that was just spoken of, that is the type of population that needs to be reached—rural areas and the underserved in urban areas.

These women do not have access. They do not have the same information or network to give them what they need to make their own decision. This is what we are all talking about today.

So I think we need to move from validation, which I think has been done, to implementation.

The reason I am saying it in this way is that you raised the question should we have our own study in the United States. I think the answer, unfortunately, is going to have to be no to that.

If we started a randomized controlled trial today, it would take many years to come to fruition. It would take millions of women, and it would likely be no more information than we have now because in the United States there is widespread screening. It would be very hard to tell people you cannot get screened and you go get screened. This would not work.

Senator HUTCHISON. Well, it would be wonderful to have a project for which no one volunteered. I think that says a lot about perhaps the education efforts that we have made.

Dr. MONSEES. Yes; so I think I would like to see focus on these outreach programs so that we can reach women today who we can help and at the same time have another strategy for basic research. The technologies that were spoken about earlier—PET scanning, magnetic resonance imaging, other types of things, such as symptom mammography, which is a nuclear medicine test, et cetera—these are technologies that we need to work on and we need to put some dollars into so that we can see what role they will have.

But if we start those projects today, I do not expect that it is going to help this generation of women. That is for the next generation of women. And if we put all of our dollars there and abandon outreach with a product, mammography, that we know we can use now and save lives, then we are going to sacrifice those women alive today.

So my absolutely recommendation is that we have a two-pronged approach here, that we start implementing and that we look for ways to prevent breast cancer and cure it.

Mammography cannot do either of those. Mammography takes advantage of what is called the window of opportunity. We can find it, perhaps, when it is there and diagnosable, but that it has not yet spread. And we can alter the national history of the disease.

That is all it can do. It cannot prevent or cure in any other way.

Senator HUTCHISON. Let me ask you, any of you, again, how important do you think it is that the National Cancer Institute come out with a clear guidelines that, yes, says what the minimal risks are but goes back to the 1993 standard of recommending mammograms between the ages of—well, I don't know if they were at 35 or 40, but either 35 or 40 to 49 every other year and then annually after that? Do you think it is important that we have a clear signal from the National Cancer Institute along these lines, perhaps with some changes, but something clear? Or do you think we can continue with the progress that we are making if the message remains muddled, as it has come out from this panel?

Ms. BRAUN. Senator, I think we need a very, very clear signal from the National Cancer Institute, and although the points are very well taken and we agree with them that women should be presented with all of the data, both the benefits and the risks of mammography, as we know them to be today, that a very clear signal is important for those who either do not have the time or the interest in reviewing all of the data themselves and, rather, would rely

on others' recommendations, and also because it will be critical, we know, in insuring insurance coverage for women in the younger age bracket that might otherwise not happen because the guidelines are not definitive. Therefore, it would give any third-party payer a rational excuse, if you would, to not cover mammography for this group.

In addition, it simply sends confusion. One of the speakers spoke earlier, and we have seen this again and again, as we have spoken to our constituents, not only for the age group 40 to 49—because neither 50 nor 40 a magical cut-off point—that it sends an unclear message about the value of mammography overall. We are concerned that it might then also cut into the utilization of mammography for women in the older age groups, as well as those younger than age 50.

Ms. VISCO. Senator, I believe that it is incumbent upon all of us, including the National Cancer Institute, to tell women clearly what the facts are. Sometimes the facts are that we don't know, and sometimes the facts are just not very simple. They are complex.

I think that is what the NCI must do. I do not think they should issue guidelines based on two studies. That is not scientifically sound. That is why we do meta-analysis and look at several studies.

So I think it is incumbent upon the National Cancer Institute to be clear about what it is we know and do not know about mammography for women in this age group, and not to simply say: "do it."

Senator HUTCHISON. Do you think it was a mistake pre-1993 to have guidelines that started this process of mammograms?

Ms. VISCO. Yes; I do, because I think the guidelines at that time were not based on scientific data. They were based on a hope and a guess that if it worked in women over 50, it should work on women in their forties. But we are talking about screening a population. We are not talking about individual women who feel that there is something wrong, or who are in a high risk category, or women who simply want to have a mammogram. We are talking about sending all women in their forties a message: get a mammogram every year.

I believe that women are entitled to much more information than that. They are entitled to know the pros, the cons, the risks, the benefits, and that is what the consensus panel said.

Senator HUTCHISON. Do you think that you could write a guideline that would state what the recommendation is and then state the risks?

Ms. VISCO. Yes; I do. I have a great deal of faith in women. I work with them all the time across the country—breast cancer activists and survivors. I think they are capable of understanding complex messages.

I think it is incumbent upon us to get them the true facts, and if it is complicated, then we have to find a way to help them understand it. That is what we must do, rather than just send a simple message that is not necessarily the right message.

Senator HUTCHISON. Dr. Monsees?

Dr. MONSEES. I fully support that women be informed and that women can make their own health care decisions. I think that that is absolutely crucial.

But one thing has been left out here, and that is that the panel statement does not accurately reflect the facts. That is a problem.

If we are going to give them the information, we had better give them the correct information. We do not say that the best mortality reduction you can expect is 30 percent when, in fact, a trial has shown 44 percent.

I will remind Ms. Visco that the same type of evidence that was once available to prove benefit for women over 50 was two statistically significant trials. We now have the same level of evidence, but even better, for women 40 to 50.

Why does it constitute proof for women over 50? But now the rules have changed. Now it has to be better than that. We have the same level of evidence for women 40 and up, and we should begin screening, we should recommend screening, but we should tell them the downside. We should say no test is perfect and these are the limitations. When it comes down to the bottom line and a woman asks, and she looks you straight in the face, and she says tell me what I can do to minimize my death from breast cancer if I am going to get it, at the top of the list is going to be mammography.

Senator HUTCHISON. Dr. Leitch?

Dr. LEITCH. I think the statement earlier that reflects the importance of the NCI coming out with a specific statement is the very one that Senator Specter made. The NIH panel has identified with the NCI. When people see the results of that consensus panel, they say this is the Government's position on this issue. How does that then play out?

Well, if we are going to have Federal programs to fund mammography, if the NCI position is that we are not certain it is beneficial or specifically does not recommend it in that age group, then how can you justify Federal funding for that particular issue.

Like it or not, the NCI is identified with that panel to some degree, even though—and here Dr. Klausner's statements are perfectly true—the panel was designed to be independent, divorced from the Government. Yet, the perception is that this view reflects the NCI.

So the NCI needs to come out with a specific statement of what their opinion is. If they do not think it is appropriate for women to be screened, they need to say that's their opinion and the reasons for it.

If the reasons in public health policy are related to costs, that needs to be stated.

We do know that mammography and women in their forties can detect small cancers. There is data to support that. It is not a benefit that is confined to women in their fifties or in their sixties. Mammography can be sensitive for women in this age group and should be seen as such. Women should know that.

The estimate that up to a quarter of tests might result in a false negative result quite over-estimates that, I think, if you look at more modern studies. And, in fact, in a study of the breast cancer detection demonstration project in the 1970's, only 10 percent of cancers that were detected in that trial in women ages 40 to 49 were not picked up by mammography.

So I think to suggest that it cannot be effective in this age group is false.

Senator HUTCHISON. Dr. Monsees?

Dr. MONSEES. I would like to raise one other point, if I might. When we are talking about truth of information and what information should be provided, we need to make sure that it is understandable and that it is spelled out completely. I will give you an example.

In the consensus statement it was said that 10 percent of mammograms are going to be false positive. We have to be very careful when we throw that term around about what that means, because the public is already afraid of breast cancer. Some people will take that to mean—although it will be wrong—that the 10 percent of women who have abnormal mammograms will either have breast cancer or will go to biopsy. But, in fact, the actual number is that biopsy will be recommended for less than 1 percent of those women—of overall women, not of the 10 percent—and that most of the callbacks or the false positives are, in fact, nothing more than an ultrasound or an additional view mammogram, et cetera, for which there is not an invasive procedure associated.

Biopsy these days is also easier than it ever was before. We have now validated, I think, in the United States lesser invasive ways to achieve tissue diagnosis for biopsy.

Senator HUTCHISON. Thank you. I think that is a very important point on which to end. I think if you step back from all of the information that we have received today, you have to accept several truths. One is that breast cancer is the largest killer of women in our country. It is something that can be detected early, and it is clear that mammograms are the best source of saving lives that we have at this point. Third, I believe that there has to be a good, solid position from our premier Government agency, the National Cancer Institute, with all of the information they have, putting it in perspective, making a recommendation to the women of our country and then stating the risks. I think it is common sense and I think it can be done.

I believe that you have pointed out today some of the factual errors in the advisory panel's earlier draft. Perhaps it got prematurely and that is not what they intended. But there is still a remedy, and that is that there is still the National Cancer Institute board itself. I think that we do need to continue the efforts in research, both in the technology for detection and also for cure. But also outreach appears to be clearly one way to save lives. I think Dr. Leitch's testimony was very targeted to that point.

So we have learned a lot. I think Senator Specter will be back shortly.

I will recess the meeting until he returns to finish asking his round of questions. I thank all of you for your testimony and your input. I know we do all have the same goal, and that is to save the over 40,000 women who will probably die from breast cancer this year.

Thank you.

[A brief recess was taken.]

Senator SPECTER [presiding]. Our hearing will resume.

When I had to depart, I was asking Dr. Leitch about the age, and Dr. Leitch was testifying about how some indicators might warrant mammograms at an earlier stage than 40.

At what age at the earliest, Dr. Leitch, would you say that collateral indicators might suggest a mammogram? What would be the earliest age?

Dr. LEITCH. For the average risk woman, I would say age 40. For women who have a family history which would suggest early onset breast cancer and a genetic component to their risk, for those women it may be appropriate to start as early as age 30, depending on the extent of the family history. This is actually an area of research.

Senator SPECTER. What is the earliest that you know a mammogram has been used on a woman, the earliest age?

Dr. LEITCH. They are done on women even as teenagers. But that is not something we recommend as a routine.

Where mammography is particularly inaccurate is in younger women, under age 30.

Senator SPECTER. I ask that question to try to get some line on this. People will be following what we are saying here. You had this cut-off at 50 by a consensus report, not precisely a cut-off but as a generalization.

What is the earliest aged woman you have ever known to have been the subject of mammography—that is, the youngest?

Dr. LEITCH. Well, I would say a woman in her teens. But I would not personally do that unless I thought the woman had a cancer, and in a teenager that is extremely unlikely.

Senator SPECTER. Ms. Braun, what is your sense of the age of 40? I ask you especially because you had a breast with cancer at 38.

Ms. BRAUN. Yes; I think, according to the incidence that we are seeing right now, there is definitely a big jump between women in their thirties and women in their forties. I think that is why it is important that women do seek out clinical breast exams and do breast self-exams every month, even though I think age 40 is a good age to start mammography screening.

Senator SPECTER. Why do you choose 40 when you had the incident at 38?

Ms. BRAUN. Based on incidence, the incidence that it is shown.

Senator SPECTER. Other people?

Ms. BRAUN. Right.

Senator SPECTER. Dr. Monsees, you were testifying about inadequate opportunity for comments when the consensus report was made. Would you amplify that? Do you have first-hand knowledge? Were you there? Did you see that they did not take enough time to have comments from other people about their findings?

Dr. MONSEES. I was in attendance during the entire conference, and when the statement was read and during the comment period of time after that, I think it is fair to say that throughout the entire conference there was never enough time for people in the audience to make questions or comments. They kept to the time limit.

Senator SPECTER. What was the time limit?

Dr. MONSEES. Well, the first day was entirely presentations. The second day were presentations up until about noon. Then the pan-

elists went to chambers to look at the evidence. They came back the following morning at, I believe, 9 a.m., to read the statement. It was read publicly and then there was about 90 minutes for comment. Then they had to go back into chambers and talk again.

Senator SPECTER. When did they make the pronouncement that women 40 to 49 would not benefit from mammograms?

Dr. MONSEES. On the third day of the conference, in the morning. I believe it was 9 a.m. The statement was read aloud by Dr. Gordis, who was the panel chair, and then they asked for questions and comments from the audience.

There were many people at the microphone when the comment session was ended. But I can tell you that over the day and a half preceding that, there were opportunities to ask questions of people who presented to the panelists. People from the audience had opposing views.

First up for questions were the panelists themselves. They had an opportunity to ask the people who were presenting to them. So that shortened the actual time for questions, and the people who were in the audience almost never got to ask all the questions they wanted to ask or to make all the comments they wanted to make.

Senator SPECTER. I want to raise and do raise the issue of the message which we have had a lot of talk about here today. It escapes me as to why, when we say that women ought to make an individual judgment, which I totally agree with—this is a free world and people ought to make their own judgments—why there would be any reticence within the arena of allowing freedom of choice at any stage to say that you ought to have the benefit of the thinking that it is helpful for those age 40 to 49—or whatever the scientific evidence may be.

One of the concerns that I have already expressed is the way patients respond to doctors. Doctors are tremendous authority figures.

You are nodding, Dr. Leitch. Do you agree that you are a tremendous authority figure? [Laughter.]

Dr. LEITCH. Well, it is true. You know, there are many women who are incredibly bright and who ask a lot of questions and are activists on this issue. But there are a lot of women who are not, and they turn to their physicians, particularly older women.

Senator SPECTER. This may be an imprecise analogy, but when I came to the Senate, Senator Thurmond was chairman of the Judiciary Committee. Senator Thurmond would ask the nominees for Federal judgeships, "Do you promise to be courteous?" I thought to myself what a nondirected question that is. What are they going to say to "do you promise to be courteous"? What person about to become a Federal judge is not going to promise to be courteous, especially when his confirmation is riding on the line?

Then, when the person always said yes, Senator Thurmond said, "I ask you that question because the more power a person has the more courteous he or she should be."

I came to regard that differently, as to what an important question that was, because judges tend to be very arrogant when they are on the bench for a period of time. It is a very difficult part of our society, the way a black robe changes demeanor. It's something we work on in the Judiciary Committee, to try to have judges who do not do that.

I make that comment because of the comments I had from the doctor who scanned my MRI and said "weeks to live." The sort of impact that has is overwhelming.

Senator Harkin said we worry about the impact of the message which has gone out here to women who are under 49.

Ms. Rowden, you were a patient. How do you feel about that?

Ms. ROWDEN. Well, I think doctors also need guidance. There is a lot of information out there, especially for the general practitioner to keep up with. I do think that women look to their doctors for guidance, and with a lot of them, if the doctor does not tell them to get a mammogram, they do not get mammograms. And it has been shown that many women do not get screening mammograms because their doctor never recommended one. That is a significant problem. So we need to educate the doctors as well as the women themselves and work together on the problem.

When I go in for my checkups, I still look to my doctor for guidance, whether it be my oncologist or gynecologist. But I try to read up before hand or do reading afterward if they raise an issue for me.

Senator SPECTER. Ms. Visco, let me begin with you on the subject of the gene issue and the research that is being conducted there. I know that you place a very, very heavy emphasis upon research for the cure.

What is your view about the expenditures on research on gene predisposition? That does not go to the issue of cure, but it does go to the issue of detection or predisposition. What is your thought about the advisability of expending substantial sums of money to isolate the gene?

Ms. VISCO. Well, I think it is important to spend a lot of money on looking at the gene because the gene not only has the ability to tell us who is at significant risk of breast cancer, but it may have the ability to tell us about the etiology of the disease. It may tell us something about how to prevent the disease or really how best to treat it.

So we are looking at the gene once it has been isolated for a lot of reasons other than whether women are predisposed.

We are concerned about the fact, as you mentioned quite rightfully in the beginning, that we now have a test that women can take to see if they may be predisposed to heritable breast cancer. But we don't know what to do with these women once the test proves positive, and we also don't have legislation in place to protect them from discrimination in employment and the provision of insurance. That is a public policy issue that I am glad we can continue to work on together.

So I think we do need more money looking at the genetic issues. We need more money looking at every issue in breast cancer.

Senator SPECTER. On the subject of screening, it is a question of the allocation of resources and the issue of the environmental factors and the action plan which Senator Hutchison raised. What assessment do you place on the value of those kinds of activities?

I know this has come before your committee. I know you did not place a value on them as high as research, but to what extent do you think they are valuable in the overall picture?

Ms. VISCO. Now, you see, I have to disagree. I think we do place as high a value on outreach, on a lot of different issues, on all issues to do with breast cancer in the goals and mission of my organization. We are most known for our support of research, but we are there on every issue in breast cancer.

The action plan is a particular situation where what we are trying to do—as you know, it is my organization's petition campaign that brought about the national action plan on breast cancer, and I cochair that plan. The steering committee consists of a public and private partnership, including the American Cancer Society, the Komen Foundation, the National Women's Health Network, and many private organizations and government representatives.

What we wanted to do was to come together. We did not want to create a new bureaucracy. We do not want a new funding stream. Research is funded through NIH, through NCI, through DOD, through other entities.

What we wanted to do was to do something different. We wanted to bring together every player, every entity that has a stake in breast cancer, bring them to the table, identify the gaps: where do we need to jump start, where do we need to act as a catalyst, and let's bring together, which we have done, working groups from across the country, representatives from all segments of society, to develop strategies and plans of action on how to fill those gaps; and then to take those strategies and not to be a new bureaucracy that implements them, but to take them to the existing entities to implement them. That is what we wanted to do.

The steering committee did exactly that, this public/private diverse partnership, and we determined that the amount of money we needed to make that happen was $4 million—looking at all of the action plans from the working groups, looking at the support that we need to go forward on the plan, that that is what we needed. We did what we thought to be the very responsible thing, to say to the government thank you, but we don't need this much money for this effort. Leave it in the National Cancer Institute budget for what we all agree is underfunded breast cancer research.

Now the National Cancer Institute does outreach, also. We have to remember that, too.

Senator SPECTER. The language on implementation of the plan's activities says in "other crosscutting Federal and private sector initiatives." In the mentioning of cross cutting initiatives, part of that picks up on items like clinical trials where they have not been, at least as I understand it, at the forefront of what the National Cancer Institute has done, such as environmental issues, and diet sort of things.

How do you assess the value of items like that in the overall picture?

Ms. VISCO. We place an extremely high value on all of those items. That is why we are at the table at the National Cancer Institute, the National Institutes of Health, and the DOD, to make certain that the existing bureaucracy and the existing funding streams are putting more emphasis in those areas. And, in fact, we would be happy to, and intend to, sit at the table with those rep-

resentatives to talk about how they need to focus the $14 million in those areas in the existing infrastructure.

Senator SPECTER. We have had Ms. Visco's figures as to what we ought to appropriate.

Ms. Braun, would you care to give us your figure?

Ms. VISCO. Before she does, I want to say, since you are so open, that I would like to increase that figure. [Laughter.]

Senator SPECTER. OK, what would you like to have?

Ms. VISCO. I would like to have $650 million in the National Institutes of Health and go back to the $210 million in the Department of Defense program that we started with in 1993.

Senator SPECTER. OK, now where did you get the figure?

Ms. VISCO. The $210 million is based on the initial funding of the program, which was not enough then, but it was enough to fund what we thought to be a reasonable number of the proposals that required and that merited funding.

In the National Cancer Institute, we are looking at issues like generic research and new discoveries that have happened over the past several years. What we want to do is make certain that those areas move forward because we believe that we are finally at a place where we know what questions to ask.

As a matter of fact, we have a signature campaign ongoing through the coalition to ask for $2.6 billion for quality breast cancer research between now and the year 2000. So we have a plan on what to ask you for. Since you are open to increasing the numbers significantly, we are going to move up our plan and ask for more in year one than we had intended.

Senator SPECTER. What I would like you to do, Ms. Visco, is to let me have as much detail as you can on how you get there and what you expect to accomplish with that much money.

Ms. VISCO. All right.

Senator SPECTER. These are very deep subjects, and I started right off with Dr. Klausner not on any of these studies that we are talking about. Is there a realistic likelihood of a cure for cancer and how much money does he need.

Now he is under some constriction because he has to report to a whole bunch of people, ending up with high level medical technicians in the Office of Management and Budget. Sometimes we do not exactly get the unvarnished opinions of some of the experts. But we do get your unvarnished operation. Philadelphia lawyers are famous for that.

Ms. VISCO. Oh, yes. [Laughter.]

Senator SPECTER. I would like not only to have your figure but how you got there and what you think can be accomplished.

Ms. VISCO. Yes; I will get that information to you.

Senator SPECTER. Ms. Braun, do you want to give us a figure in conclusion? You are going to have to go some to top $2.6 billion.

Ms. BRAUN. This is a nice place to sit. [Laughter.]

We absolutely concur that the figures are not high enough where they are, and we agree with the coalition on the amount of funding that ought to be allocated.

One area that we are particularly concerned with and because of our own peer reviewed research program we look very carefully at the areas into which we allocate our funds and into which research

endeavors we will be funding, just to insure that we are looking toward areas—molecular biology and genetics, for example—that can be lead to a cure or cures for breast cancer.

But also we must look at potential causative factors on one end of the spectrum. On the other end of the spectrum are the issues of survivorship that people who have had breast cancer or will have in the future, even if cured, will undoubtedly face.

Senator SPECTER. Ms. Braun, do you have a figure?

Ms. BRAUN. A figure?

Senator SPECTER. That's what I'm asking you for.

Ms. BRAUN. $1 billion.

Senator SPECTER. Ms. Rowden, you are from the same organization. Do you want to concur in that or do you want to give us a different figure?

Ms. ROWDEN. I would concur with Susan.

Senator SPECTER. Dr. Leitch.

Dr. LEITCH. The American Cancer Society is partnered in this effort to petition the Congress, and we would agree with that requested amount as well.

Senator SPECTER. Dr. Monsees.

Dr. MONSEES. I will defer because I think that what has been talked about here has probably been well thought out and I am not an expert in that.

Senator SPECTER. All right. We thank you very, very much for coming in. Your testimony is very helpful. You can be assured that we are going to give this a lot of attention.

I have just been discussing the possibility of doing some field hearings on this subject. It is a little different atmosphere if you go back to the States and talk to people about it, and I intend to do that in Pennsylvania.

Thank you. Thank you all very much for coming in.

SUMMARY STATEMENT OF DAVID G. HOEL, PH.D.

We would now like to call Dr. David G. Hoel, our last witness.

Our final witness is Dr. Hoel, member of the NIH Consensus Development Conference on Breast Cancer Screening for Women. He is chairman of the Department of Biometry and Epidemiology and Associate Director of the Hollings Cancer Center of the Medical University of South Carolina.

Prior to his at the university, Dr. Hoel served in several positions at the National Institute of Environmental Health and Sciences and was a visiting scientist and associate director of the Radiation Effects Research Foundation, Hiroshima, Japan.

Welcome, Dr. Hoel. The floor is yours.

Dr. HOEL. Thank you. Thank you, Chairman Specter.

Senator SPECTER. Your full statement will be made a part of the record. We would appreciate it if you could do your oral testimony within the 5 minutes. Thank you.

Dr. HOEL. Fine. Thank you. I appreciate the opportunity to testify before you this morning.

In my capacity as a member of the panel on breast cancer screening for woman ages 40 to 49, I would like to describe the process by which the panel is assessing available research and deriving its conclusions.

Last fall, panel members were invited by the National Institutes of Health's Office of Medical Applications of Research to participate in the Consensus Development Conference which was held January 21–23 at NIH.

The panel was charged with developing consensus statements in response to five specific questions which were posed. The questions were as follows:

One, is there a reduction in mortality from breast cancer due to screening women ages 40–49 with mammography with or without physical examinations? How large is the benefit? How does this change with age?

Two, what are the risks of screening women ages 40 to 49 associated with mammography and with physical examination? How large are the risks? How do they change with age?

Three, are there other benefits? If so, what are they? How do they change with age?

Four, what is known about how the benefits and risks of breast cancer screening differ based on known risk factors for breast cancer?

Five, what are the directions for future research?

The panel was provided with copies of nearly 150 published research papers and reports related to the questions. In addition, the National Library of Medicine provided the panel with copies of over 300 abstracted research papers.

Prior to the consensus conference, the panel received abstracts and research papers from the invited conference speakers. During the conference, panel members had the opportunity to question the speakers and receive copies of their slides. The major randomized clinical trials of mammography and breast cancer mortality were represented and the latest data and analyses were presented to the panel and conference attendees.

The consensus panel was made up of individuals from a variety of disciplines including radiology, oncology, epidemiology and statistics, as well as representatives from consumer groups.

The panel had a preliminary meeting on December 12–13, 1996, and at that time the five questions were discussed and specific assignments were made with regard to the first four questions. The purpose of this activity was to prepare a simple outline of the key issues for each of the questions prior to the conference in January.

The conference was held January 21–23, 1997. After the completion of the conference presentations, the panel began its deliberations and writing. The completed first draft of the consensus document was finished on January 23 and was presented that morning to the conference attendees. Comments and questions were offered by conference attendees and the committee subsequently returned to a working session at which time the comments from the conference participants were discussed and revisions were begun.

During this period, work was halted in order to accommodate a press conference. At the conclusion of the press conference, the panel adjourned and is now in the process of completing the consensus statement.

There are four key points pertaining to the activities of the panel:

One, the panel was restricted to providing answers to the five specific questions in its charge.

Two, the panel is currently involved in the completion of its work.

Three, the panel has had no contact or interactions with any of the sponsoring bodies; namely, the National Cancer Institute, the National Institute on Aging, the Office of Research on Women's Health of the NIH, and the Center for Disease Control and Prevention.

Four, the panel's conclusions are the consensus view of members who have a broad variety of backgrounds and disciplines.

PREPARED STATEMENT

Thank you. Please insert my prepared statement into the record. I would be happy to answer any questions.

[The statement follows:]

PREPARED STATEMENT OF DAVID G. HOEL

Mr. Chairman and Members of the Committee, I am David G. Hoel, Professor and Chairman of the Department of Biometry and Epidemiology at the Medical University of South Carolina in Charleston. I appreciate the opportunity to testify before you this morning.

In my capacity as a member of the Panel on Breast Cancer Screening for Women Ages 40–49, I would like to describe the processing by which the panel is assessing available research and deriving its conclusions. Last Fall Panel members (list attached) were invited by the National Institute of Health's (NIH) Office of Medical Applications of Research (OMAR) to participate in the Consensus Development Conference which was held January 21–23, 1997, at NIH. The panel was charged with developing consensus statements in response to five specific questions which were posed. The questions are as follows:

1. Is there a reduction in mortality from breast cancer due to screening women ages 40 to 49 with mammography, with or without physical examinations? How large is the benefit? How does this change with age?

2. What are the risks of screening women ages 40 to 49 associated with mammography, and with physical examination? How large are the risks? How do they change with age?

3. Are there other benefits? If so, what are they? How do they change with age?

4. What is known about how the benefits and risk of breast cancer screening differ based on known risk factors for breast cancer?

5. What are the directions for future research?

The panel was provided with copies of nearly 150 published research papers and reports related to the questions. In addition, the National Library of Medicine provided the panel with copies of over 300 abstracted research papers.

Prior to the consensus conference, the panel received abstracts and research papers from the invited conference speakers. During the conference, panel members had the opportunity to question the speakers and received copies of their slides. The major randomized clinical trials of mammography and breast cancer mortality were represented, and the latest data and analyses were presented to the panel and conference attendees.

The consensus panel was made up of individuals from a variety of disciplines including radiology, oncology, epidemiology and statistics as well as representative from consumers groups. The panel had a preliminary meeting in December 12–13, 1996, and at that time the five questions were discussed and specific assignments were made with regard to the first four questions. The purpose of this activity was to prepare a simple outline of the key issues for each of the questions prior to the conference in January.

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a press conference. At the conclusion of the press conference, the panel adjourned and is now in the process of completing the consensus statement.

There are four key points pertaining to the activities of the panel.

(1) The panel was restricted to providing answers to the five specific questions in its charge only.

(2) The panel is currently involved in the completion of its work.

(3) The panel has had no contact or interactions with any of the sponsoring bodies, namely, the National Cancer Institute, the National Institute on Aging, the Office of Research on Women's Health of the NIH and the Center for Disease Control and Prevention.

(4) The panel's conclusions are the consensus view of members who have a broad variety of backgrounds and disciplines.

Thank you for this opportunity to address you and to answer any questions you may have.

RISKS OR BENEFITS

Senator SPECTER. Thank you very much, Dr. Hoel. What is your thinking on Dr. Klausner's comment that the panel overemphasized the risks and underemphasized the benefits?

Dr. HOEL. This is the first I had heard that comment.

Senator SPECTER. Was Dr. Klausner consulted by the panel?

Dr. HOEL. Pardon?

Senator SPECTER. Was Dr. Klausner consulted by the panel?

Dr. HOEL. No.

Senator SPECTER. Before the panel reached its conclusions?

Dr. HOEL. No; as I said, we had no meetings with individuals from the NCI. In fact, we didn't even have, say, a welcoming visit that night. We wanted to stay perfectly independent.

Senator SPECTER. Do you not think it would have been useful to have had somebody from the NCI there to give you their views? You don't have to take them, but would it not at least be relevant to know what Dr. Klausner thinks about the subject?

Dr. HOEL. I don't think that was the—I can't speak for the Office of Medical Applications and Research. But my understanding is that it is to be a panel of nongovernment individuals who will simply review the research literature and materials.

Senator SPECTER. Well, who selected the individuals, if you know?

Dr. HOEL. I assume it was the Office of Medical Applications Research of NIH and, I also understand although I didn't meet with, a steering committee.

Senator SPECTER. I just raise the question because you have Dr. Klausner's very dramatic comment on being shocked. You have the comment which Dr. Daniel Kopens of Harvard Medical School, who said that the committee's report was fraudulent. You have that kind of reaction.

I would just wonder why Dr. Klausner wouldn't at least be consulted or talked to to get some input.

Dr. HOEL. Well, I cannot answer that. We were following the procedures that were provided us by the Office of Medical Applications Research.

I should say on his question about the balance, you see, we were, as I mentioned in my summary statement, we were directed to answer five specific questions. This was probably a basis of how long the answers were, and the question about risks—they are not that well known; I mean, the details about false positives, false nega-

tives, estimates of radiation risk and so on. That is a longer answer because it has more subtopics.

Senator SPECTER. What do you think of Dr. Monsees' comment that there was not enough time for input, comments from people who were in attendance?

Dr. HOEL. We heard a lot of comments from the audience. But I know in every case there were more individuals who wanted to comment on the papers.

Senator SPECTER. Dr. Klausner has stated that the national cancer advisory board will meet on February 25–26, and the board and the National Cancer Institute will discuss the consensus conference and make their own evaluation of the benefits and risks of screening women 40 to 49.

Now we are going to have another group which is going to meet on it.

Now I understand that in a free society people are able to say anything they want at any time. But I just pose the question about having a consensus report which has a banner of the National Institutes of Health on it—it is a little hard to find out exactly how it was constituted although obviously we can do that—and the prospect of having a different conclusion. Dr. Klausner has already expressed himself, that the benefits were understated and the risks overstated, and his shock.

Looking to the future, is there not a better way to organize our thinking and organize our conclusions, and if there are going to be dissents to have them in the context of a dissent, as opposed to having these different messages go out?

Dr. HOEL. Well, I think you have to understand that the panel was not asked to recommend whether there should be screening as a national policy.

Senator SPECTER. But didn't it pretty much come to a conclusion, or has the media misinterpreted it, that screening mammography is not really useful for women 40 to 49 ?

Dr. HOEL. What we said was that there was no measurable mortality benefit until about 10 years post-entry into the trials. Also, the trials themselves have various problems.

Now there are some new ones that are beginning that are directed more at addressing this question.

Senator SPECTER. No measurable mortality benefits?

Dr. HOEL. Until about 10 years postentry into the trials.

Senator SPECTER. What was your thinking on the Swedish study which contradicted that conclusion?

Dr. HOEL. Well, this is looking at all of the Swedish and American studies. In fact, in the report, the draft report—and you have to understand that it is still an ongoing process and we are trying to rewrite it so there will not be confusion about the 10-year point of where you start to see a benefit in cancer mortality.

Senator SPECTER. Well, looking to the future on activities, would it be preferable not to issue a draft report until the final report is ready and all of these factors have been digested and the final report is made?

Dr. HOEL. Well, that is a difficult question. I think that one of the benefits we had was in reading the draft to the conference participants, we were able to get feedback from them and we'd be able

to take that into consideration. So this was a very valuable input to us.

Senator SPECTER. Well, you could get feedback from them in a variety of ways without making a public disclosure of the draft report.

Dr. HOEL. Yes; you could. But I'm saying this is basically how the process is carried out in the consensus conferences.

Senator SPECTER. OK. We very much appreciate your work, Dr. Hoel. I know it is not easy and I know there were people from the panel quoted in the media expressing chagrin about their scientific findings and having such a public outcry. It is not an easy matter. But in the context of a message going out to so many women in the United States and everywhere as to what the import is, it is at least my thinking, and I believe some of the others on this panel, that we ought to more closely evaluate the kind of message that comes out, to see if we cannot have a little more clarity before a draft report is circulated.

This chapter is going to go on and on. As I say, I am going to do field hearings in my own State, and there is going to be another group meeting on February 25–26. As I said at the outset, Secretary Shalala is going to come in to testify, but wanted the scientists to testify earlier.

This is all very important as it impacts on the work of the subcommittee and our appropriation process and, obviously, most importantly on the impact of women who have to make these important decisions.

MATERIAL SUBMITTED SUBSEQUENT TO CONCLUSION OF THE HEARING

I would like to have inserted into the record statements by Senator Craig and Senator Snowe, and also into the record a very poignant letter from Dr. Jeanne Petrek dated February 3, 1997, resigning from the consensus panel because of her strong disagreement with its conclusions.

[CLERK'S NOTE.—The following statements and letter was received by the subcommittee subsequent to conclusion of the hearing. The statements and letter will be inserted into the record at this point.]

PREPARED STATEMENT OF SENATOR LARRY E. CRAIG

Mr. Chairman, I want to thank you for holding this hearing today to address the serious issue of breast cancer screening for women ages 40–49. I appreciate the opportunity to highlight this important issue. I look forward to hearing the testimony of the witnesses here today as well as assessing the recommendations of the NIH consensus development conference.

As you know, breast cancer remains the most deadly and prevalent cancer affecting American women today. The majority of women who are diagnosed with breast cancer have no identifiable risk for this disease. Breast cancer is the single leading cause of death for women in their forties and fifties. This year alone, 33,000 women in their forties will be diagnosed with breast cancer.

We need to promote behavior that encourages women to use the available methods that assist in detecting this deadly disease. Mammography plays a vital role in the detection of breast cancer. Taking into account that mammography is not a perfect tool for early detection of breast cancer, we now have compelling proof that mammography screening for women ages 40–49 can substantially reduce the death rate from breast cancer. Intervention through routine screening for breast cancer through mammography, clinical breast exams and monthly self-exams can help save the lives of women at a time when medical science is unable to prevent this disease.

I am pleased to tell you that just yesterday, I was one of 98 members of the Senate to vote in favor of a resolution expressing the sense of the Senate requiring stringent guidelines for mammography testing for women between the ages of 40 and 49.

It is imperative that we direct appropriate resources into research for prevention, early detection and a cure. We need to focus on making sure that all women have access to high quality mammograms, regardless of age. Until we have a cure for this disease, all women need access to the best screening currently available.

PREPARED STATEMENT OF SENATOR OLYMPIA SNOWE

Thank you, Mr. Chairman, for allowing me to testify before you today on the decision of the National Cancer Institute's consensus conference panel to refrain from recommending that women in their forties seek routine mammograms. I appreciate your long-standing leadership on issues related to women's health, and I commend you for holding this critical hearing. In fact, this issue is so important that yesterday, with the Chairman's assistance, the Senate voted unanimously to pass my resolution on this very issue.

Breast cancer is one of the major public health crises facing American women today, striking one in every eight women during their lifetime. It will strike 180,000 American women this year, and kill 44,000 women—more than 10,000 of whom will be diagnosed with breast cancer in their forties. For women in this age group, it is the leading killer, and more women this year will be diagnosed with cancer in their forties than in their fifties.

Mammograms are the most powerful weapon we have in the fight against breast cancer. They enable us to detect and treat breast cancer at its earliest stages when the tumors are too tiny to be detected by a woman or her doctor, providing a better prognosis for treatment. An estimated 23.5 million mammograms were performed in 1992 at a cost of approximately $2.5 billion—a valuable down-payment in our fight against an unmerciful killer.

The question about whether women in their forties should seek regular mammograms has been an open-question for years. Yet persuasive new studies by Swedish researchers and others [Malmo; Gossenberg; Smart, Hendrick, Rutledge and Smith] indicating that mammograms benefit women in this age group promised to put this question to rest once and for all. In response to these studies, the National Institutes of Health convened a consensus conference to revisit this critical issue.

On January 23, the consensus panel decided against recommending that women in their forties seek routine mammograms. In making its decision, the panel gave undue weight to hypothetical risks, such as false-negative results that potentially provide women with a false sense of security, false-positive results that produce unnecessary anxiety, the potential for over treatment, and radiation exposure.

If we ever hope to improve survival rates for breast cancer, women of all ages must receive accurate and consistent information regarding the importance of mammograms. Women and their doctors look to the nation's preeminent cancer research institution—the National Cancer Institute—for clear guidance and advice on this issue. Yet, the consensus panel refused to provide clear guidance, leaving a muddled picture at a time when women are begging for answers.

Confusion on this issue is not new. In 1989, NCI, along with the American Cancer Society and the American Medical Association, issued breast cancer screening guidelines which advised women to begin having mammograms at age 40. In 1993, NCI rescinded these guidelines, stating that their review of clinical trials produced no evidence that mammograms significantly reduced breast cancer deaths for women in their forties. At the time, Congress and many experts—including groups such as the American Cancer Society—questioned the appropriateness of this conclusion, based on the available scientific evidence. This is when I first introduced legislation urging NCI to reexamine this issue.

By rescinding its guidelines, NCI produced widespread confusion and concern among women and physicians regarding the appropriate age at which to seek mammograms. This confusion eroded public confidence in mammography, and reinforced the "information barrier" which discourages women from seeking care. It also lead many health insurers to believe that coverage of mammograms for women in their forties is unnecessary—a point we should not overlook. Four years later, we are still mired in this controversy and these hurdles still exist.

Yet new studies strongly suggest that routine mammograms for women in their forties can save lives. For example, one study conducted by Smart, Hendrick, Rutledge and Smith found a 24-percent lower death rate among women who received mammograms in their forties when the world's population-based trials were com-

bined; and Swedish researchers in 1996 in two studies found a 44- and 36-percent lower death rate among women who received mammograms in their forties. And several studies have concluded that breast tumors in women under 50 grow far more rapidly than breast cancer in older women, suggesting that annual mammograms are of value to women in their forties.

In studying the research and scrutinizing the statistics, the Panel appears to have lost sight of the human dimension of this question, and gave undue weight to the costs of screening, rather than the benefits. The Panel emphasized that 2,500 women would be have to be screened to save one life. But this one life represents someone's mother, wife, sister, or daughter.

The panel also emphasized that up to one-fourth of all invasive breast cancers are not detected by mammography in women in their forties. Yet, the flip side of this statistic is that three-fourths of all cancers in this age group are detected through mammography. While it may not be perfect, that clearly amounts to saved lives.

Finally, the NCI panel also overemphasizes the risks of false-positives, suggesting that many women would undergo unnecessary surgical procedures. Yet, women with positive findings subsequently undergo more refined diagnostic tests, including diagnostic mammograms, ultrasounds, and needle biopsies to confirm the presence of cancer, before any treatment decisions are made.

Appropriately, the Director of NCI, Dr. Richard Klausner, expressed his surprise and disappointment over the decision of the consensus panel, and has asked the NCI Advisory Board to convene next month to revisit this issue. Former NIH Director, Dr. Bernadine Healy, affirmed his views.

This is why I offered a sense of the Senate resolution yesterday with my colleague from Maryland, Senator Mikulski, on this very issue. This resolution expressed the sense of the Senate that studies needs to further determine the true benefit of mammograms for women in their forties. It also urges National Cancer Institute's Advisory Board, which will meet later this month, to consider reissuing the mammography guidelines it rescinded in 1993 recommending that women in their forties seek routine mammograms. Alternatively, NCI should direct women to other organizations which have issued clear guidelines on the issue, such as the American Cancer Society. I am pleased that the Senate voted in favor of this resolution so overwhelmingly.

American women and their physicians deserve to have clear guidance on this issue. Yet the consensus panel "passed the buck" by refusing to provide this clear guidance. I strongly believe that in light of the new persuasive evidence, NCI should recommend routine mammograms for women in their forties, until future research persuades us otherwise. Not only will this clarify this issue in the minds of American women, but it has significant implications for insurance coverage as well. And most importantly, it will save lives. Thank you.

LETTER FROM JEANNE PETREK, M.D., FACS

MEMORIAL SLOAN KETTERING CANCER CENTER,
New York, NY, February 3, 1997.

Dr. JOHN FERGUSON,
Office of Medical Applications of Research, NIH,
Bethesda, MD.

DEAR DR. FERGUSON: It is with considerable regret that I resign from the NIH Consensus Development Panel. My reasons are as follows.

I agree that randomized clinical trials (RCT's) do not provide evidence that mammographic screening should start in all American women beginning at age 40. However, I yet believe that mammographic screening is advisable for many women 40 to 50 years of age, depending upon clinical factors and the woman's informed decision. This belief is primarily based on the small, but significant, reduction in breast cancer deaths found in the meta-analysis of the RCTs and the improvements in mammography during the 15 years since even the most recent trial.

There is no question but that a new RCT will yield scientific evidence. However, it will require 2 years to design and fund, some 5 years to accrue and 5 to 10 years to evaluate survival. (It will require 20 to 30 years to evaluate mammogaphic screening for radiation carcinogenesis.) But the treating physician must deal with patients now.

The draft would indicate that the majority of panelists believe that screening in the 40's is without value. An example appears in a New York Times (1/28/97). The panelist is talking to a patient in her 40's who was treated with mastectomy and chemotherapy. The patient asks: "What should I tell my 29 year old daughter?" Dr. Laufman says: "I told her that I would tell her daughter what I would tell my own

daughter: start having mammograms when you're 50. And stay very, very tightly tuned to the research as it develops."

The different perspectives on the value of screening in the 40's apparently cannot be separated from what individual panelists bring to the consensus document. This is apparent from the current one-sided draft of the "consensus" document. The draft diminishes the survival benefit. It overemphasizes the risks, while making no attempt at a balanced presentation of risks versus benefits. The draft has not appreciably changed or improved since its inception, despite changes that I have recommended and despite my conversations with panel members on these issues.

The document is unacceptable to note and I cannot have my name associated with it.

Sincerely yours,

JEANNE PETREK, M.D.

SUBCOMMITTEE RECESS

Senator SPECTER. That concludes our hearing. Thank you very much. The subcommittee will recess and reconvene at the call of the Chair.

Dr. HOEL. Thank you.

[Whereupon, at 12:53 p.m., Wednesday, February 5, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

MAMMOGRAPHY

THURSDAY, FEBRUARY 20, 1997

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Philadelphia, PA.

The subcommittee met at 9:30 a.m., in the ceremonial courtroom, Federal courthouse, Philadelphia, PA, Hon. Arlen Specter (chairman) presiding.

Present: Senator Specter.

NONDEPARTMENTAL WITNESSES

STATEMENTS OF:

DINA F. CAROLINE, M.D., Ph.D., CHIEF, DIVISION OF GASTROINTESTINAL RADIOLOGY AND MAMMOGRAPHY, DEPARTMENT OF DIAGNOSTIC IMAGING, TEMPLE UNIVERSITY HOSPITAL

BONITA FALKNER, M.D., ACTING DIRECTOR, INSTITUTE OF WOMEN'S HEALTH, ALLEGHENY UNIVERSITY OF THE HEALTH SCIENCES

STEPHEN A. FEIG, M.D., CHIEF, DIVISION OF MAMMOGRAPHY AND PROFESSOR OF RADIOLOGY, DIVISION OF BREAST IMAGING, THOMAS JEFFERSON UNIVERSITY

DANIEL C. SULLIVAN, M.D., ASSOCIATE PROFESSOR OF RADIOLOGY, UNIVERSITY OF PENNSYLVANIA MEDICAL CENTER

ROBERT C. YOUNG, M.D., PRESIDENT, FOX CHASE CANCER CENTER

OPENING REMARKS OF SENATOR SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The Appropriations Subcommittee on Labor, Health and Human Services, and Education will begin this hearing.

The focus of our hearing today is on the issue of mammograms for women in the age group 40 to 49, but we will be inquiring into a broader range of issues as we pick up that very important subject. The broader range of issues will include the problems of cancer generally, problems after breast cancer, funding by the U.S. Government on breast cancer research, and the National Institute of Health. And we will inquire into the possibility of assistance on the recent discoveries on genes, what collateral issues there are on the right to privacy, how gene research may be used in order to act against the ravages of breast cancer, which is such a major killer of women in America today. One out of every eight women gets breast cancer, and we are searching for ways to combat it.

The funding for breast cancer has gone up tremendously during the past several years, now in excess of $400 million. And the question really is, what is adequate? That question was asked directly of Dr. Klausner, the head of the National Cancer Institute in the hearing in Washington recently.

We are committed to increasing the NIH budget. That budget has gone up consistently during my tenure in the U.S. Senate, notwithstanding cuts in other fields. Whether the chairman of the subcommittee has been Senator Weicker or Senator Chiles—now Governor of Florida—Senator Harkin, or my chairmanship, we have found the funds to increase that important item.

We have a Federal budget of $1.7 trillion, which is a staggering sum of money—really unquantifiable. I am personally convinced that we can have a balanced budget in America and still take care of our priority items like medical research. Senator Harkin and I have eliminated some 134 programs from the subcommittee, a saving of about $1½ billion, so we can focus our money on education, Pell grants, guaranteed student loans, and NIH research, including breast cancer. So it is a matter of assessing priorities.

Then the panel came out with the conclusion that mammograms were not useful for women. I think that is the categorization—we will talk about it at some length today—for women 40 to 49. It was immediately greeted with substantial cynicism and criticism, and Dr. Klausner said he was shocked by it. My own view, from what I know in the field, is that it is not a correct finding, but we need to hear from the experts.

Dr. Klausner is convening a group of the National Cancer Institute to go into the matter further and will be filing an additional report. Secretary Shalala of Health and Human Services will be appearing before our subcommittee in early March. I am hopeful it will be March 5. The date has not yet been finalized. This issue is far from over, and there is major concern that, notwithstanding the advantages of mammograms, it is really not the ultimate answer, more research is necessary on better ways of detecting breast cancer.

For the past several years, we have used the techniques of the CIA on imaging from outer space. The CIA has put up $2 million, a rather unusual allocation for the CIA, but they did that—perhaps influenced at least in some small part that I was chairman of the Intelligence Subcommittee at the same time I was chairman of the appropriations Labor HHS Subcommittee. There is nothing like being chairman, for those of you who do not know the ways of the Senate. And we are having clinical trials underway.

We have a very fast-track appropriation—$2 million, which we got through. And those contracts were let last September, setting a record for that, from our hearings last March, and then getting the clinical trials underway by September, with the contracts let.

We have a distinguished panel of witnesses today. And I want to express my thanks and the thanks of the subcommittee and the full committee, and really the entire Senate and the Congress, that you have come today. While our hearing room is not filled with people, there is substantial exposure by those magic markers to my left, the television cameras. And I think it is very important the American people understand the issues, what is going on with

breast cancer and what is going on with mammography and what the needs are and the financing, and that there is very intense work underway for the billions of women who are really very concerned about their own problems with breast cancer.

INTRODUCTION

So, with that not-so-brief introduction, I would look to call our distinguished panel of witnesses: Dr. Dina F. Caroline, chief of the division of gastrointestinal radiology and mammography at Temple University; Dr. Stephen Feig, chief of the division of mammography and professor of radiology, division of breast imaging, at Thomas Jefferson University; Dr. Daniel C. Sullivan, associate professor of radiology at the University of Pennsylvania Medical Center; Dr. Bonita Falkner, acting director of the Institute of Women's Health, Allegheny University of the Health Sciences; and Dr. Robert C. Young, president of the Fox Chase Cancer Center.

Would you all step forward, please.

Our practice in the subcommittee and, for that matter, most of the Congress, is to put the full statements in the record and to ask the witnesses, to the extent possible, to limit their opening statements to 5 minutes, and leave the maximum amount of time for dialog and interchange among the panelists at the conclusion of the testimony.

I am joined here by Bettilou Taylor, who is a staffer second to none in the U.S. Senate. She has been working in this field for many years. And if people want the real answers, they call Bettilou or they call Craig Higgins, who really do such outstanding work in this field.

We are going to proceed in alphabetical order. The list I had is not alphabetical. We will move Dr. Falkner up ahead of Dr. Feig, in alphabetical order. And when you have a group of this preeminence, I do not want to make the decisions about sequence. And we will start with Dr. Dina Caroline from Temple.

SUMMARY STATEMENT OF DR. DINA CAROLINE

Dr. Caroline, thank you for joining us. You are an M.D., and a Ph.D. Is it necessary to call you doctor, Doctor?

Dr. CAROLINE. Absolutely not. You can call me Dr. Mom if you like.

Senator SPECTER. Well, we welcome you here, and the floor is yours.

Dr. CAROLINE. Good morning, Hon. Senator Specter. I am here representing Temple University Hospital in Philadelphia. This is a nationally known teaching institution, serving the health care needs of the local community. The hospital also provides the clinical environment to support the training and research needs of the Temple Medical School, founded in 1892. Temple University Hospital now has over 500 patient beds. In the Department of Diagnostic Imaging at the Health Science Center, we perform over 5,000 mammograms annually.

The recommendations regarding mammographic screening for women ages 40 to 49 has been evolving since screening was introduced in 1977, when the NCI and ACS recommended it for women with first-degree relatives with breast cancer. Since 1983, the

American Cancer Society has recommended screening for women ages 40 to 49 every 1 to 2 years. Through 1989, these guidelines were adopted by additional major medical organizations. In the early nineties, individual radiologists were beginning to advocate yearly screening for women aged 40 to 49, while other radiologists and other health care professionals questioned the value of screening altogether.

This conflict of screening women ages 40 to 49 came to a head in 1993, when NCI changed its recommendations, no longer stating that, "experts do not agree on the value of routine screening mammography for women ages 40 to 49." Other organizations, including the American Cancer Society and American College of Radiology, disagreed with the changes. The recent NIH conference convened January 20 of this year, with the intention of achieving consensus regarding mammography screening of asymptomatic women beginning at age 40. The failure of the panel to achieve its goal has caused an uproar in the academic and lay communities.

It is important to understand the context in which the issue has received so much attention. Breast cancer is often referred to as an epidemic in the United States because of its prevalence, occurring in about one out of eight to one out of every nine women over their lifetime. Literally every adult in the United States is affected at some level by breast cancer. For women, the fear of the disease strikes deeply on physical, psychological and social levels.

The rise in interest and public awareness and research funding for breast cancer has paralleled the rise in influence and power of women in the United States in general. The issue strikes every woman deeply and emotionally with disparate forces, coupling intelligent, rational people with the gut-wrenching fear of breast cancer. It becomes difficult to separate analysis of the scientific data from personal bias, fears and desires.

As new scientific data is acquired, recommendations for screening may be expected to evolve. Analysis of data as it is acquired takes time, and there is necessarily a lag between the time that data is published and it undergoes scientific scrutiny and is translated into policy by the major medical societies and finally by Federal agencies. In medical research and access—in particular, the issue at hand, breast cancer screening for women ages 40 to 49—public demand for rapid response to new information may have exceeded the ability of the system to respond. The ramifications of setting policy are enormous because of the implications regarding the financial coverage for screening mammography. Recommendations made by nationally recognized bodies are expected to be used as guidelines for Medicare. And these same recommendations are frequently used by insurance companies.

The controversy regarding breast cancer screening for women ages 40 to 49 focuses on several issues. These have been discussed at length at the consensus conference. Dr. Stephen Feig, who is a participant at this hearing here, has written extensive and convincing responses to many of the criticisms opposing or questioning the value of screening women ages 40 to 49 for breast cancer. I will mention only a few.

The most important issue for acceptance of a screening procedure is establishing the efficacy of that procedure; that is, whether

screened populations shows a decrease in mortality from the disease compared to the unscreened population. The potential benefit of screening mammography must be considered in perspective of the possible adverse effects of screening mammography. These include false positive results, subjecting women to biopsies because of equivocal or worrisome findings on the mammogram which prove to be benign at biopsy.

False positives are common because the goal of mammography is not to miss any cancers. Thus, we are willing to accept a certain number of false positives, which are acknowledged to cause anxiety to the women involved and add to the cost of mammography. False negative mammograms are also an acknowledged real problem. The increasing availability and use of percutaneous core biopsies is helping to decrease the number of false positive surgical biopsies.

Senator SPECTER. Dr. Caroline, could you summarize the balance, and your full statement will be in the record.

Dr. CAROLINE. Sure.

PREPARED STATEMENT

My final assessment for the available data favoring breast cancer screening for women ages 40 to 49 is sufficiently strong compared to the negative information to advocate for the position. I would stress that I feel strongly that continued research to improve early detection and prevention of breast cancer must be supported and funded. This includes well controlled screening studies for women in the age group and to her modalities of funding, and possibilities for other non-imaging modalities as well.

Thank you.

Senator SPECTER. Thank you very much, Dr. Caroline.

[The statement follows:]

PREPARED STATEMENT OF DINA F. CAROLINE, M.D.

Temple University Hospital in Philadelphia is a nationally known teaching institution serving the health care needs of the local community. The Hospital also provides the clinical environment to support the training and research needs of the Temple Medical School. Founded in 1892, Temple University Hospital now has over 500 patient beds. In the Department of Diagnostic Imaging at the Health Science Center, over 5,000 mammograms are performed annually.

Recommendations regarding mammographic screening for women ages 40 to 49 have been evolving since screening was introduced in 1977 when NCI and ACS recommended it for women with first degree relatives with breast cancer. Since 1983, the ACS has recommended screening for women ages 40 to 49 every 1 to 2 years. Through 1989, these guidelines were adopted by additional major medical organizations. In the early 1990's, individual radiologists were beginning to advocate yearly screening for women aged 40 to 49 while other radiologists and other health care professionals questioned the value of screening altogether.

This conflict of screening women ages 40 to 49 came to a head in 1993 when NCI changed its recommendation no longer stating that "experts do not agree on the value of routine screening mammography for women ages 40 to 49." Other organizations including ACS and ACR disagreed with the change. The recent NIH conference convened January 20th with the intention of achieving consensus regarding mammography screening of (asymptomatic) women beginning at age 40. The failure of the panel to achieve its goal has caused an uproar in the academic and lay communities.

It is important to understand the context in which this issue has received so much attention. Breast cancer is often referred to as an epidemic in the United States because of its prevalence occurring in about one-eighth to one-ninth of women over their lifetime. Literally every adult in the United States is affected at some level by breast cancer. For women the fear of the disease strikes deeply on physical, psy-

chological, and social levels. The rise in interest and public awareness and research funding for breast cancer has paralleled the rise in the influence and power of women in the United States in general. The issue strikes every woman deeply and emotionally with disparate forces coupling intelligent rational people with the gut wretching fear of breast cancer. It becomes difficult to separate analysis of the scientific data from personal bias, fears and desires.

As new scientific data is acquired, recommendations for screening may be expected to evolve. Analysis of data as it is acquired takes time and there is necessarily a lag between the time that data is published that it undergoes scientific scrutiny, and is translated into policy by the major medical societies and finally by the federal agencies. In medical research and access, in the particular issue at hand, breast cancer screening for ages 40 to 49, public demand for rapid response to new information may have exceeded the ability of the system to respond. The ramifications of setting policy are enormous because of the implications regarding the financial coverage for screening mammography. Recommendations made by nationally recognized bodies are expected to be used as guidelines for Medicare and these same recommendations are frequently used by insurance companies.

The controversy regarding breast cancer screening for women between the ages of 40 to 49 focuses on several issues. These have been discussed at length at the consensus conference. Dr. Stephen Feig, a participant at this hearing has written extensive and convincing responses to many of the criticisms, opposing or questioning the value of screening women ages 40 to 49 for breast cancer. I will mention only few.

The most important issue for acceptance of a screening procedure is establishing the efficacy. That is, whether screened populations show a decrease in mortality from the disease compared to unscreened populations. The potential benefit of screening mammography must be considered in perspective of the possible adverse effects of screening mammography. These include false positive results—subjecting women to biopsies because of equivocal or worrisome findings on the mammogram which prove to be benign at biopsy. False positives are common because the goal of mammography is not to miss any cancers. Thus, we are willing to accept a certain number of false positives, which are acknowledged to cause anxiety to the women involved and add to the cost of mammography. False negative mammograms are also an acknowledged real problem. The increasing availability and use of percutaneous "core" biopsies is helping to decease the number of false positive surgical biopsies.

Responses to the advocates of screening mammography (40 to 49) challenges raising the questions of potential risks or adverse effects to screening mammography have been strong, if not uniformly convincing. The potential risk of the cumulative effects of the low doses of radiation to the breasts has historically deterred many women from seeking, and physicians from recommending, screening mammography. Dr. Feig has addressed this issue and clearly has shown that even assuming a "worst case scenario", the benefit of mammography far outweighs the risk of "excess" deaths from radiation-induced cancers.

The issue of the diagnosis and management of ductal carcinoma in situ (DCIS) is important, raising concerns of over diagnosis and over treatment of a pathologic entity whose natural history is often not aggressive. Pathologists are now distinguishing between aggressive (comedo-type) and non-aggressive forms of DCIS. There is a small (about 2 percent) annual incidence of subsequent invasive cancer in patients with DCIS. This rate is doubled in patients with positive family history of breast cancer. Autopsy studies of women without clinical breast cancer show a large number of cases with DCIS. This holds true for women under and over the age of 50—but the issue is no different for either age group. Granted that some women diagnosed with DCIS may be overtreated, that option seems preferable to not treating those that will become invasive.

Data supporting the efficacy of screening mammography in women 40 to 49 years of age has accrued slowly. Convincing the medical community of its validity has by no means been a bandwagon jumped upon by all at first encounter. This is because in the large screening studies there were not enough women in the age group 40 to 49 to show a significant reduction in mortality. Only by combining the data from all the studies available and extending the time over which information was analyzed have trends towards mortality reduction begun to emerge in a convincing manner. The technique of analysis, problems with design and methodology of the venous protocols were presented at the consensus meeting. New data screening projects in Sweden are showing impressive mortality reduction. In my opinion, a reasonable working hypothesis would be that a large yearly screening study performed by facilities conforming to current standards (complying with the Mammography Quality Standards Act, 1992) would show even more dramatic results.

In my assessment the available data favoring breast cancer screening for women ages 40 to 49 is sufficiently strong compared to the negative information to advocate for the position. I would stress that I feel strongly that continued research to improve the early detection and prevention of breast cancer must be supported (and funded). This includes a well controlled screening study in women aged 40 to 49 using mammographic screening techniques conforming to the MQSA of 1992. Evaluation of new and emerging imaging modalities such as MRI, digital mammography, nuclear medicine tumor imaging, and high resolution ultrasound are but a few of the modalities currently being evaluated as screening tools. Nonimaging modalities such as serological test and genetic markers also are under active investigation.

It is crucial that these modalities be given optimal opportunities to mature and then that the accrediting agencies be adaptable—constructed in such a way as to be able to react with some efficiency to integrate new information and modify existing recommendations in a timely manner and perhaps most importantly that the insurers respond appropriately to the recommendations.

Thank you for inviting me to participate in this hearing. References for material contained in my testimony are available upon request.

SUMMARY STATEMENT OF DR. BONITA FALKNER

Senator SPECTER. We now turn to Dr. Bonita Falkner, acting director of the Institute for Women's Health and professor of medicine and pediatrics at the Medical College of Pennsylvania's Hollman School of Medicine at the Allegheny University of Health Sciences. In her role as the director of the Institute for Women's Health, she directs programs in health research, health education and comprehensive health care services for women.

Welcome, Dr. Falkner. The floor is yours.

Dr. FALKNER. Thank you, Senator Specter. I appreciate the opportunity to testify before you today. And it is gratifying to see your attention on this important aspect of women's health.

Breast cancer is the No. 1 cancer in women in the United States, and is second only to lung cancer in the number of women that it kills each year. A woman's lifetime risk of developing breast cancer is now one in eight. So far, our best defense against breast cancer is detecting it at its earliest and most treatable stages. And that is where screening mammography comes in. Allegheny has long made the detection and treatment of breast cancer one of its top priorities. Our breast centers offer specialized care to women who are at risk of or had breast cancer, as well as comprehensive treatment and support for women with breast cancer.

We work cooperatively with the Korman Foundation, the American Cancer Society and other organizations to offer screening mammograms to high-risk, underinsured and uninsured women. We also offer mobile mammography programs in the Delaware Valley and Pittsburgh areas, which provide no-cost or low-cost mammograms in community settings, including communities with high-risk populations. Last year, our mobile mammography units provided more than 8,000 screenings, including screenings for women in their forties. Physicians and scientists all agree that mammography absolutely saves lives when used as a regular screening for women ages 50 and above. Study after study has shown that screening mammography decreases mortality by 25 to 30 percent in these women.

Today's attention has turned to the controversy in screening for breast cancer—namely, whether it should be recommended for all women in their forties. There is no question that breast cancer is a significant health concern for women in this age group. Breast

cancer is the leading cause of death for women ages 40 to 49 in the United States. A 40-year-old woman has a 2-percent chance of being diagnosed with invasive breast cancer or a ductal carcinoma in situ in the next 10 years. Her risk doubles by the time she reaches 49 years. Nevertheless, there is only a 0.3-percent chance of dying from breast cancer during this decade.

The question, rather, is whether screening mammographies should be recommended across the board for women in their forties. The distinguished panel assembled by the National Institutes for Health did a study of eight clinical trials conducted worldwide over the past three decades. After careful consideration of the pros and cons, it concluded that women in this younger age group could not be given a single generic recommendation. Rather, the decision should be made on a case-by-case basis by a woman and her physician together. This moves the recommendation of the committee from a public health recommendation for a population of women to a medical recommendation for individual women.

We agree with this conclusion when interpreted in the context of optimizing the health of individual women. Within this 10-year age range, from 40 to 50 years, women have greatly varying medical situations that demand individualized decisionmaking. Some fall into populations that put them at higher risk and clearly call for increased vigilance—they have a mother or sister with breast cancer, they are African-Americans or Ashkenazi Jews; they have a history of breast problems. Some women will have begun menopause or be menopausal. Some will be on estrogen replacement therapy.

A physician consulting with a patient on mammography takes all of these variables into consideration, and the physicians temper their advice with their own experience. Many doctors advise women selectively to have a screening mammogram based upon their risk factors. Other physicians choose to err on the side of caution and recommend annual mammography for all women in their forties. There are no easy answers, and scientific uncertainty exists.

The trials conducted to date have not enrolled statistically large numbers of women ages 40 to 49, and many trials began decades ago, when mammography technology was poor, possibly skewing the results. There may be risk factors that have not yet been identified or benefits of screening mammography still to come to light. New trials are now underway with today's technology, and it may show an increased value for mammography. Additionally, future technology has the potential to refine and improve our current methods for early detection of breast cancer.

Very knowledgeable people have carefully examined the trials that have been done so far. Depending on the interpretation of the results, they have varying findings. One conclusion reached is that the trials show no observable benefit from screening in younger women. Others interpreting the data differently find about a 15-percent decrease in mortality when women receive screenings in their forties. And this could translate to as many as 1,600 lives saved in a year.

Given all of these factors, we continue to conclude that screening mammograms are appropriate for many women in their forties, and we would like to offer four additional concerns.

Senator SPECTER. Dr. Falkner, could you summarize; your full statement will be in the record.

Dr. FALKNER. The scientific merits of mammography in younger women should not confuse the facts for women 50 and above. For this 50 to 69 age group, studies have shown that mammography saves lives. Women in their forties should have access to physicians' counseling on the issue, and access to mammography. And we find it particularly troublesome to consider that the panel's failure to endorse this procedure has the potential to lead to failure on the part of insurers to pay.

PREPARED STATEMENT

And finally, with the known excess mortality among minority and disadvantaged women, particular effort must be made to provide access to physician counseling and breast screening for all of these women in these ages.

Thank you for the opportunity to testify.

Senator SPECTER. Thank you very much, Dr. Falkner.

[The statement follows:]

PREPARED STATEMENT OF BONITA FALKNER, M.D.

Mr. Chairman and members of the Committee, I am Bonita Falkner, M.D., Acting Director of the Institute for Women's Health and Professor of Medicine at Allegheny University of the Health Sciences. I appreciate the opportunity to testify before you today.

It is gratifying to see such attention paid to an important aspect of women's health—screenings for breast cancer. Breast cancer is the No. 1 cancer in women in the United States, and is second only to lung cancer in the number of women it kills each year. A woman's lifetime risk of developing breast cancer is now one in eight. So far, our best defense against breast cancer is detecting it at its earliest, most treatable stages. And that's where mammography comes in.

Allegheny has long made the detection and treatment of breast cancer one of its top priorities. Our Breast Centers offer specialized care to women who are at risk of or have had breast cancer, as well as comprehensive treatment and support for women with breast cancer. We work cooperatively with the Korman Foundation, the American Cancer Society and other organizations to offer mammograms to high-risk, underinsured and uninsured women. We also offer mobile mammography programs in the Delaware Valley and Pittsburgh areas which provide no-cost or low-cost mammograms in community settings, including communities with high-risk populations. Last year, our mobile mammography units provided more than 8,000 screenings—including screenings for women in their 40's.

Our commitment to this area is also evident nationally. Our physicians provide the leadership for the National Surgical Adjuvant Breast and Bowel Project, one of the National Cancer Institute's prestigious cancer treatment and prevention research projects representing the nation's foremost work in breast cancer.

Medical research, at Allegheny and at other institutions throughout the country, has led to ever-improving treatments for breast cancer. For example, trials led by the NSABBP showed that lumpectomy and radiation therapy have results equivalent to mastectomy, and were the first to show that chemotherapy after surgery could improve survival.

Physicians and scientists all agree: Mammography absolutely saves lives when used as a regular screening for women ages 50 and above. Study after study has shown that mammography decreases mortality by 25 to 30 percent in these women.

Today's attention has turned to controversy in screening for breast cancer—namely, whether it should be recommended for all women in their 40's.

There is no question that breast cancer is a significant health concern for women in this age group. Breast cancer is the leading cause of death for women ages 40 to 49 in the United States. A 40-year-old woman has a 2-percent chance of being diagnosed with invasive breast cancer or ductal carcinoma in situ in the next 10 years. Her risk doubles by the time she reaches 49 years. Nevertheless, there is only a 0.3 percent chance of dying from breast cancer during this decade.

The question, rather, is whether mammograms should be recommended across the board for women in their 40's.

The distinguished panel assembled by the National Institutes for Health did a study of eight clinical trials conducted worldwide over the past three decades. After careful consideration of the pros and cons, it concluded that women in this younger age group could not be given a single generic recommendation. Rather, the decision should be made on a case-by-case basis by a woman and her physician together. This moves the recommendation of the committee from a public health recommendation for a population of women to a medical recommendation for individual women.

We agree with this conclusion when interpreted in the context of optimizing the health of individual women. Within this 10-year age range from 40 to 50 years, women have greatly varying medical situations that demand individualized decisionmaking. Some fall into populations that put them at higher risk and clearly call for increased vigilance—they have a mother or sister with breast cancer; they are African-Americans or Ashkenazi Jews, they have a history of breast problems. Some women will have begun menopause or be postmenopausal; some are on estrogen replacement therapy.

A physician consulting with a patient on mammography takes all of these variables into consideration, and physicians temper their advice with their own experience. While many doctors advise women selectively to have mammograms based on their risk factors, others choose to err on the side of caution and recommend annual mammograms for all women in their 40's.

There are still no easy answers. Scientific uncertainty exists. The trials conducted to date have not enrolled statistically large numbers of women ages 40 to 49, and many began decades ago when mammography technology was poorer, possibly skewing results. There may be risk factors that have not yet been identified, or benefits of mammography still to come to light. New trials now underway with today's technology may show an increased value for mammography. Additionally, future technology has the potential to refine and improve our current methods for early detection of breast cancer.

Very knowledgeable people have carefully examined the trials that have been done so far. Depending on the interpretation of the results, they have varying findings. One conclusion reached is that the trials show no observable benefit from screening in young women. Others, interpreting the data differently, find about a 15-percent decrease in mortality when women receive screenings in their forties—and this could translate to as many as 1,600 lives saved in a year.

Given all of these factors, we continue to conclude that mammograms are appropriate for many women in their forties. We would also like to offer three additional concerns:

That the controversy over the scientific merits of mammography in younger women not confuse the facts for women 50 and above. For women in the 50 to 69 age group, studies have shown time and again that mammography saves lives.

Second, that women in their 40's have access to a physician's counseling on this issue and access to mammography. We find it particularly troublesome to consider that the consensus panel's failure to endorse the procedure has the potential to lead to a failure on the part of insurers to pay for the procedure.

Third, with the known excess modality among minority and disadvantaged women, particular effort must be made to provide access to physician counseling and breast screening for these women at all ages.

We agree wholeheartedly with the consensus panel's statement that a woman should have access to the best possible information in an understandable and usable form, and that her health care provider must have sufficient information to facilitate her decisionmaking process. I'd like to add that it is important that the physician have adequate time to spend in discussion with the patient as well.

Thank you for the opportunity to appear before you today. This concludes my prepared statement. I would be happy to answer any questions you may have

SUMMARY STATEMENT OF DR. STEPHEN A. FEIG

Senator SPECTER. We now turn to Dr. Stephen A. Feig, chief of the division of mammography at Thomas Jefferson University Hospital, professor of radiology there, chairman of the Mammography Accreditation Committee, and the ad hoc Committee on Mammography Screening Guidelines for the American College of Radiology's Breast task force. Dr. Feig's analysis on radiation risks of mam-

mography was presented to the NIH Consensus Development Conference.

We do welcome you here, Dr. Feig, and the floor is yours.

Dr. FEIG. Thank you, Senator Specter.

This morning I am speaking on behalf of Thomas Jefferson University Hospital, as well as the Philadelphia Chapter of the American Cancer Society.

As a participant in the last month's NCI Consensus Development Conference, I heard investigators from here and abroad present data which provided indisputable proof of substantial benefit of screening with women ages 40 to 49. American women and their families should be heartened by these results, even though they may be understandably disappointed, confused and even outraged that these reports were ignored by the panel.

When in 1993, the NCI dropped its former recommendation to screen women in their forties, it specified the type of scientific proof which would be needed to restore its endorsement. Statistically significant proof of mortality reduction in randomized clinical trials was not available at that time. Such proof has now been obtained. It has been published in respected medical journals such as Cancer and the International Journal of Cancer, and was presented at the NCI meeting. American women should know that a meta-analysis of the most recent followup data from seven population-based randomized trials shows a 25-percent reduction in breast cancer deaths among women in their forties, and that two of the Swedish trials did even better, showing statistically significant reductions of 35 percent and 44 percent for women who began screening in their forties.

Moreover, randomized trials will inherently underestimate the benefit for women who are screened because, by design, the trials compared breast cancer deaths among women who are offered versus who are not offered screening. Yet not all of the women who were offered screening agreed, while some not offered screening obtained it on their own, outside the trials.

There are also other reasons why the benefit from current mammography should be even greater than that found in the trials. These would include improvements in mammography technique and equipment since the 1980's, when the trials began, the use of two mammographic views per breast rather than one, and shorter screening intervals of every year rather than every 2 years as in most of the trials. Annual screening is much more effective than biannual screening, especially for women in their forties. Several studies have shown that annual screening of women between 40 and 49, with current mammography techniques, should be able to reduce breast cancer deaths by at least 40 percent. These studies were available to the panel, yet they were ignored in their report.

Now that the required proof of benefit has been obtained, the NCI should accept, advise and promote such screening rather than look for new, unconvincing reasons not to do so. Requirements for advising screening should not be made into a game of "catch me if you can." Breast cancer is far too serious a disease for that type of chicanery.

The 1993 NCI process was severely criticized in a report of the U.S. House of Representatives Committee on Government Oper-

ations, entitled "Misused Science: The NCI's Elimination of Mammography Guidelines for Women in their Forties," which concluded, and I quote, "that the NCI failed to examine objectively all of the available evidence of mammography screening, and excluded the presentation of favorable information on mammography screening."

Inexplicably, the NCI staffers planning this conference did not learn from the mistakes they made in 1993, and arranged a conference which reads the same, old 1993 conclusion despite the existence of overwhelming new evidence.

Why was screening down-played by the panel? Mortality reduction from screening women in their forties did take longer to appear due to a relatively smaller number of younger women in the trials, as well as their faster breast cancer growth rates. If younger women had been screened every year, their benefit would have appeared about the same time and would have had about the same magnitude as that for older women who had been screened every other year.

The American Cancer Society, accordingly, is considering revising its own guidelines to explicitly advise screening women in their forties every year rather than every 1 to 2 years as it now does. Some of the benefits, it is true, for women who enter the trials in their forties may have been due to cancers detected after they reached age 50. A comparable situation exists in every age group—women who began screening at age 50, 60, or 70. But we do know that at least 75 percent of the benefit for women who entered the trials in their forties was due to cancers that were detected before age 50.

Senator SPECTER. Dr. Feig, would you summarize? Your full statement will be made a part of the record. Please.

PREPARED STATEMENT

Dr. FEIG. Yes; in America today, 20 percent of all breast cancer deaths and 33 percent of all of the years of life expectancy lost to breast cancer are due to breast cancers found in women in their forties. Not to advise screening until age 50 is unjustifiable and unconscionable.

Thank you, Senator.

Senator SPECTER. Thank you, Doctor.

[The statement follows:]

PREPARED STATEMENT OF STEPHEN A. FEIG, M.D.

My name is Stephen Feig and I am a physician practicing at Thomas Jefferson University Hospital in Philadelphia where I am Director of Breast Imaging and Professor of Radiology at Jefferson Medical College. I chair the American College of Radiology Committee on Mammography Screening Guidelines. Today, I am speaking on behalf of Thomas Jefferson University as well as the Philadelphia Chapter of the American Cancer Society.

As a participant in last month's NCI Consensus Development Conference, I heard investigators from here and abroad present data which provided indisputable proof of substantial benefit of screening women ages 40 to 49. American women and their families should be heartened by these results even though they may be understandably disappointed, confused and even outraged because these reports were ignored by the panel.

When in 1993, the NCI dropped its former recommendation to screen women in their forties, it specified the type of scientific proof which would be needed to restore its endorsement. Statistically significant proof of mortality reduction in randomized clinical trials was not available at that time. Such proof has now been obtained, has

been published in respected medical journals such as Cancer and the International Journal of Cancer, and was presented at the NCI meeting. American women should know that a meta-analysis of the most recent follow-up data from seven population-based randomized clinical trials shows a 25-percent reduction in breast cancer deaths and that two of the Swedish Trials did even better showing reductions of 35 percent and 44 percent for women who began screening at age 40 to 49.

Moreover, randomized trials will inherently underestimate benefit for women who are screened because by design the trials compared breast cancer deaths among women offered versus not offered screening, yet, not all women offered screening agreed while some not offered screening obtained it on their own outside the trials.

There are other reasons why benefit from current mammography should be even greater than that found in the trials. These include improvement in mammography technique and equipment since the 1980's when the trials began, use of two mammographic views per breast rather than one, and shorter screening intervals of every year rather than every other year as in most of the trials.

Annual screening is much more effective than biennial screening especially for women in their forties. Several studies have shown that annual screening of women ages 40 to 49 with current mammographic techniques should be able to reduce breast cancer deaths by at least 40 percent. These studies were available to the panel, yet were ignored in their report.

Now that the required proof-of-benefit has been obtained, the NCI should accept, advise, and promote such screening rather than look for new unconvincing reasons not to do so. Requirements for advising screening should not be made into a game of "catch me if you can". Breast cancer is far too serious a disease for that type of chicanery

The 1993 NCI process was severely criticized in a report of the U.S. House of Representatives Committee on Government Operations entitled "Misused Science: The NCI's Elimination of Mammography Guidelines for Women in Their Forties" which concluded that the NCI "failed to examine objectively all of the available evidence of mammography screening" and "excluded the presentation of favorable information on mammography screenings" inexplicably, the NCI staffers planning this conference did not learn from the mistakes they made in 1993 and arranged a conference which reached the same old 1993 conclusion despite the existence of overwhelming new evidence.

Why was screening benefit downplayed by the panel? Mortality reduction from screening women in their forties did take longer to appear due to a relatively smaller number of younger women in the trials as well as their faster breast cancer growth rates. If younger women had been screened every year, their benefit would have appeared about the same time and would have had the same aptitude as that for older women who were screened every other year. The American Cancer Society is considering revising its own guidelines to explicitly advise screening women ages 40 to 49 every year rather than every 1 to 2 years as it now does

Some of the benefits for women who entered the trials in their forties may have been due to cancers detected after they reach fifty. A comparable situation exists for women who begin screening at age fifty, sixty, or seventy. Yet at least 75 percent of the benefit for women who entered the trials in their forties was due to cancers detected before age fifty.

In America today, 20 percent of all breast cancer deaths and 33 percent of all years of life expectancy lost to breast cancer are due to breast cancers found in women in their forties. Not to advise screening until age 50 is unjustified and unconscionable.

Not only did the NCI consensus panel ignore the proven benefit, but also missrepresented possible adverse consequences from screening. False negative mammograms do not just occur below age fifty but are seen in all age groups. Mammography is not a perfect test, but it is the best screening test we have and no better test is available for the foreseeable future.

Only 3 percent of screening mammograms are positive, requiring additional procedures for evaluation, but nearly all of these procedures involve nothing more than additional mammographic views or ultrasound. These may cause some mild anxiety in some women but surely this is preferable to the anxiety of dying from breast cancer.

Only 0.5 percent of women screened in their forties each year need to be biopsied. Cancer is found in 25 percent of these biopsies compared with 33 percent for women in their fifties. Thus, false positive biopsy results are only slightly lower than in older women.

Radiation dose from current mammography is extremely low. Radiation risk is a theoretical possibility. If there is any risk, it is slight compared with the proven benefit of this life saving procedure.

Detection of ductal carcinoma in situ represents a screening success. These are real cancers, but since they are detected at any early stage, cure rates are over 99 percent. It is possible that some of them may not progress to invasive cancer, but there is no present way to predict which ones these will be. To insinuate as the NCI did that ductal carcinoma in situ in general should not be detected and should not be treated is like playing a reckless game of Russian roulette with women's lives.

Thank you for the opportunity to present this statement. I will be glad to respond to any questions you may have.

SUMMARY STATEMENT OF DR. DANIEL SULLIVAN

Senator SPECTER. We now turn to Dr. Daniel Sullivan, associate professor of radiology at the University of Pennsylvania Medical Center and section chief for breast imaging. He is a graduate of the University of Vermont College of Medicine and has also been a professor of radiology at Duke University Medical Center and Yale Medical School. Dr. Sullivan served as a panel member of the NIH Consensus Conference on Mammography, which took place in January.

Dr. Sullivan, welcome; the floor is yours.

Dr. SULLIVAN. Thank you, Senator Specter.

As you stated, I am chief of breast imaging at the Hospital at the University of Pennsylvania. I also served as a member of the NIH consensus panel looking at the issue of mammography for women in their forties. And before I make a couple of other points along the lines of previous panelists, I want to emphasize that the draft statement released on January 23 from the consensus conference was not and is not the final statement of the consensus panel.

Over the last 3 weeks the panel has continued to revise the draft, with the input of leading health policymakers, such as yourself, cancer experts and advocacy groups and others. It is my personal belief that the draft statement of January 23 understates the benefits of annual mammograms for women in their forties and overstates the risks. And it is my hope that the final consensus document will reflect a more balanced viewpoint.

In my prepared statement, I have discussed some of the specific issues, and I will not read that and go through that again at this time, but I will be happy to answer questions.

I endorse many of the comments that Dr. Feig has made. He has addressed some of these same issues, such as the differences of opinion among panel members between evaluating individual trials versus the meta-analysis and the issue of the clinical significance of DCIS. Based on my clinical experience and knowledge of the relevant data, I believe that for the majority of women in their forties, especially in their mid- and late-forties, the benefits of annual mammography outweigh the potential harms.

Although it is true that the benefit on a population basis is smaller than the benefit for elder groups of women, to me, that does not mean that the benefit of screening is not significant. Therefore, I advocate annual mammography for women in their forties.

Dr. Feig referred to the importance of annual mammography in women in their forties, and I have included a discussion of that in my statement, and I endorse that. And we can discuss that, again, further if you wish.

Moving on to some suggestions about where governmental agencies or government policy could help. Clearly, continued support for breast cancer research is needed. I know you have been a strong leader in promoting increased funding for NIH research in general, as well as funding for breast cancer specifically. And one of those large efforts has to do with the transfer of defense technologies to the evaluation of digital mammograms, which I am involved in at the University of Pennsylvania.

Senator SPECTER. You say defense technologies?

Dr. SULLIVAN. Defense technology. The program is sometimes referred to as "from missiles to mammograms."

These investments in research have yielded a decrease in the mortality rate for breast cancer in the last few years, particularly for white women. This has not yet been achieved for African-American women. This increase in survival undoubtedly reflects things from screening mammography as well as improvements in breast cancer treatment. Clearly, we need more information about the basic biology of breast cancer. We need breakthroughs in terms of real prevention of breast cancer, and we need to understand why the improvements in survival are not reaching all segments of our population.

Second, legislative protection for access to mammography for all women is necessary. We know that third-party payers are not consistent with respect to their willingness to reimburse for mammogram screening. Over the past 10 years, many States, including Pennsylvania, have passed laws mandating that third-party payers cover mammography. However, provisions of these laws vary from State to State, and some States do not have such laws. Congress should consider legislation to make this protection uniform across the country.

I have included in my statement a couple of more suggestions, but I will not read that at this time. And I conclude that I believe many people, both men and women, want to have clear, understandable information about choices open to them for health maintenance. Others rely on their trusted health care providers to make recommendations for them. Both are valid approaches and deserve our support.

I support the call for clear, understandable information about the efficacy of mammography so that women can make informed decisions. But it is equally important to provide similar information to physicians and other health care providers who will be advising their patients. Guidelines or recommendations from professional organizations that have studied the issue are entirely appropriate and necessary. Such informed guidelines will assist health care providers who may not have the background or time to evaluate all the available evidence themselves.

PREPARED STATEMENT

In conclusion, for women who ask my advice, I reply that annual mammography is likely to be a significant benefit for women in their mid- to late-forties, and I hope and expect that this opinion will be the recommendation of most if not all organizations that study the issue. I am working to ensure that this viewpoint is ade-

quately reflected in the final statement of the NIH consensus panel.

Thank you.

Senator SPECTER. Thank you very much, Dr. Sullivan.

[The statement follows:]

PREPARED STATEMENT OF DANIEL C. SULLIVAN, M.D.

Chairman Specter, staff members, guests. Thank you for this opportunity to testify before the Senate Subcommittee on Labor, HHS, and Education Appropriations regarding the recently convened NIH consensus development conference on breast cancer screening. In addition to my role as Chief of Breast Imaging at the Hospital of the University of Pennsylvania, I also serve as a member of the NIH consensus panel which is looking at the issue of mammography for women in their forties

Prior to discussing the central points of my testimony, I would like to make some preliminary remarks related to the work of the consensus panel. Let me begin by emphasizing that the draft statement released on January 23rd was not and is not the final statement of the consensus panel. Over the last three weeks, the panel has continued to revise the draft, and the input of leading health policymakers, such as yourself, cancer experts, and advocacy groups, among others, has been useful as we work to craft a final statement on this issue. It is my personal belief that the draft statement of January 23, 1997 understates the benefits of annual mammograms for women in their forties and overstates the risks and it is my hope that the final consensus document will reflect a more balanced viewpoint.

By necessity, much of the panel and public discussion on this issue has centered on matters of clinical and value judgments guided by the available scientific data. Unfortunately, these data do not provide a clear and unambiguous answer on the question at hand. Because no single randomized controlled trial includes large numbers of women in their forties, many physicians, including myself, rely on the results of meta-analyses, a statistical technique for combining data from several small studies to increase the power of the analysis. Results from the meta-analyses of the eight existing randomized controlled trials show a 17 percent mortality reduction for women who began screening in their forties. However, others point out that the results of a meta-analysis are strongest when one combines studies that are similar in design and execution. While there are many points of similarity among the eight randomized controlled trials, there are also differences. Therefore, they look at the results of each trial separately and point out that only three of the eight trials so far show statistical significance for women in their forties. Furthermore, there are differences of opinion about whether the magnitude of a given benefit, either from a meta-analyses or from an individual trial, should be considered "small," "modest," or "significant."

The panel was asked to address specific questions, such as, "What are the benefits of mammography for women age 40 to 49, and What are the risks?" The panel was not asked to make policy recommendations or weigh the benefits versus the risk. Again, however, it would be difficult, if not impossible, to answer such questions without invoking one's value judgments or clinical opinions. For example, our knowledge of the natural course of ductal carcinoma in situ (DCIS) is, unfortunately, incomplete. DCIS is an early form of breast cancer in which the cancer cells are still located in the ducts where they formed and have not spread into the surrounding breast tissue or other parts of the body. Most clinicians, including myself, believe that all cases of invasive breast cancer start as DCIS and, therefore, a goal of mammography screening is to detect and remove DCIS before it becomes invasive breast cancer. However, some believe that many cases of DCIS will not become clinically significant and, therefore, subjecting women to treatment for all DCIS is not advisable. We do not have the necessary scientific data to definitively settle this debate and differing opinions about the natural course of DCIS lead to conflicting positions regarding the risk/benefit analysis of mammography for women in their forties

Despite the difficulties posed by the lack of clear-cut scientific results, based on my clinical experience and knowledge of the relevant data, believe that for the majority of women in their forties, especially in their mid- to late forties. the benefits of annual mammography outweigh the potential harms. Although it is true that the benefit, on a population basis, is smaller than the benefit for older groups of women, to me that does not mean the benefit of screening is not significant. Therefore, I advocate annual mammography for women in their forties.

As you know, the frequency at which we should recommend mammography for women in their forties has been a topic of much debate. The current guidelines of the American Cancer Society and the American College of Radiology, for example,

suggest that women in their forties have mammograms every one or two years. This ambiguity in the guidelines has been a source of confusion to women and many referring physicians. Much evidence has accumulated over the past two decades that younger women have a higher proportion of fast-growing breast cancers than older women. The technical term for this biological attribute of tumor growth is the sojourn time. To adequately detect faster growing tumors at an early stage, we must screen more frequently than would be necessary for early detection of slow growing tumors. There are good data to suggest that results from some of the randomized controlled trials underestimate the benefit of mammography for women under age 50 because the screening interval was every 2 years. The evidence suggests that we should screen younger women every year to achieve maximum benefits. This is not to say that there would be no benefit from screening at 2 year intervals, but that the benefit for populations with a short mean sojourn time, such as women under 50, would be significantly better with annual screening.

There are several areas of governmental policy where your continued leadership, and the help of other government agencies, could be extremely helpful. First, continued support for breast cancer research is clearly needed. I know that you have been a strong leader in promoting increased funding for NIH research in general as well as funding for breast cancer research in particular. Your efforts are greatly appreciated by me and my colleagues at the University of Pennsylvania Medical Center. As a result of these investments, the mortality rate for breast cancer has finally started to decline in recent years among white women, although the same cannot be said for African-American women. This increase in survival undoubtedly reflects gains from screening mammography, as well as improvements in breast cancer treatment. Nevertheless, we need more information about the basic biology of breast cancer; we need breakthroughs in terms of real prevention of breast cancer; and we need to understand why the improvements in survival are not reaching all segments of our population.

Second, legislative protection for access to mammography for all women is necessary. We know that third-party payers are not consistent with respect to their willingness to reimburse for mammography screenings. Over the past 10 years, many states, including Pennsylvania, have passed laws mandating that third party payers cover mammography. The provisions of these laws vary from state to state, and some states have no such law. Congress should consider legislation to make this protection uniform across the country.

One of the disadvantages of mammography is the number of false positive interpretations that lead to additional tests and procedures for what turns out to be benign disease. There are several factors that contribute to the false positive rate, all of which need attention. The quality of the images and their interpretation are important factors. The FDA acting under the Mammography Quality Standards Act of 1992 is key to improving the technical quality of mammographic images and addressing the issue of radiologist variability in mammogram interpretation. However, even with optimal technical and interpretative mammographic quality, the technique still has limitations and some false positives are inevitable. Alternative or adjunctive non-invasive diagnostic techniques resulting from current and future research may help to reduce this problem. Once again you have shown your leadership in this area by supporting a study underway at the University of Pennsylvania Medical Center to explore the use of defense technologies in the early and accurate detection of breast cancer I am pleased to say that I am part of the team involved in this important work.

Yet another contributor to the problem of false negative interpretations is a heightened fear of lawsuits. Delayed diagnosis of breast cancer is one of the most frequent causes of malpractice suites in this country. This causes many radiologists to practice defensive medicine, contributing to the number of false positive interpretations. It is my view that meaningful tort reform might have some impact on reducing the false positive rate.

One final area where the Federal Government could be helpful is facilitating implementation of the National Mammography Database (NMD). A committee of the American College of Radiology proposed the NMD some years ago. The intent was that all radiologists in the country would interpret mammograms with standard terminology and would transfer the results to a central database. The aggregated data would be an enormously important resource for research, and for the quality improvement activities of the FDA. A few problems have hindered widespread implementation of the NMD. One is the question of an appropriate "home" for this resource. It should not be within the FDA or the American College of Radiology. Perhaps there is an entity within the NIH that would be an appropriate base for the NMD. Second is the issue of funding and long-term stability. Perhaps some combination of public and private funding could be developed. Third, is a concern about

the protection of the patient, radiologist, and practice data from disclosure. Clearly, this would need legislative protection at the Federal level.

In conclusion, many people, both men and women, want to have clear, understandable information about choices open to them for health maintenance. Others rely on their trusted health care providers to make recommendations for them. Both are valid approaches. I support the call for clear, understandable information about the efficacy of mammography so that women can make informed decisions. It is equally important to provide similar information to physicians and other health care providers who will be advising their patients. Guidelines or recommendations from professional organizations that have studied the issue are entirely appropriate and necessary. Such informed guidelines will assist health care providers who may not have the background or time to evaluate all the available evidence. For women who ask my advice, I reply that annual mammography is likely to be of significant benefit for women in their mid and late forties. I hope and expect that this opinion will be the recommendation of most, if not all, organizations that study this issue. And I am working to ensure that this viewpoint is adequately reflected in the final statement of the NIH Consensus Panel

Thank you very much for giving me this opportunity to testify. I would be happy to answer any questions you may have.

SUMMARY STATEMENT OF DR. ROBERT C. YOUNG

Senator SPECTER. We now turn to Dr. Robert C. Young, president of the Fox Chase Cancer Center, Philadelphia. Dr. Young came to Fox Chase in 1988 from the National Cancer Institute, where he was associate director of the Community Oncology Program. Before that, he served as chief of the NCI's Medicine Branch for 14 years. He was recently appointed to the National Cancer Policy Board as director at large of the American Cancer Society's national board of directors.

Dr. Young, we thank you for coming, and the floor is yours.

Dr. YOUNG. Thank you, Senator Specter.

Albert Einstein once said, "Things should be made as simple as possible, but no simpler." This is the crux of the problem with mammography for women 40 to 50 years of age. For women above 50, the message is clear and unequivocal: regular mammography reduces breast cancer mortality by 30 percent. Simply put, mammography saves lives. For women in the 40-to 50-year age group, the scientific data are less clear. The results of the studies done to date have been, at best, murky. Several of the smaller studies show little benefit. Others show none at all.

The most positive results derived from a large Swedish study, which demonstrated a 12-percent reduction in mortality for women in this age group who were screened every 2 years. That mortality reduction did not become apparent until 8 years after the randomized trial began. No one wants it to be this murky, but neither should anyone be surprised.

The risk of breast cancer increases steadily with age. For women under 40 without any other risk factors, the risk is quite low, and there is no convincing argument for mammography screening at all. At the other end of the age spectrum, for women over 50, the case for screening is open and shut. It is inevitable, however, when dealing with a rising increase in risk, that at some point there will be a gray area.

For mammography screening that gray zone occurs between the ages of 40 and 50. The factors which contribute to the confusion are the low incidence of breast cancer in women of this age, difficulty

in detecting disease because of the nature of the breast tissue, and differences in the biology of the tumors themselves.

Because of these compounding factors, small or short-term studies yield equivocal and even misleading results. It takes much larger, longer-term trials to demonstrate the smaller effect anticipated in this age group. In that regard, it is noteworthy that the largest and longest trials show the most positive result. We should not, however, allow ourselves to be paralyzed or to become equivocal just because not all of the trials demonstrate that mammography reduces mortality in women age 40 to 50. Nor do I think it is adequate for the medical profession to throw the issue back at women and tell them to make their own decisions.

A number of very well-designed large studies, most notably those done in Sweden, have shown a small but definite improvement in survival. To my mind, that is sufficient justification for not only continuing screening women in this age group, but also for encouraging them to be screened regularly. The reality is that public health guidelines cannot and should not ever be based exclusively on the existence of unequivocal scientific data. Guidelines are just that—guidelines.

Even when reasonable people disagree, as they frequently do in science, the purpose of guidelines is to give people the best advice, not the purest. But prudent guidelines should always balance benefit with risk. In the particular instance of mammography in 40- to 50-year-olds, while the benefit is small, the risks appear to be minuscule. There is little or no evidence that screening inflicts any physical harm on the women who undergo it.

The argument against mammography screening then becomes largely economic—the dollars spent for mammograms and followup examinations to detect a relatively small number of breast cancer cases. From this perspective, most women and the doctors would opt for the small but well-defined benefit. And, as a society, I believe we have already made the choice to invest in mammography as a means of saving the lives of our wives, mothers, sisters and daughters. I believe this investment should also include those women 40 to 50.

There are other investments we need to make as well. We need to continue to improve mammography technology to make it a more sensitive and valuable tool than it already is. But even the best applications of mammography will not solve the breast cancer problem, and it will not save those women whose disease cannot be picked up by mammography. For these women with breast cancer, we need new tools and better understanding of the basic biology of breast cancer so that we can identify those individuals who are truly at risk, and develop better screening, prevention and treatment techniques.

PREPARED STATEMENT

The concerns about the efficacy of mammography screening in women 40 to 50 will not be solved by more of the same studies. Ultimately, the solutions will be found in research that addresses the more fundamental questions and leads to new ways to prevent or eliminate this terrible killer of women.

Thank you for your time and attention.

Senator SPECTER. Thank you very much, Dr. Young.
[The statement follows:]

PREPARED STATEMENT OF ROBERT C. YOUNG, M.D.

Albert Einstein once said, "Things should be made as simple as possible, but no simpler." This is the crux of the problem with mammography for women 40 to 50 years of age. For women above 50, the message is clear and unequivocal. Regular mammography reduces breast cancer mortality by 30 percent. Simply put, mammography saves lives.

For women in the 40 to 50 year age group, the scientific data are less clear. The results of the studies done to date have been at best murky. Several of the smaller studies show little benefit; others show none at all. The most positive results, derived from a large Swedish study, demonstrate a 12-percent reduction in mortality for women in this age group who were screened every 2 years. That mortality reduction did not become apparent until 8 years after the randomized trial began. Prior to that, screened and unscreened women had identical breast cancer death rates.

No one wants it to be this murky, but neither should anyone be surprised. The risk of breast cancer increases steadily with age. For women under age 40, without other risk factors, the risk is quite low and there is no convincing argument for mammography screening at all. For women over 50, the case for screening is open and shut. It is inevitable, however, when dealing with a rising increase in risk, that at some point there will be a gray area, an intersection at which the convergence of various factors make it difficult to arrive at clear cut, unambiguous conclusions. For mammography screening, that gray zone occurs between the ages of 40 and 50. The factors which contribute to the confusion are lower incidence of breast cancer in women of this age, difficulty in detecting the disease because of the nature of the breast tissue, and differences in the biology of the tumors themselves. Because of these compounding factors, small or short-term studies yield equivocal and even misleading results. Much larger, long-term trials are required to demonstrate the smaller effect anticipated in this age group. In that regard, it is noteworthy that the largest and longest trials show the most positive result.

We should not, however, allow ourselves to be paralyzed or to become equivocal because not all of the trials demonstrate that mammography reduces mortality in women age 40 to 50. Nor do I think it is adequate for the medical profession to throw the issue back at women and tell them to make their own decisions. A number of very well designed, large studies, most notably those done in Sweden, have shown a small, but definite improvement in survival. They even suggest that the more aggressive nature of breast cancer in younger women might require annual rather than biannual screening in order to be most effective in extending lives. To my mind that is sufficient justification for not only continuing screening for women in this age group, but also for encouraging them to be screened regularly.

The reality is that public health guidelines cannot and should not ever be based exclusively on the existence of unequivocal scientific data. Guidelines are just that—guidelines. Even when reasonable people disagree, as they frequently do in science, the purpose of guidelines is to give people the best advice, not the purest. Guidelines must be clear and understandable and not weighed down by the conditional statements and conflicting conclusions. But prudent guidelines should always balance benefit with risk. In the particular instance of mammography in 40- to 50-year-olds, while the benefit is small, the risks appear to be minuscule. There is little or no evidence that screening inflicts any physical harm on the women who undergo it. The argument against mammography screening then becomes largely economic—the dollars spent for mammograms and follow-up examinations to detect a relatively small number of breast cancer cases. From this perspective, most women and their doctors would opt for the small, but well defined benefit. And as a society, I believe that we have already made the choice to invest in mammography as a means of saving the lives of our wives, mothers, sisters, and daughters. I believe this investment should include those women 40 to 50.

There are other investments we need to make as well. We need to continue to improve mammography technology to make it a more sensitive and valuable tool than it already is. But even the best applications of mammography will not solve the breast cancer problem, and it will not save the women whose disease cannot be picked up by mammography. For these women with breast cancer, we need new tools and better understanding of the basic biology of breast cancer so that we can identify those individuals who are truly at risk and develop better screening, prevention and treatment techniques. The answers to the questions posed here today about the efficacy of mammography screening in women 40 to 49 are not likely to come from more of the same studies. Ultimately, the solutions will be found in re-

search that addresses the more fundamental questions and leads to new ways to prevent or eliminate this terrible killer of women.

Thank you for your time and attention.

MEDICAL INSTITUTIONS

Senator SPECTER. Our region is really very fortunate to have such phenomenal medical institutions. I recently was with Dr. Young at Fox Chase, January 23, at an outstanding symposium. We had Dr. Klausner there, and the work with his group is really outstanding. The hospital at the University of Pennsylvania, under the direction of Dr. Bill Kelly, there have been marvelous results. I recently had the occasion to benefit from the medical services there.

Just yesterday I was at Allegheny speaking to the group, a wonderful amalgam. It is a little hard to articulate the name of Allegheny Medical College of Pennsylvania. It is my neighborhood hospital. I reminisced yesterday about going there on the initial occasion when my younger son had his stomach pumped many years ago, after swallowing mothballs. Allegheny is my neighborhood hospital wherever I go, because I spend a lot of time in Pittsburgh with my newer responsibilities.

Jefferson is an extraordinary institution. Our two sons were born there. I have benefited from the treatment there. And Temple, under the leadership of Dr. President Hunduly. And we do not have someone here from Einstein, another extraordinary institution, but we are very, very fortunate in having the kind of leadership that we have in medicine here.

That also brings us a great many problems about how we are going to pay for the care of the poor, which these hospitals render, and how we are going to pay for medical education, with so much funding going through managed care today. So there are rewards and there are problems. Again, I thank all of you for coming and for your testimony here.

Let me focus at the outset on a statement which was made by Dr. Falkner, which may be at the core of the issue. That is where Dr. Falkner says that others—referring to doctors—choose to err on the side of caution and recommend annual mammograms for all women in their forties. Does that essentially mean, Dr. Falkner, that it is the cautious thing to do and it may produce results, and ultimately is the best course to have mammograms for women in their forties?

Dr. FALKNER. Well, I think what I was reflecting on was the practice of some physicians who are hearing the mixed messages from the national guidelines and have concerns about the possibility of missing the diagnosis. And so, as a caution, what they will do in their practices is recommend to their patients annual mammograms.

Senator SPECTER. What is the essential problem? What is the downside? The downside is there may be a false positive and there may be a biopsy which should not have occurred? Is there any other downside? May I address that to the panel generally? What other problem may arise in addition to costs, which I am going to come to, which obviously is a factor? But aside from a false positive and then a biopsy which would be unnecessary if you did not have

a false positive, is there any other problem from a mammogram given to a woman in her forties?

Dr. Feig, I see you leaning forward.

Dr. FEIG. Well, actually, the fact is that 75 percent of women with breast cancer have no major risk factors. If we were only to screen women who are at risk for breast cancer, we would miss 75 percent of the cancers. The downside, Senator, are really very minuscule. The panel overplayed these.

Senator SPECTER. Now, wait a minute. Very minuscule. What are they? As minor as they may be, what are they?

Dr. FEIG. Additional procedures. Now, most people would think, from additional procedures, you mean biopsies. That is not the case at all. Most additional procedures mean an extra mammographic view or a breast ultrasound. Only about 3 percent of women coming for mammography each year are in their forties.

Senator SPECTER. Neither of those is invasive?

Dr. FEIG. Neither is invasive.

Senator SPECTER. So what is the harm?

Dr. FEIG. Among women in their forties coming for mammographies, only about one-half of 1 percent will need to be biopsied. So that is very, very slight.

Senator SPECTER. Is there any harm besides the false positive which leads to a biopsy which proves to be unnecessary? But of course you do not know that until you have done it.

Dr. FEIG. That is right. That is the gold standard, which is the biopsy.

Senator SPECTER. I had three biopsies on my nose the other day. I was madder than hell after I got them back. They were all negative. And sometimes I think that I am overly diagnosed, but I would rather be overly diagnosed. There is no such word as "underly", but underdiagnosed. But what I am trying to zero in on is what is the problem. Are there any problems?

Dr. FEIG. No; there is really no objective problem. I think that there is anxiety from getting an additional mammographic view or ultrasound. I do not know of anyone who would not rather have that really minimal anxiety to the anxiety of dying from breast cancer.

Senator SPECTER. Well, we had two hands up. Dr. Young, I will come to you first. But before the comment, I want to ask you a question. You made the comment about no mammograms for economic reasons. And I am personally very much opposed to rationing, very much opposed to decisions made on grounds of dollars, because I know we are a very, very wealthy nation.

I think the question is whether we have enough doctors, hospitals, mammogram machines, and MRI's to do the job. When I had an MRI a few years ago and found out the high cost of it, the thought came to my mind that you could do MRI's at 3 a.m. The marginal cost would be very minimal, and people would be very well served to have MRI's at a time that might be a very low cost. Because in my case, it was a life-saving procedure.

And as many of you know, I had pains on the side of my head and my shirt collar was too tight, and they could not find any symptoms or anything serious. And I wanted an MRI because I had heard of it and I knew it was not invasive. And the doctor told me

I should not, could not and would not have one. And, with enough persistence, I got one. And it proved to be lifesaving—with a meningioma in my forehead—and that gave me a little different slant on things.

One of the items which your profession has difficulty in doing is getting attention from the Congress. Everybody has problems getting attention from the Congress. I think the issue of breast cancer in women has gotten attention from the Congress for some time. But it is only the personal experiences.

If we had taken a closer look at mental health—because Senator Domenici, our leader, has had two children who have mental problems, and we are trying to get that included in insurance rates. On fetal tissue, for a long time, it was in a prohibited range until Senator Thurmond had a daughter with diabetes and understood the advantages and very carefully not to have abortions to produce fetal tissue, but once you had the availability, to utilize it. So when the people in Washington have the problems, then we start to understand the issues a little better.

Dr. Young, before your own comment, I would like to ask you to pursue the question: Do we have enough mammogram machines in America to test all the women who might possibly be benefited from those tests?

Dr. YOUNG. Yes; I think there is no doubt that we do. My point in my conversations and my presentation was that I think that the relative risk of mammography in this age group, as I stated, were I think minuscule, as Dr. Feig mentioned as well. There are several—I mean, first of all, men should not ignore the fact that having your breasts squeezed to get a mammogram is for some women quite uncomfortable. I consider that, on balance, not a big enough risk. It is a theoretical risk.

Senator SPECTER. Tell us about the procedures on that. I do not know the details of it. I would be interested to know the level of discomfort and the comment about squeezing.

Dr. YOUNG. I think it is variable and I think the vast majority of women find it not an extraordinarily unpleasant experience. Some women, for a variety of reasons, including their breast tissue and size and so forth, find it uncomfortable—occasionally very uncomfortable. The number of women that have that problem I think are very small indeed. I think when you are talking about the survival benefit versus a short-term discomfort, they are easily balanced.

One of the things that the consensus conference spent a lot of time on is the theoretical radiation risk of mammography. And of course mammography radiation exposure has declined over the years, so it is getting safer and safer. No one has ever reported a single woman in the United States who ever developed breast cancer from mammography. So while it may be a theoretical risk, it must be extraordinarily small. And those are the other things, in addition to the things that were mentioned before, that are theoretical risks.

On balance, I do not believe that the risks outweigh the potential benefit for the discovery of breast cancer in this age group of women and what I view as a clear-cut small but definite decrease

in mortality associated with mammography screening in this age group.

Senator SPECTER. Thank you very much.

Dr. Caroline, you had a comment?

Dr. CAROLINE. I just wanted to reaffirm the comments before about the psychological effects. Everybody understands the anxiety and psychological stress of having a false positive diagnosis. But, again, as you said, and which was subsequently said, nobody in their right mind would ever trade having a false positive biopsy, even if it came to that, and a very small percentage of people that do, than having missed a real breast cancer and the problems that would ensue from that. And I think that that is something that we are all willing to accept.

We are working—and by having more percutaneous biopsies as opposed to surgical biopsies, this is a less invasive procedure. And then you reduce some of the anxieties, some of the aftereffects. And I think everybody is willing to accept those. I do not understand people who would not be able to. I think I can also address a little bit about the comfort and discomfort of mammography.

It is something which, again, is uncomfortable, but should not be a painful procedure. We need further development, of course, even in the bioengineering of the mammography machines. But people in the American College of Radiology and other groups have been working to try to make it as comfortable as possible, given the fact that in order to get an optimum radiograph you need to compress the breasts in order to get the optimum x-ray picture from it. But this has been developed in such a way that it can be somewhat uncomfortable, but should never be unduly painful. And even on that very small issue, progress is being made.

I just wanted to make one more quick comment about some of the economic issues we were talking about when we were talking about the need to ration medical care, but even the medical care guidelines for women who are over 65 and other medicare patients in Pennsylvania are only allowed to have screening mammograms every other year. Even for the women over 50, it is not covered every year.

Senator SPECTER. On the subject of the false positive, at the risk of being intrusive into the medical profession, I had a personal experience with a false positive many years ago, which was very distressing. And it came to my attention at that time that a little more care could have been exercised by my doctor in not telling me so much at an early stage when the false positive was false but not very positive, and a little farther down the line it turned out not to be positive.

My father used to say to me: "Arlen, know what you say; do not say what you know." And there could be just a little less disclosure until there is a little more of a scientific basis for it. Patients do not need to know all of the possibilities until it is fairly well narrowed. And I understand the difficulties of the psychology of the medical profession and the so-called bedside manner, but I just wanted to make that one brief comment.

I want to go back to medicine now, instead of homespun philosophy.

Dr. Feig emphasized the point about it is better on an annual basis. There have been a number of comments to that effect. There had been a conclusion some time ago that at least the annual for women in their fifties. And I believe that, and you can correct me on this, we have not seen that come about from Medicaid or Medicare. To the extent that Medicare covers women in their fifties, and it does to some extent, but is there a concurrence or a unanimity view on this opinion that women in their fifties ought to have mammograms every year?

Dr. Feig, you have already testified to that. Is that your conclusion?

Dr. FEIG. Yes; annual screening will always be better than screening every other year, because cancers can arise and grow between the screenings. If you have 2 years between screenings, there is a greater chance that a cancer will grow to an incurable size during that time.

Senator SPECTER. Does anyone disagree with that analysis on the table, that we ought to have annual mammograms?

[No response.]

Senator SPECTER. That leads us to a question as to what is the congressional role in this kind of determination. Dr. Sullivan testified that we ought to mandate mammogram payments by third-party carriers for women 40 to 49. And that raises some difficulty as to what intervention there ought to be by Congress on mandates, contrasted with what ought to be the interaction of the market and medical profession and the insurance companies.

We are seeing a great many problems, as we all know, with managed health care now on the so-called gag rule, which HHS took action to change as to Medicare and Medicaid. We had a hearing last November 13 on that subject. And we are seeing some changes by managed care on the so-called drive-by mastectomy. We legislated on drive-by deliveries. There is a real danger, if Congress starts to legislate ailment by ailment. I am working on legislation now which will try to set an overall structure, so that there is a medical decision without it being an insurance company dollars consensus issue. But there is a question as to how far Congress should go in making mandates or in making decisions.

I would be interested in the followup question. I think everybody on the panel thinks there ought to be mammograms for women in their fifties. Do you think we ought to go so far as to have a congressional enactment to that effect if HHS does not administratively make that determination?

Dr. Feig, let us start with you.

Dr. FEIG. Yes; I think that women find themselves in a quandary if they follow medical guidelines and their physicians recommendations in asking for mammograms annually after age 50 and find that Medicare cannot pay for it. Certainly it places physicians in a quandary as well. We certainly do not want to violate any Medicare rules by advising screening.

Senator SPECTER. Why not? Why do you care about violating Medicare rules?

Dr. FEIG. For reimbursement purposes.

Senator SPECTER. What do you mean for reimbursement purposes? How about your patients?

Dr. FEIG. Well, are they allowed to pay us on their own every other year?

Senator SPECTER. Well, now we have three alternatives. So far, Medicare will pay for it and the patient will pay for it, and maybe nobody will pay for it. And I do not wish to emphasize your response, but this is a good point of issue as to the doctor's judgment on a matter aside from who was going to pay. And what we need to get to, I think, is so that the medical judgment dominates and we find a way to work out the payment.

Now, if the doctor has a record of not being professional, or reckless in recommendations—and there are some complaints about doctors to that effect, and some of the insurance companies do complain—but, aside from that, how do we structure our delivery system so that it is a medical judgment which directs it, aside from the issue of who is going to pay?

Doctor Feig, you brought the subject up.

Dr. FEIG. Well, I think that we should perform mammography every year for women in their fifties. But I do not think that physicians should be held in violation of Medicare if we advise screening or to get screening that is not reimbursed by Medicare: And so I think if there could be some mechanism by which women could get mammography and if she pays on her own—it is certainly not fair for the hospital to take up this cost itself. If there were such a mechanism, I think that certainly would be preferable to the situation that we may now have.

Senator SPECTER. Well, I think that is a very good answer. And then it becomes a judgment for Congress.

Recently, when we had the hearings on the panel's findings, Senator Snowe brought a sense of the Senate resolution to the floor, which passed 98 to nothing. And then it so happens, schedule-wise, that our subcommittee hearings were the next day.

There was an op-ed piece in the Washington Post criticizing politicians—that is a derogatory profession—from getting engaged in this subject and meddling with the doctors. But when you come to an issue like whether there ought to be Medicaid payment for two or more mammograms annually, maybe we have to decide it.

I was not sure what the standards were for mammography, as to payments by the Federal Government, but for women over 35 and under 40, a limit of one test during that 6-year period. For women over 39 but under 50 at high risk, one test annually. Not at high risk, one test biannually, every 2 years. For women over 49 but under 65, one test annually. For women over 64, one test biannually. And so it is a fairly complicated schedule. And I think it is one that we need to reconsider.

Let me run a little overtime on what we had allotted for this panel to take up another subject. And that is the subject of gene therapy of, or rather, determination by the genes as to a predisposition for breast cancer and what use could be made of that. There has been considerable comment about the problem of testing for gene predisposition on the ground that a person cannot get insurance if the insurance company knows there is a predisposition for breast cancer. And if someone knows that they have a medical problem and they do not answer it on a questionnaire, the insurance company can later decline payment on the ground of falsifica-

tion, of fraud, and the inducement of the policy. And we are working on legislation which would grant primacy to that area. No reason why a person should be precluded, in a practical sense, from finding out about a predisposition, because that then gives them knowledge which would preclude insurance coverage.

But the question which I would like your comment on is, what do we now know that we can do for a woman if we find out from a determination of the gene that there is a predisposition to cancer?

Dr. Falkner, would you give us your view on that?

Dr. FALKNER. I think that identifying the gene does not offer anything new in terms of the specific treatment. But it does give a very strong—I mean it is the highest risk one can have is to have the gene. In my mind it is useful information. But we do not quite know what use to make of it yet.

Senator SPECTER. Well, then how is it useful? There is no point in having the gene test and letting women know that, which causes obviously a lot of psychological stress, unless we can make some use of it.

Dr. FALKNER. Well, the use at present is identifying someone at a very high risk who then can be followed very vigilantly for early intervention.

Senator SPECTER. Dr. Young, you have had your hand up. You made a comment about we need new tools.

Dr. YOUNG. Well, I think one of the most extraordinary things that is happening in medicine as it relates to cancer is the discovery of genes that both cause and predispose people to various kinds of cancer. We are in a discovery phase of this, and one of the most paralyzing events would be the insurance companies' willingness to exclude such individuals from coverage on the basis of evolving knowledge. There are many things that are going to emerge from the discovery of genes that predispose to breast cancer.

First of all, you can look within families and find women who have an intense family history of breast cancer but do not harbor the gene, and, therefore, that individual and that individual's descendants have a risk that is the same as everybody else in the community. So there are powerful pieces of information that could be generated out of this. We may need vastly different screening technologies for people who are genetically predisposed to risk. And there are a variety of strategies that can be used to reduce breast cancer risks.

Senator SPECTER. Do you think it is useful to know if a woman has a gene which makes her predisposed to breast cancer?

Dr. YOUNG. I think it is in several ways. One, this is certainly a patient who would want to learn carefully how to do breast self-examination. This is an individual who would certainly want at least yearly mammograms, probably beginning at 40 years of age and continuing throughout.

Senator SPECTER. Perhaps earlier?

Dr. YOUNG. Perhaps earlier. We do not have data on that. But it is certainly something that is now studiable, because we have discovered a population that are genetically predisposed to risk.

Senator SPECTER. Dr. Sullivan.

Dr. SULLIVAN. I think the answer to the question might also be we are not really sure yet whether this would be a useful thing for all women. Certainly, for many women, as Dr. Young just said—and this is not an area of my expertise, but, for example, Dr. Barbara Webber at the University of Pennsylvania is an expert in—and she would suggest to those women that they get mammograms every 6 months. There are no studies to indicate that this is more valuable than getting it every year, but that is what her recommendation would be, even starting at a younger age. As you said, in addition, she has a study to look at the value of MRI in those patients. And so there are other techniques that could be used potentially to find cancer earlier in these women.

Another much more extreme option or choice for some women with this family history and this gene would be to consider a prophylactic mastectomy. That is not an acceptable choice for many women, but for a few women it is.

Senator SPECTER. Under what circumstance? That seems very, very harsh and very extreme to me. Under what circumstance would that be chosen?

Dr. SULLIVAN. I do not think we can say from a medical point of view it is warranted, but if a woman comes from a family history of mother, sisters, grandmother, and if that woman herself has a strong fear of breast cancer, that might be her choice. But that would be a very small number of women.

Dr. YOUNG. One of the other strategies that is less aggressive than that might be to put these women on tomixifen, an antiestrogen. There is a study that is underway now that has actually accumulated the number of women necessary to resolve the question. And we just need a few more years to find out whether tomixifen reduces breast cancer development in women at predefined high risk. They are retrospectively going back and looking within the population to identify women who have the RCS–1 and BRCS–2 defects to see whether tomixifen can also reduce their risk.

So there are a number of strategies that become possible once you learn about this kind of genetic information.

Senator SPECTER. Dr. Feig, would you care to make a comment about the value of having this determination as to predisposition through gene detection?

Dr. FEIG. Well, I think all of us would agree that screening is effective at age 50 and over. And most of us would agree it is effective beginning at age 40. If we were to be able to say that a woman with a breast cancer gene had the same risk at age 30 as the average woman does at age 40 or age 50, then, by inference, we should begin screening that woman at the earlier age at which her breast cancer risk is the same as the risk of the average woman at an older age.

Senator SPECTER. Do you care to make a comment on this, Dr. Caroline?

Dr. CAROLINE. I concur with what Dr. Feig said. And I also think that what you said about trying to protect people with nongenetic defects is extremely important. And that may be the single issue right now that is hampering a tremendous amount of forward research that is possible.

Senator SPECTER. Do you think just that factor?

Dr. CAROLINE. Absolutely.

Senator SPECTER. I think we can legislate on that. I think there would be a consensus in the Congress to do that, to guarantee that primacy.

A final question for you, Dr. Sullivan. You said the panel was a draft study. It certainly has caused quite a lot of concern. Part of the concern I have is that it will go beyond women 40 to 49 and discourage mammograms if people do not read the fine print too closely. There is a comment publicly about mammograms not being useful for women 40 to 49, and many will read it more broadly. Why did the panel come out with a draft conclusion before they had a chance to refine it and come to a final judgment?

Dr. SULLIVAN. Well, before answering directly to that question, I should say my answer should not be taken as being critical of the office at NIH that organized the conference, because I think they did it—they were well intentioned in doing it. But the format for the NIH Consensus Development Conference followed the format they used earlier for a variety of other questions, and the format is to have a 2-day conference, ending with a press conference with a draft statement, and then following up with a final statement after that. For most of the earlier questions and earlier conferences, the draft statements adequately reflected the consensus of the panel at that time.

I think, for this question, it was much more complex, with a much larger body of data to analyze. And I think, in retrospect, the format used was not appropriate for this conference or for this question.

Senator SPECTER. Well, I do not raise the issue in a critical context. We have experience and we move on to the next issue. But I think it is like the physician telling an individual patient you have got a false positive. It may be too soon to say that until you do some more tests, which I personalize by my own tests. While it may be a practice to have a draft report, it might be a better idea to take a step backward and say, what is this draft report going to do in a public context and, what is going to happen?

That is what some of us in political life have a little more experience with—what the public reaction will be. When somebody in public life makes a statement that is out of bound, we hear about it in a big hurry, and have some better ways to judge that, in terms of public reaction.

Dr. SULLIVAN. Can I add another comment to that?

I think the panel members themselves were not—having not been through this process before, were not familiar with the process and the ultimate implication. One of the things that is part of the process was for the public relations department from OMAR to prepare a press release for the press conference. And following the public session on Thursday at 11 o'clock, the press offer officer distributed that press release for the panel to review. And the panel refused to review it at that time because they felt they had not reached a consensus and no press release could reflect that.

And after some further discussion, at 5 minutes to 1, 5 minutes before the press conference, the press officer asked the panel again to review the press statement and see if any of it was useful. They

did at that time, and very quickly said, in a moment of consensus, that that press release did not—was not adequate and should not be released, and no part of it was useful, even though that press release did in fact reflect what the draft statement said at that time. And so I think the panel members felt that a public statement should not be made and did not realize the implications in fact that the draft statement would be available to the press and the implications of that.

Senator SPECTER. Well, that is an illustration of do not put anything in writing if you do not expect to see it on the front page. Well, thank you very much, Dr. Young, Dr. Falkner, Dr. Sullivan, Dr. Feig, and Dr. Caroline. We very much appreciate your testimony.

The subcommittee is going to have a similar hearing in Pittsburgh on Monday, and one in Harrisburg a week from then, on the 3d of March, and we will be doing more of this work in Washington, and we appreciate what you are doing. We are determined to try to give you the kind of financial support you need on research in this very important field. We have asked Dr. Klausner and the others, what do you need, what would be useful, as we try to assess the priorities in Washington, to give appropriate funding for these very, very important research projects. So, thank you.

PANEL 2

STATEMENTS OF:

LU ANN CAHN, REPORTER, WCAU–TV, NBC–10

BARBARA DELUCA, EXECUTIVE DIRECTOR, LINDA CREED BREAST CANCER FOUNDATION

BARBARA MALLORY, M.S.N., R.N., NURSE CONSULTANT, PHILADELPHIA DEPARTMENT OF PUBLIC HEALTH

LAWRENCE ROBINSON, M.D., M.P.H., PHILADELPHIA DEPARTMENT OF PUBLIC HEALTH

FRANCES M. VISCO, ESQ., PRESIDENT, NATIONAL BREAST CANCER COALITION

OPENING REMARKS OF SENATOR SPECTER

Senator SPECTER. I might call our next panel, Ms. Lu Ann Cahn, Ms. Frances Visco, Ms. Barbara DeLuca, Ms. Barbara Mallory, and Dr. Lawrence Robinson. We are going to proceed with this distinguished panel, again, in alphabetical order. And we welcome, first, Ms. Lu Ann Cahn, who reports for TV 10. I can never be sure what network that is, Ms. Cahn.

Ms. CAHN. NBC.

Senator SPECTER. That is extra advertising. We are going out live over Pennsylvania cable. We thank you for joining us today. I am just joking, but we were used to channel 10 for so many years, it is a little hard. But channel 10 is 10, NBC, and channel 3 is channel 3, KYW. It does not say CYS, so that adds to the confusion.

Ms. Cahn reports for channel 10 and has coanchored the weekend edition of News 10 Today. Prior to coming to Philadelphia, she was a reporter in Miami, well known to the viewers of Philadelphia for her personal story of battling breast cancer. She was diagnosed at the age of 35, and her 1992 special report, "Breast Cancer: My

Personal Story," won her two Emmy Awards. She has campaigned both in Harrisburg and Washington for additional funding for breast cancer research and mammography testing. And she has been successful.

The floor is yours, Ms. Cahn. And you have more than a sound bite.

SUMMARY STATEMENT OF LU ANN CAHN

Ms. CAHN. Good morning, Senator. Thank you. Thank you for inviting me here.

Of course you know me as a reporter, but this is a subject that I am not objective about at all, and so I am going to take off my journalist hat and speak as a breast cancer survivor.

As you said, 5 years ago, I was told I had breast cancer. I was 35 years old. I had a mammogram, but it did not detect the tumor in my right breast. I found the lump with regular breast self-exams. So I know full well mammograms are not perfect, especially for younger women. Still, I am absolutely appalled the NIH decided not to recommend regular mammograms for women in their forties. It reminds me very much of the way I was diagnosed with breast cancer. I was 34 at the time, when I had my first mammogram, because I felt a lump in my breast. The mammogram again detected nothing.

Several months later, I went to my doctor and she felt the lump and she too said it was nothing. But she also said, if you are worried about it, here is the name of a breast surgeon. Well, I left thinking only a hypochondriac would pursue this any further, and I believe this is the same message the NIH is sending to American women in their forties. It is up to you if you get a mammogram, but we are not worried about it.

I was finally diagnosed with breast cancer by the breast surgeon several months after being told not to worry. This year, almost 6,000 women in their forties will die of breast cancer while NIH is relaying a very confusing message, which will be interpreted by many women in their forties that they do not have to worry. Now, you may say this is a very odd story to use for an analogy, considering it shows again mammograms do not always work for younger women. Often they do not. My breast cancer did show up on a second mammogram as I was being diagnosed. I was then 35.

My point is this: As a reporter and a breast cancer survivor, I have spoken to thousands of women about breast cancer. Many in their forties have told me they believe a mammogram saved their life. If only 2 out of every thousand women screened have their lives extended because of regular mammogram screening, I believe that makes a fairly low-cost procedure well worth it. I am sure you would feel that way if it was your mother, sister, daughter, or wife.

I have spent countless hours over the last 5 years informing women that getting mammograms is not enough. We also have to do breast self-exams. We also have to see our doctors every year for checkups. We also have to fight to make sure we are working on developing something better than a mammogram as an early detection tool. I have absolutely no scientific data or study to back up this belief, but I would bet that those women who get regular mammograms are better informed about breast exams and other things

they need to do to make sure that if they do get breast cancer they find it early.

I believed in the last 5 years that we made great progress in getting women in for mammograms and informing them that you could not rely on this one test. But now, with one outrageous decision, I feel that NIH has undone much of that work, giving women in their forties who want to stick their heads in the sand every reason to continue to do that. It pains me to sit on a panel with women I respect a great deal, who I know are on the opposite side of this issue.

I wish we all could come here with a united consensus. I unfortunately believe that this may confuse the issue even further. But I cannot buy the argument at this point that perhaps an early diagnosis would probably make no difference in the outcome anyway. I believe it does make a difference. It gives that woman more time to fight, to know there is a killer in her body, to make decisions on how to battle her own disease. If she loses that battle, at least she would not die wondering if she had only done this, if she had only done that, if she had only had a mammogram.

Surely, years from now, there will be a group of women who will say, I did not go get a mammogram because I saw headlines saying I did not need to, and now I am dying of breast cancer. I cannot believe that NIH wants to take on that responsibility at a time when there is no better screening tool available to women in their forties. Mammograms are not what we want for the future, but it is really all we have right now. And I believe that NIH, as a whole, made a decision for the public that individually they probably would not recommend for their own family members.

PREPARED STATEMENT

I personally do not care what NIH says. Any woman who asks me, in their forties, what she should do, I would tell them to get a mammogram.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF LU ANN CAHN

Five years ago, I was told I had breast cancer. I was 35 years old. I had a mammogram, but it did not detect the tumor in my right breast. I found the lump with regular breast self-exams.

So, I know full well mammograms are not perfect, especially for younger women. Still, I am absolutely appalled the NIH decided not to recommend regular mammograms for women in their 40's.

It reminds of the way I was diagnosed with breast cancer. I was 35 when I had my first mammogram because I felt a lump in my breast. The mammogram detected nothing. Several months later I went to my doctor and she felt the lump. She, too said it was nothing, but she also said, "* * * if you are worried about it, here is the name of a breast surgeon * * *". I left thinking only a hypochondriac would pursue this any further. I believe this is the message the NIH is sending to American woman in their 40's. "It is up to you if you get a mammogram, but we are not worried about it.".

I was finally diagnosed with breast cancer by a breast surgeon several months after being told not to worry.

This year, almost 6,000 women in their forties will die of breast cancer while the NIH is relaying a confusing message, which will be interpreted by many women in their forties that they do not have to worry.

Now, you may say, this is an odd story to use for an analogy considering it just shows mammograms do not work for younger women.

My breast cancer did show up on a second mammogram as I was being diagnosed. I was 35.

My point is this—as a reporter and a breast cancer survivor I have spoken to thousands of women about breast cancer. Many in their forties have told me they believe a mammogram saved their lives. If only two out of every thousand women screened have their lives extended because of regular mammogram screening, I believe that makes a fairly low-cost procedure well worth it. I am sure you would feel that way if it was your mother, sister, daughter, or wife.

I have spent countless hours over the last five years informing women that getting mammograms is not enough. We also have to do breast self-exams. We also have to see our doctors every year for checkups. We also have to fight to make sure we are working on developing something better than a mammogram as an early detection tool.

I have absolutely no scientific data or study to back up this belief, but I would bet those women who get mammograms are better informed about breast exams and the other things they need to do to make sure that if they get breast cancer, they find it early.

I believed in the last five years we made great progress in getting women in for mammograms and informing them that you could not rely on that one test alone. Now, with one outrageous decision, I feel the NIH has undone much of that work—giving workmen in their forties who want to stick their heads in the sand every reason to continue to do that.

I do not buy some of the arguments from some of those I respect the most who are leading the battle against breast cancer. How can you believe an early diagnosis would probably make no difference in the outcome anyway? It makes a difference. It gives that woman more time to fight, to know there is a killer in her body, to make decisions on how to battle her own disease. If she loses that battle, at least she would not have to die wondering if she had only done this, if she had only done that, if she had only had a mammogram.

Surely, years from now there will be a group of women who will say I did not go get a mammogram because I saw headlines saying that I did not need to and now I am dying of breast cancer.

I cannot believe the NIH wants to take on that responsibility at a time when there its no better screening tool available to women in their 40's.

It is not what we want for the future, but it is all we have now. I believe the NIH, as a whole, made a decision for the public that individually they probably would not recommend for their own family members.

MEDICAL DETERMINATION BY NIH

Senator SPECTER. Thank you very much, Miss Cahn. I know you have to depart shortly and cannot be with us for the dialog, the questions and answers later, so I would like to ask you a question or two now.

When you make the comment, as you said, that as we have been told, if you are 40 to 49 and you want to get a mammogram, it is up to you. While the individual may choose to get a mammogram, the consequence will be, if there is a medical determination by NIH or the Department of Health and Human Services that, as a generalization, women 40 to 49 do not benefit from mammograms, we are going to find the insurance companies not paying for them. And that is going to be a major discouraging factor, as we heard from the last panel. Who is going to pay? What advice do you have to women who hear the insurance company is not going to pay?

Ms. CAHN. I would tell them to find a way to get a mammogram. There are organizations, like Linda Creed right here in Philadelphia, that will help you find a low-cost mammogram. I believe it has become a screening tool, readily available. It is unfortunate that it is not being paid for by insurance companies. I personally think it should be, until we find something better.

I also would like to see a lot of money going toward something better, because this will not do. But, in the meantime, I think

women still have to do it—also understanding it is not the only thing they have to do. But I do not think they can ignore this. And even if their insurance company does not pay for it, I think that if you were my friend, I would say, find a way.

Senator SPECTER. Why did you seek a mammogram at the age of 34?

Ms. CAHN. I actually started feeling a lump. And at the time the recommendation would say get a baseline at 35, and I was 6 or 7 months away from becoming 35. And in fact, my doctor said to go ahead and get one, you are almost 35. And it was really supposed to be a baseline.

Senator SPECTER. So you had already felt a lump?

Ms. CAHN. I had started feeling something, and told the people who were doing the mammogram that I felt something. And they took special—or they took extra x rays of that spot and still told me nothing was there. A lot has happened since that time. A lot more information has come out. I mean I think, at the time, doctors relied more on mammograms and did not understand how imperfect they were for younger women. And again, I think we have done a lot in terms of educating women to do this, but do not just do this; understand it does not mean you can just rely on this and it does not mean that you have done everything you are supposed to do.

Senator SPECTER. In our shower at home, there is a little card hanging there about self-testing, with a diagram. It would be useful, I think, both for the record and for television if you made a brief description—nobody has in this hearing or any hearing I have been at—as to just what is involved in a self-examination. I think it would be useful for women to hear about that.

Ms. CAHN. Right. And this is the way that I found my breast cancer. I found it myself, despite the negative mammogram, and it should be done once a month, about a week after menstruating, because that is when the breast is less lumpy and you can find something that was not usual. I think a lot of women still feel uncomfortable doing this, but it just takes a few minutes and it could save your life. It involves using three fingers—and the American Cancer Society has a great program to teach you how to do it. Your doctor should be able to teach you how to do it. Not only should you be doing it every month, but you should go to your doctor.

Senator SPECTER. Can you talk a little bit more about it now, to teach women how to do it?

Ms. CAHN. I would like to, but basically it involves a circular motion. There are a couple of different methods of doing it, and I am sure someone from the American Cancer Society might be a better teacher. But I can tell you it involves going around the breast with three fingers in a circular motion. At least that is the way I do it. There are other methods of doing it.

But the most important thing—and you go around the whole breast to see if you feel a lump, something that you did not feel the month before. And the reason why it works is that you become very familiar with your breasts. If something is there that was not there before, chances are, if you do a breast exam, you will catch it, and maybe have a better chance than your doctor, who only sees you once a year.

And most women do find their breast cancer that way. So I would highly recommend it. And I know I did not give a great description. The shower is a good place to do it; standing up or laying down on the bed is a good place to do it. And again, it only takes a few minutes. It is not that complicated a thing. It is just something we need to do.

Senator SPECTER. Well, thank you. Thank you very much, Ms. Cahn. We very much appreciate your being here.

SUMMARY STATEMENT OF BARBARA DE LUCA

We turn now to Ms. Barbara DeLuca, who is executive director of the Linda Creed Breast Cancer Foundation and has served in that capacity since 1991. Ms. DeLuca was diagnosed with breast cancer in June 1990, and her experience has motivated her to put her substantial energies into fighting for compassionate health care and abolishing breast cancer.

Welcome, Ms. DeLuca.

Ms. DELUCA. Thank you, Senator Specter. I am pleased to be here today as executive director of the Linda Creed Breast Cancer Foundation. Our organization provides free mammograms for needful women, breast health education, support for those affected by breast cancer, and actively works to secure necessary funding and legislation. I appreciate your holding this special hearing. And thank you for the opportunity to provide testimony today. The opinions and concerns of Pennsylvanians on the frontlines of the current breast cancer debates need to be heard.

The question concerning us today: Should women in their forties be given screening mammograms every year or every other year? The answer arrived at by the NIH Consensus Conference is every other year is enough. The reason: There is no clear indication that yearly mammograms save lives in this age group. An unspoken reason is that mammograms cost dollars.

I believe that women must be afforded each and every screening tool that can rule out or discover breast cancer as early as possible. After 25 or 30 years, mammography is still the standard and most widely used screening tool, but it is not perfect. There is a 10- to 15-percent false negative or false positive failure rate.

A quick survey of six members of our foundation, women who were diagnosed with breast cancer in their forties, yielded very interesting results. Five of these six women said they had just had a mammogram a week or two before their cancer was discovered by a palpation or a biopsy. But nothing had shown up on the film. Yet, despite her own experience, each person felt strongly and reiterated this very loudly, that women in their forties need a screening mammogram every year.

Seven years ago, a mammogram failed to diagnose breast cancer in my dense tissue. Since that time, new modes of detection have been undergoing testing in clinical trials. The MRI is a three-dimensional image that provides great detail, but is still far too expensive to be used as a screening tool. It has the added benefit of not using radiation. Digital mammography produces a sharper picture with better resolution, using one-third less radiation. And technology developed for star wars and detection devices used in

Desert Storm to check troop movements are now being tested for adaptation to medical imaging.

The argument is not whether to recommend mammograms every year or every other year. That answer is easy. Yes; we need to use any tool available to us. The issue needs to be resolved and put to rest. As an activist and educator, I strive to get women to take control of their health and be consistent with their examinations and tests. I trust them to question, to comprehend medical advice, and to make wise decisions for themselves.

PREPARED STATEMENT

Information that is equivocal only complicates the ability of women to make informed decisions. But the larger truth is that we must find ways to make the MRI more useful, more available, and less expensive. We must find a blood test. Such a test could indicate 6 years in advance if a man is likely to get prostate cancer. We must find ways to turn off cancer cells, arrest the disease development, so that early detection really does mean cure. And, most importantly, we must truly learn how to prevent breast cancer so we no longer have to live in fear of it.

Senator SPECTER. Thank you very much, Ms. DeLuca. I want to come back, when we have the dialog and questions and answers, and ask you as to your thinking of the MRI. It really is more expensive.

[The statement follows:]

PREPARED STATEMENT OF BARBARA DELUCA

I am Barbara DeLuca, Executive Director of the Linda Creed Breast Cancer Foundation. Thank you for the opportunity to provide testimony today. I appreciate Senator Specter's holding this special hearing. The opinions and concerns of Pennsylvanians on the front lines of the current breast cancer debates need to be heard.

The question concerning us today: Should women in their forties be given screening mammograms every year or every other year?

The answer arrived at by the NIH Consensus Conference is "Every other year." The reason: There is no clear indication that yearly mammograms save lives in this age group. An unspoken reason is that mammograms cost dollars.

I believe that women must be afforded each and every screening tool that can rule out or discover breast cancer as early as possible. After twenty-five or thirty years, mammography is still the standard and most widely used screening tool, but it is not perfect. There is a 10 to 15 percent false negative or false positive failure rate.

A quick survey of six members of our foundation, women who were diagnosed with breast cancer in their forties, yielded interesting results. Five of these six women said they had just had a mammogram a week or two before their cancer was discovered by palpation or biopsy, but nothing had shown up on the film. Yet, despite her own experience, each person felt strongly that women in their forties need a screening mammogram every year.

Seven years ago a mammogram failed to diagnose breast cancer in my dense tissue. Since that time new modes of detection have been undergoing testing in clinical trials.

The MRI is a three-dimensional image that provides great detail but is still far too expensive to be used as a screening tool. It has-the added benefit of not using radiation.

Digital mammography produces a sharper picture with better resolution, using one-third less radiation.

Technology developed for Star Wars and detection devices used in Desert Storm to check troop movements are now being tested for adaptation to medical imaging.

The argument is not whether to recommend mammograms every year or every other year. That answer is easy. "Yes. We need to use any tool available to us."

This issue needs to be resolved and put to rest. As an activist and educator, I strive to get women to take control of their health and be consistent with their ex-

aminations and tests. I trust them to question, to comprehend medical advice and to snake wise decisions for themselves. Information that is equivocal only complicates the ability of women to make informed decisions.

But the larger truth is that we must find ways to make the MRI more useful, more available and less expensive. We must find a blood test. Such a test can indicate six years in advance if a man is liable to get prostate cancer. We must find ways to "turn off" cancer cells, arrest the disease development so that early detection can really mean "cure." And most importantly, we must truly learn how to prevent breast cancer so we no longer have to live in fear of it.

SUMMARY STATEMENT OF BARBARA MALLORY

Senator SPECTER. I would like to turn now to Ms. Barbara Mallory, Community Health and Public Nurse Consultant with the Philadelphia Department of Public Health and staff nurse at Memorial Hospital in Bergen County, NJ. Ms. Mallory serves on the executive board of the Nurses of Pennsylvania, headquartered in Philadelphia, and also is a member of the board of directors of healthy cities, and affiliated with the World Health Organization. She received her master's and bachelor's degree in science and nursing at Thomas Jefferson University.

Welcome, Ms. Mallory, the floor is yours.

Ms. MALLORY. Thank you, Senator Specter, my distinguished colleagues. Good morning. I am Barbara Mallory, here today representing nurses of Pennsylvania, an advocacy group for nurses and patients. I thank you for this opportunity to add comment to the NIH consensus statement, which suggests that screening mammography does not benefit women in the 40 to 49 age group.

I should warn you, I do not intend to focus on statistics and numbers, particularly not numbers provided by dollar signs. Every cancer professional I have spoken to suspects, as I do, that too much consideration has already been given to financial rather than human costs.

Recently, my organization has participated in the drafting of legislation that would end drive-by mastectomies. One of my roles was to speak with women who have had breast surgeries. Through my conversations, I met many women, as young as 33 years old, who have had breast cancer diagnosed as a result of breast self-exams or by routine mammographies. These women and their families have certainly benefited from screening.

One woman, and we will call her Joan, is a 24-year-old mother of three children. Although she practiced breast self-exams faithfully every month, neither she nor her physician were able to detect the small lesion which was identified by mammography. After further tests, the tumor was removed with a lumpectomy. The lesion was cancer, but it was identified early, and thankfully, so far, it has not recurred. Had it not been for her routine screening, the lesion probably would have gone undetected until it reached the palpable stage—a more dangerous stage.

Hers is not the only story which points to the need for regular screening. There are countless other women with names and faces which may not be considered statistically significant; however, the significance of these women's lives cannot be discounted.

Also, the debates stem from the attention given to ductal carcinoma in situ, otherwise known as DCIS. Since the mid-1980's, there has been a 200-percent increase in the number of DCIS le-

sions detected by mammography. Approximately one-half of these lesions are found in women under the age of 50. Up to 25 percent of these lesions will lead to invasive cancers. Researchers argue that the 25-percent risk of progression to invasive cancer does not warrant aggressive surgical intervention and does not warrant routine screening. Now, I said I was not going to focus on statistics, but I feel compelled to inform you that I would not want to be one of the women with a 25-percent chance of having a form of cancer which would prematurely end my life.

I suppose this is another case of, is the glass half full or half empty? Except the consequences here are far more deadly.

I think most women would agree that a 1-in-4 chance of developing metastatic cancer represents a significant risk. Without mammography, women with these lesions will be missing an important opportunity for the early identification of this potentially life-threatening disease. True, the technology is not perfected, but it is the best we have to offer. How can we contemplate limiting this opportunity?

As this debate continues, we are opening the door for a great deal of miscommunication and subsequent back-stepping. We should anticipate that insurance companies will feel comfortable in stripping women of the option to obtain screening mammograms.

We have seen a growing ominous trend in health care to balance financial cost by rationing the quality and quantity of health care services offered. Yes; health care is expensive in dollars, but inadequate health care is infinitely more expensive. As advocates for our patients, health care providers are challenged to control cost not by rationing services and technology, but by functioning efficiently. We as health care professionals cannot continue to allow for these types of ambiguous messages to be passed on to the public.

It is a good thing that mammography is able to detect small, unpalpable lesions. The technology has been helpful. The fact that most lesions are treated aggressively represents the choice of women and their physicians. And this is a choice they must be permitted to make.

There are two salient points that I would like to stress. While women are dying, we are disputing whether to recommend and encourage the use of the best efforts we have to offer. Breast cancer remains the leading cancer cause of death among women 15 to 54 years of age. Admittedly, our best efforts have not gone far enough. Mammography techniques remain unable to reliably provide clear pictures on younger, denser breast tissue. Perhaps the use of missile technology will solve this deficiency in the near future.

Second, since the health care industry will continue to transform itself into a system which exploits opportunities to increase the bottom line, we need to examine the full implication of our messages. Will that message improve upon what we have done, or will it merely give women cause to think that they are not at risk after all? Can we afford that message?

PREPARED STATEMENT

In closing, I would like to extend my gratitude as well as the appreciation of women who are impressed and moved by your com-

mitment to remember the human implications of this controversy. As you know, there are many other dimensions to health care that require investigation, and I feel reassured to know that you have an appreciation of women's health issues.

Thank you, Senator Specter, and I welcome any questions you have.

Senator SPECTER. Thank you very much, Ms. Mallory. We will have questions.

[The statement follows:]

PREPARED STATEMENT OF BARBARA MALLORY, MSN, RN

Mr. Chairman, members of the committee, distinguished panelists and colleagues, good morning. I am Barbara Mallory, here today representing Nurses of Pennsylvania, an advocacy group for nurses and patients. I thank you for this opportunity to add comment to the NIH consensus statement which suggests that screening mammography does not benefit women in the 40–49 age group. I should warn you, I do not intend to focus upon statistics and numbers, particularly not numbers preceded by dollar signs. Every cancer professional I have spoken to suspects, as I do, that too much consideration has already been given to financial rather than human costs.

Recently, my organization has participated in the drafting of legislation that would end drive-by mastectomies. One of my roles was to speak with women who have had breast surgeries. Through my conversations, I met many women, as young as thirty-three, who have had breast cancer diagnosed as a result of self breast exams or by routine mammographies. These women and their families certainly have benefited from screening.

One woman, we'll call her Joan, is a 42 year old mother of three children. Although she practiced self breast exams faithfully every month, she nor her physician were able to detect the small lesion which was identified with mammography. After further tests, the tumor was removed by a lumpectomy. The lesion was cancer, but it was identified early and, thankfully, so far it has not recurred. Had it not been for her routine screening, the lesion probably would have gone undetected until it reached a palpable stage—a more dangerous stage. Hers is not the only story which points to the need for regular screening. There are countless other women with names and faces which may not be considered statistically significant; however, the significance of these women's lives cannot be discounted.

Also, this debate stems from the attention given to Ductal Carcinoma In Situ (DCIS). Since the mid-1980's there has been a 200 percent increase in the number of DCIS lesions detected by mammography. Approximately one half of these lesions are found in women under the age of fifty. Up to 25 percent of these lesions will lead to invasive cancers. Researchers argue that the 25 percent risk of progression to invasive cancer does not warrant aggressive surgical intervention and does not warrant routine screening. Now, I said I would not focus on statistics, but I feel compelled to inform you that I would not want to be one of the women with the 25 percent chance of having a form of cancer which may prematurely end my life.

I suppose this is another case of "is the glass half full or half empty?"—except the consequences here are far more deadly. I think most women would agree that a one in four chance of developing metastatic cancer represents a significant risk. Without mammography, women with these lesions will be missing an important opportunity for the early identification of this potentially life threatening disease. True, the technology is not perfected, but it is the best we have to offer. How can we contemplate limiting this opportunity?

As this debate continues we are opening the door for a great deal of mis-communication and subsequent backstepping. We should anticipate that insurance companies will feel comfortable in stripping women of the option to obtain screening mammograms. We have seen a growing, ominous trend in health care to balance financial costs by rationing the quantity and quality of health care services. Yes, health care is expensive in dollars; but inadequate health care is infinitely more expensive. As advocates for our patients, health care providers are challenged to control costs not by rationing services and technology but by functioning efficiently.

We, as health care professionals, cannot continue to allow for these types of ambiguous messages to be passed on to the public. It is a good thing that mammography is able to detect small unpalpable lesions, the technology has been helpful. The fact that most lesions are treated aggressively represents the choice of women and their physicians. This is a choice they must be permitted to make.

There are two salient points I would like to stress:

While women are dying, we are disputing whether to recommend and encourage the use of the best efforts we have to offer. Breast cancer remains the leading cancer-cause of death among women 15–54 years of age. Admittedly, our best efforts have not gone far enough. Mammography techniques remain unable to reliably provide clear pictures on younger, denser breast tissue. Perhaps the use of missile technology will solve this deficiency in the near future.

Second, since the health care industry will continue to transform itself into a system which exploits opportunities to increase the bottom line, we need to examine the full implications of our messages. Will that message improve upon what we have done? Or will it merely give women cause to think that they are not at risk after all. Can we afford that message?

In closing, I would like to extend my gratitude as well as the appreciation of women who are impressed and moved by your commitment to remember the human implications of this controversy. As you know, there are many other dimensions to health care that require investigation, I feel reassured to know that this committee has appreciation of women's health issues. Thank you Senator Specter for your continued dedication to the promotion and protection of women's health. Thank you for this opportunity to address this committee, I welcome any questions you may have.

SUMMARY STATEMENT OF DR. LAWRENCE ROBINSON

Senator SPECTER. We now turn to Dr. Lawrence Robinson, deputy health commissioner for the Philadelphia Department of Public Health. He is responsible for the coordination of programs for comprehensive medical and health education services. He is a graduate of Harvard and the University of Pennsylvania School of Medicine. Both Harvard and the University of Pennsylvania School of Medicine; how did you work that out? [Laughter.]

Dr. ROBINSON. Thank you, Senator Specter, for the opportunity to speak today.

It is interesting, in addition to that, some of the other things that I do as the deputy health commissioner for the city of Philadelphia, I also work for the American Cancer Society as a volunteer. I am a board member of the State Cancer Society, and also I am the chairman of the national black leadership initiative on cancer, which is a program funded out of the National Cancer Institute. I am here today to support mammography screening for women between the ages of 40 and 49. I think that this is particularly important for minority women.

I know, Senator, that you are a supporter of minority health, and this is of particular interest, particularly in terms of the city of Philadelphia. We are one of the largest providers of ambulatory health care. We have over 125,000 patients in our ambulatory health centers. And of course the majority of the people served in that situation are minorities and from lower socioeconomic conditions.

Not only does early screening initiate the start of healthy behaviors, which I heard discussed at the other end, but it also identifies cancers. I think one of the things that we need additional research in is the fact that cancer seems to be a different disease in minority populations, particularly among African-American women. We find that the death rate or risk of death from cancer, breast cancer, is much greater in that population. And also the cancer seems to be more aggressive in that population.

We need, of course, to know a lot more about it. Because, in terms of our clinical trials, the majority of the trials that you have heard expressed today have been done on the majority population,

mostly on white women. So when you look at the clinical trials, trying to separate out the issues, it is difficult, because the participants in the trials do not have the right percentage of minority representation.

I would like to also tell you something else, too, which I think really explains the situation from a case study that we did. Every year we have a major health fair here in Philadelphia, and it is called Operation Health. We do it in conjunction with the National Guard. And we literally set up a MASH unit in the middle of the park, and we open that to screenings, all different types of screenings, immunizations. And we had a mobile mammography unit there. The interesting thing about this particular setup is that it was open to people just to walk off the street and get a mammography. All they had to do was sign up. We really did not even require preregistration for things like that.

This project was supported by the National Guard, Fox Chase Cancer Center, which provided us with the mobile mammography unit, and of course the health department. The event drew over 5,000 participants. As I said, it targeted lower socioeconomic residents of Philadelphia. We did 43 mammographies during this particular screening session. And I think it is very interesting to note that many of the women who took advantage of this were under 50.

During the screening program, we identified six abnormal results that were confirmed by the mammography technologists. Of course, this is a very high percentage, and it is much higher than we would have expected if we had done screening in the general populations. I think that this particularly points out the need to do screening in targeted populations, particularly populations that have a lower socioeconomic condition, and of course have a much higher prevalence of these diseases.

PREPARED STATEMENT

I have the breakdown of the ages for those six. It was 52, 46, 48, 78, 46, and 46. So there were two of the individuals who were found positive who were under 50 in this case. And I think that, just as a case study, I think that really points out the need for us to continue to offer screening for women under 50, particularly in populations that are minority.

Senator SPECTER. Thank you very much, Dr. Robinson. I have looked at the summary of your curriculum vitae, which said a graduate of Harvard and the University of Pennsylvania School of Medicine. And Bettilou Taylor gave me the details of your impressive record. You received your bachelor's at Harvard College and your M.D., from the University of Pennsylvania, and also a master of public health from Johns Hopkins. Very, very distinguished institutions.

[The statement follows:]

PREPARED STATEMENT OF LAWRENCE ROBINSON, M.D.

My name is Dr. Lawrence Robinson, MD, MPH. I am currently Deputy Health Commissioner for the City of Philadelphia, Health Promotion and Chronic Disease Prevention are my areas of specialties. I concentrate on the area of Cancer Prevention and work as a Board member of the American Cancer Society and the Chairman of the National Black Leadership Initiative on Cancer. I support mammog-

raphy screening for woman between the ages of 40 to 49. I think this is particularly important for minority women, black, Hispanic, etc. Not only does early screening initiate the early start of healthy behaviors but it identifies cancers.

I will relate to you a case study which I believe supports this assertion. The Philadelphia Health Department, The Pennsylvania National Guard and the Fox Chase Cancer Center participated in an annual health event entitled Operation Health. This event drew over 5,000 participants targeting lower socioeconomic residents of Philadelphia. A mobile mammography unit sponsored by Fox Chase Cancer Center performed 43 mammograms. Many of the women who received these mammograms were under 50. During this screening 6 abnormal results were confirmed by mammography technologist. The percentage of abnormal results (15 percent) is much higher than expected.

This points out the need to do screening particularly when it involves outreach to underserved areas. Also it is possible to find cancer in women who are under 50.

SUMMARY STATEMENT OF FRANCES M. VISCO

Senator SPECTER. We now turn to our leader in the field of breast cancer, Ms. Frances M. Visco. Ms. Visco is both a lawyer and a health activist. She is the first president of the National Breast Cancer Coalition, and a member of its board of directors. She also serves on the board of the Linda Creed Breast Cancer Foundation, and was appointed the president and one of the three members of the President's Cancer Panel. She also sits on the Department of Defense Breast Cancer Research Program, which reviews the Department of the Army Research Program. And she cochairs the national action plan on breast cancer.

Ms. Visco graced us with her presence when we had the hearing in Washington recently, and we thank you again for coming today and for your leadership in this field. The floor is now yours.

Ms. VISCO. Thank you, Senator. I would like to start by focusing on the question that you asked in Washington, and some of you alluded to in your remarks, and that is the dollars that are needed for breast cancer research. As we are all aware in this room, we do not know how to prevent breast cancer. We do not know how to cure it in every woman. And we do not know how best to detect it. We need more research dollars to find those answers.

And as you know, the national breast cancer coalition, this year, is asking for $590 million in the National Institutes of Health and $150 million in the Department of Defense Breast Cancer Research Program, to continue high-quality, investigative research. I know that you are concerned on how the money is being spent that we have.

And as I have told you in the past, the coalition last year held a think tank meeting at the Aspen Institute, where we began to look at that very issue and began to look at the design of research decisionmaking in this country. This June, we will again bring together a diverse group of experts to look at a plan, over the next 5 years, on how much money we actually need for breast cancer in this country and how this money should be spent.

We are looking forward to your input in the process, and I will bring you all the information we have to date. I hope you will participate with us throughout this process. I also want to move to the issue that you raise about mandating medical coverage.

I agree that mandating coverage by body part is not the best public policy and that it is actually not very good public policy. However, women in this country are left with nothing else. The

problem is that we failed to overhaul the health care system in this country when we had the opportunity a few years ago. And as I have said many times in the past, while we can argue over whether mammography for women in their forties will save lives, there is no argument that if every woman and her family has access to health care in this country, that, without question, will save many lives.

This is a wealthy nation, and yet we have 50 million individuals who are uninsured. And of the millions who have insurance, most of them are underinsured. We need to focus on that problem. We need to not only get mammograms for women, we need to make certain they have the followup treatment.

As you know, the CDC, the Center for Disease Control, has the Breast and Cervical Cancer Prevention Act, which is a misnomer, because neither of those things prevent. Neither mammography nor a Pap smear prevent the disease, but they have hundreds of millions of dollars, and enter into sharing agreements with States, Pennsylvania being one of them, to provide screening mammography and Pap smears for underserved women.

The problem is that these women often fall through the cracks, because there is no treatment for them. What we want them to do—and we will be coming to you and to other Members of Congress with a plan—to enact legislation so that there is a treatment component with the CDC screening program. I just want to briefly talk about the mammography issue, because, as you know, I was diagnosed with breast cancer at age 39 by a screening mammogram.

I had a lumpectomy. I had radiation and chemotherapy. And yet, I do not believe that the data show that we should do population screening of women age 39 to 49. What I want to talk about, though, is the issue that women in their fifties, for whom we all agree there is a reduction of mortality, the majority of those women are not getting mammograms. And we need to devote resources and attention to those women, and make certain that they get the message that mammograms do save lives—followed by treatment, of course. We need to get more and more women in for mammograms in that age group.

PREPARED STATEMENT

For women in their forties, I believe strongly that women are entitled to know the risks and benefits, entitled to know the data, and that they should make a decision, in conjunction with their medical provider. I do not think physicians should make the decision. I do not think we have enough data on which to make public health pronouncements or population screening generally. I think women are entitled to the data, and then they need to make up their own mind about their health care.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF FRANCES M. VISCO

I would like to thank Senator Specter and the members of this committee for holding these public hearings and furthering the public's education about the faces behind mammography screening for women under 50. My name is Fran Visco, I am

a breast cancer survivor, an attorney and the President of the National Breast Cancer Coalition, a grassroots advocacy organization of more than 350 organizational and 50,000 individual members. We have a network of activists in each state who are trained on the issues and equipped as effective advocates to achieve our goal of eradicating breast cancer through action and advocacy. But now I would like to speak personally.

I was diagnosed with breast cancer in September 1987, when I was 39 years old. My breast cancer was diagnosed through screening mammography. I had lumpectomy, radiation and chemotherapy. But I am here personally to speak in support of the findings of the consensus panel.

I have been following the coverage of the consensus panel in the papers and on television since shortly before the panel convened. I am amazed at the attention given to this question and frankly appalled at the resources we continue to devote to this question and at the outrage that met the panel's conclusions. In the past month I have lost two very close fiends and great activists to breast cancer. They were both younger than fifty when they died. A mammogram did not save their lives. Where is the outrage over that fact?

We are acting as though this issue—whether to recommend population screening of women 40 to 49, is the most important question in breast cancer. Let's save our outrage for the fact that we don't know how to prevent this disease, how to cure it, how to detect it truly early, or what to do for an individual woman once we do find it. Let's save our outrage, our resources, our energy, our time, for the 44,000 women who die each year. For the tens of thousands of women who have no access to health care.

What happened here? The Consensus Panel brought together a well regarded and diverse group of experts; scientists, doctors and consumers to consider the data in a thorough and open forum. They reached their conclusions without bias or interference. Specifically, the consensus panel looked at the data—from trials not designed to answer the question we're asking and that don't ask any question about minority women—and saw that a meta-analysis of the trials shows a 16 percent decrease in mortality for women under fifty, but the decrease does not begin to show up for ten years, raising the question among others, of whether the women, who are by now in their fifties, are actually benefiting from mammography at that age. Nothing new really. But we keep asking the question. I don't think we're really looking for the answer anymore. I think we're chasing after statistical significance—and we're going to get it no matter what, if we have to play with confidence intervals, wait a long enough time, throw out the trials that don't fit our preconceived notions, get lost in the details. But the big picture doesn't change. We all admit the numbers are not overwhelming. Whatever benefit may exist is small.

Some seem to argue that should not matter, that public policy should be driven by the fear that we will "confuse women." Well, I have more faith in women's ability to understand the truth. What is our goal here? Is it to avoid confusing women or to save women's lives? A simple message is less confusing—but in this situation the simple message is wrong. We all want it simple—we want mammography to work in all women. It doesn't. We want breast cancer to be reduced to a sound bite. It can't be. We can't continue to sell women false hope, simply because we don't want them to be confused.

What should we do? Rather than worrying about confusing women, let's devote our resources to designing mechanisms to empower women to understand the message—if you are under fifty there are certain things you should know about mammograms. Get the information and discuss it with your health professional.

Let's focus our resources and energy on getting women over 50 to get mammograms—the majority do not. Let's make certain these women have access to quality mammography and to follow up treatment if needed.

Let's fund the research that will find the cure, prevention, truly early detection. And if we really want to save women's lives, let's focus our outrage, our energy, our commitment on guaranteeing access to quality health care for all women and their families. There is no dispute that that public policy will save many lives.

Senator Spector, you have been a leader in Congress on issues breast cancer. The NBCC has often asked you to support policy that is not popular, but that is right. I hope you'll do so now. Let's not continue to give women false hope; let's face the truth—the data to support population screening in this age group are simply not there. Let's give women the tools they need to understand and then let them decide the course of their own care.

TREATMENT COMPONENT

Senator SPECTER. Thank you very much, Ms. Visco. I am very much interested in your approach as to the treatment component, which you talk about. And I will be working with you. I am very much interested in the activities of the various groups which you are working with. You cover a great many lives, and there is a lot of input there.

To the extent that you would care to now particularize how you arrived at your figures, I would be interested to know. We are going to be in the budgeting process soon. We do not make all the decisions for NIH. We do not manage them to that extent. I am committed, as you know, to a very major increase for NIH this year again. I know that Congressman Porter, who is chairman on the other side, and Senator Harkin is. And how far we are going to go, we are going to have to see.

I am going to be taking this to the floor of the Senate in the budget process. And I am going to be asking the Senators for a ringing endorsement of the 7.5-percent increase for NIH. Because we will need that allocation for our subcommittee in order to have the money, and because we also have a heavy responsibility on education and drug care in our subcommittee. But I would be interested to know, analytically, how you arrived at the figure of $590 million for NIH and $150 million for the Department of Defense.

Ms. VISCO. I can start with the Department of Defense. I sit on the integration panel, so I have seen the proposals that come to our panel, which makes programmatic decisions. I have seen the proposals that have fared very well in the peer review process, and yet we do not have the funds to cover them.

We simply do not have enough dollars to cover all of the proposals that should be funded. So we base that figure on a percentage of those fundable proposals in areas of importance to research. And if we had that much money for this coming year, we believe we would be able to fund a more appropriate percentage of the fundable proposals.

As you know, the DOD Breast Cancer Research Program is looking at areas where NIH does not have funding to look at. For example, we fund a great deal of idea grants. A large percentage of our money goes to idea grants. And those are scientists who have ideas that are scientifically valid ideas, but they may lack preliminary data. It is the idea they need to test in order to form the basis of the larger traditional proposal that they will submit to NCI later on.

Senator SPECTER. How about the $590 million for NIH?

Ms. VISCO. The $590 million for NIH is based upon the comparable analysis, looking at what we see that has come to NIH in the fundable range in particular areas and has not been funded.

Senator SPECTER. Ms. DeLuca, you commented about the MRI's. I would be interested in your thinking as to whether the MRI is a better test, or might be. They are fancy machines, but they are not used much of the time. They could be made available if we had some systematized way. That is a subject I took up with Mr. Clinton, as a matter of fact, after I had my experience, to make those

MRI's usable around the clock. If they could save a life, people would be willing to go there at 3 a.m.

Ms. DELUCA. I think that is so. I have spoken to physicians who have given me indications that the quality of the pictures that are received from an MRI is so much superior and so much clearer, and things that would be very impossible to detect on a mammogram become clear on an MRI. That is from the medical side. I do not pretend to be able to make that judgment.

But I also understand that an MRI test can be at least 10 times more than the cost of a mammogram, and I understand that is prohibitive. It is probably not reasonable to make that a screening tool, unless we can find some criteria to make it reasonable for certain people under certain circumstances.

Senator SPECTER. What we really need to find out is how many MRI's are unused and at what times, and to see what the availability is. And we may find that the criterion does not have to be too high. If they are available and if the marginal cost of operating them are minimal, it is not convenient to do it in the middle of the night. But I would urge people to line up around the blocks to have an MRI in the middle of the night if they could get one.

Ms. DELUCA. I think women would do that. I have no doubt that they would if they think they could get the answers.

Senator SPECTER. I think we need to get that determination. I am going to ask the Secretary of Health and Human Services to conduct that survey.

Ms. Mallory, do you think we ought to legislate on drive-by mastectomies? I think we may well do that. We did that on drive-by deliveries. How far should we go down this road of drive-by congressional decisions? Do you have a lot of confidence in the Congress?

Ms. MALLORY. I actually have much more confidence in the Congress than I do the health care industry.

Senator SPECTER. That may be thanking us by damning praise. [Laughter.]

Ms. MALLORY. I am pleased to hear that you will be expecting to have some legislation passed to end the drive-by mastectomies.

Senator SPECTER. What I want to do, and I have talked to my staff about this and I will put this on the record now, because I want to develop it, there is some legislation which has been proposed on drive-by mastectomies. And we legislated last year on drive-by deliveries. It is now a requirement of 48 hours.

And it is a very tempting field politically, when one of these amendments is offered. Hardly a member will vote against something that comes up. But we do not have the competence to micromanage medicine. And what I think we need to do is to have an overall legislative package which will make the decision a medical decision and not a dollars-and-cents decision.

Now, the dollars and cents are not irrelevant, but the doctors ought not to be gagged in recommending a specialist, and they ought not to be penalized for exceeding the capitation rate. But we have to find it for all problems, not just for specific problems. Because we are not going to be able to particularize all of them. And there have to be provisions for a second opinion, and there have to

be provisions for the managed health care. They have got to make decisions about what they pay for, because there are qualifications.

Specialists should not have to be dealing with someone who is not qualified, but with an administrator. And there have to be appeals procedures. And that is what we are going to be looking for, something that goes beyond the specific ailment.

But we are working on that, right, Ms. Taylor? That is where all the work is done.

Dr. Robinson, let me ask you a question which goes in a little bit different direction, and that is how we do a better job on minority care. We have 10 million children who are not covered in health care, and I have a comprehensive health bill. This is the third Congress that I have put it in, starting in the 103d Congress, with Senate bill 18, and again in the 104th, to work toward universal coverage, and on an incremental basis, following up on Kassebaum-Kennedy from last year.

A number of the Senators on the other side of the aisle have approached me on cosponsorship, and we have to find a way to pay for it. I would be interested in your view of the differences between the kind of care available in America to minorities contrasted with other citizens, other residents.

Dr. ROBINSON. I think it is very interesting you mention that. I always think of myself as being different when I predict that ultimately we will move toward a universal care program. I think it is inevitable, when we look at it from the standpoint of what every other major industrialized country has already done.

Senator SPECTER. Dr. Robinson, I think there is care available actually if you go to the emergency ward. People are not turned away on care, but it is very expensive to go to the emergency ward. We need to find a way that people can get the care without that very high societal cost. And the ultimate question is whether we have enough doctors and hospitals and MRI's and mammogram machines and pharmaceutical equipment to do the job, and then to work out the delivery system.

My health care bill analyzes costs. And where there are savings—for example, on low birthweight babies, a child as big as my hand, they come into the world every day weighing 1 pound or less, and they carry scars for a lifetime, and they are very expensive. Prenatal care could save billions of dollars on thousands of children who are born, and that could be applied in other ways—just as an illustration. A nurse care physician assistant could be a tremendous help, a tremendous savings, but we have to find a way to deliver it without being unduly intrusive with the Federal Government, so that we do not establish a bureaucracy that puts it in the Government's hand. At least that is my opinion.

Dr. ROBINSON. It is interesting also that the city of Philadelphia actually is the main provider of care; 52 percent of the patients at our ambulatory health centers are uninsured—have no insurance at all. And so certainly there is a need to provide access to care, because I do not think that the issue is capacity. Because I think that we have the capacity to offer the care. It is how we reach the access or how the people get to that care.

SUBCOMMITTEE RECESS

Senator SPECTER. Well, thank you very much, Dr. Robinson. Thank you, Ms. Mallory, Ms. DeLuca, Ms. Visco, again, for your help today. We have a record as to what we have done here. This will be reviewed by others who are members of the committee, and we are going to be pursuing this matter in other field hearings, as I say, and in Washington. And we appreciate your input.

This is a big subject. I think we are making progress. But I think we have to do a great deal more. So we will work together on it.

That concludes our hearing, the subcommittee will recess and reconvene at the call of the Chair.

[Whereupon, at 11:30 p.m., Thursday, February 20, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

MAMMOGRAPHY

MONDAY, FEBRUARY 24, 1997

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN
SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Pittsburgh, PA.

The subcommittee met at 9:30 a.m., in the Allegheny County courthouse, Pittsburgh, PA, Hon. Arlen Specter (chairman) presiding.

Present: Senator Specter.

NONDEPARTMENTAL WITNESSES

STATEMENTS OF:

THOMAS S. CHANG, M.D., ASSISTANT PROFESSOR OF RADIOLOGY, UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE AND STAFF RADIOLOGIST AT MAGEE-WOMEN'S HOSPITAL

HOWARD A. ZAREN, M.D., DIRECTOR, MERCY BREAST CENTER, MERCY CANCER INSTITUTE, THE MERCY HOSPITAL OF PITTSBURGH

VICTOR G. VOGEL, M.D., M.H.S., PROFESSOR OF MEDICINE AND EPIDEMIOLOGY, DIRECTOR, COMPREHENSIVE BREAST CANCER PROGRAM, UNIVERSITY OF PITTSBURGH CANCER INSTITUTE

D. LAWRENCE WICKERHAM, M.D., ASSOCIATE CHAIRMAN AND DIRECTOR OF OPERATIONS, NATIONAL SURGICAL ADJUVANT BREAST AND BOWEL PROJECT AND FACULTY MEMBER, DEPARTMENT OF HUMAN ONCOLOGY AT THE ALLEGHENY UNIVERSITY OF THE HEALTH SCIENCES

OPENING STATEMENT OF SENATOR SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The hearing of the Appropriations Subcommittee of Labor, Health and Human Services, and Education and Related Agencies will now proceed. We thank you for coming, especially our distinguished panels of witnesses.

This hearing will focus on the issue of mammography, and it arises from a report of the panel of the National Cancer Institute which made a conclusion that mammograms for women in the age category of 40 to 49 were not warranted. That is a shorthanded statement for their finding.

And as I have noted in the morning newspaper, that message has resonated from Pittsburgh to Washington and back again. Walking through the airport this morning, I saw the national publication with mammograms as the feature, and it has caused a tremendous amount of interest and a tremendous controversy.

We have had a series of hearings on this subject in Washington and field hearings in Pennsylvania with a view to gathering expert opinions from the physicians who are experts and also the sense from women who have been breast cancer victims to see if that finding by the panel is well founded.

When I see the report in the morning press about saving the lives of 2 women out of 10,000 or perhaps, as they put it, only 2 women out of 10,000, it seems to me that those are 2 lives which ought to be saved.

I have an especially strong feeling about the subject because not too long ago the doctors counseled me against an examination, an MRI, and I finally got it after being very insistent upon it, and it produced a life threatening disclosure for me, a meningioma, which I would not have known about had I not insisted on having the MRI.

I am not insensitive to the fact that I can get examinations a little more easily than some people in our society can get them.

When I see the reports about mammograms only assisting 2 women out of 10,000, the thought which comes to my mind is, should we engage in rationing even to that extent.

I personally am very much opposed to rationing. I believe that the question is whether we have enough doctors and hospitals and machines like mammogram machines or MRI's or pharmaceutical equipment to provide health care for all Americans.

[Child crying.]

Senator SPECTER. There is another protesting voice. There is a voice against rationing also. Now, let us not have both cameras go there. One camera is sufficient. [Laughter.]

I made a political announcement not too long ago and I had my granddaughter who was about 14 months at the time, and right in the middle of my very important speech, she started to crawl across the grass. You may not have noticed the announcement. I ran for president last year. Not too many people noticed that. [Laughter.]

At any rate, I am well attuned to items of priority attention like children, which do warrant the extra attention.

So that what we really have to decide, in my opinion, and I serve as chairman of the Appropriations Subcommittee of Health and Human Services, is whether we have the facilities, the personnel and the equipment to provide health care for all Americans.

I believe that we do, and the complicated part is finding a mechanism to deliver health care to all Americans, and that is what I think we have to work out in cooperation among the doctors and hospitals and even sometimes Senators or Members of the House of Representatives.

I am very much concerned that government not play too heavy a hand. I was very much opposed, as I think you know, to the President's health care plan on the ground that there was too much bureaucracy.

I am very much concerned with what is happening with HMO's now, on a lot of limitations, the gag rule and limitations on what referrals may be made. I note that that is a lead editorial in this morning's press as well.

But this issue of mammograms is one of enormous importance. The Director of the National Cancer Institute said that he was

shocked by the panel's findings, but the more recent information out of the NCI is that they are not going to overrule the panel, at least not yet. They are going to try to find more information.

So this hearing is very important as we listen to experts from this area where we have preeminent medical researchers and preeminent hospitals.

We are going to have testimony from Secretary Shalala next week, I think on March 5, and I am going to try to persuade Secretary Shalala or maybe the facts will persuade Secretary Shalala to have Medicaid and Medicare pay for mammograms for women 40 to 49, because we know as a practical matter, if there is any basis for the insurance carriers not to pay for mammograms, they will take that course.

I do not say that in a critical way of the insurance carriers. That is the way business is conducted. If they have some basis for taking that approach, they do.

So our job is to see to it that we bring the best of medical science to view on it. We hear from the women who are victims. We know that breast cancer is a terrible killer in America, striking one out of eight women. Thousands of women die each year from breast cancer.

The funding has gone up. It now exceeds some $400,000,000 a year. That funding has been increased, notwithstanding who has been the chairman of the committee, Senator Weicker, Senator Chiles, or Senator Harkin, and I am now the chairman.

And I have already made a pledge to have a 7.5-percent increase on NIH funding which would be an additional $952,000,000. That always brings smiles from the doctors.

Well, that is, believe it or not, relatively short as opening statements go. I now want to welcome our very distinguished panel of medical experts: Dr. Thomas Chang, Dr. Howard Zaren, Dr. Victor Vogel, and Dr. Lawrence Wickerham.

Our practice is to proceed in alphabetical order because of the difficulty of doing anything else with the kind of a distinguished array of participants that we have here.

SUMMARY STATEMENT OF DR. THOMAS CHANG

So we turn first to Dr. Thomas Chang, an assistant professor of radiology at the University of Pittsburgh School of Medicine and Magee Women's Hospital.

Dr. Chang graduated from MIT and Washington University Medical School in St. Louis, did his training at Pennsylvania Hospital, Thomas Jefferson University in Philadelphia, and the Western Pennsylvania Hospital.

Dr. Chang, we welcome you here. We have an array of lights. To the extent that you can keep your statement within 5 minutes, we would appreciate it. All written statements will be made a part of the record in full, but if you could maintain the 5 minute opening, that will allow us the maximum time for dialog, questions and answers.

Welcome, Dr. Chang. The floor is yours.

Dr. CHANG. Thank you very much.

First, I would like to point out that there is an amended written statement. The one that has the line across the middle of the page

is the amended one. For those of you who have the unamended one, please get the amended one at your earliest convenience.

I appreciate your interest in the controversy over breast cancer screening for women ages 40 to 49. We in the field of women's health care thank you for the positions you have taken in the past to promote women's health issues and thank you now for convening this timely hearing.

I am a radiologist specializing in women's imaging, with a significant portion of my practice devoted to breast radiology, including mammography, breast ultrasound and needle biopsies of the breast. I am an active member of the breast care team at the University of Pittsburgh Medical Center and at Magee-Women's Hospital, one of only several specialty women's hospitals in the country.

For the past few years, I have closely followed the debate that, as you mentioned, Newsweek magazine just last week dubbed "The Mammogram War." I had the opportunity to attend the NIH conference on mammography last month and left the meeting with several thoughts and observations.

First, I was disappointed that the panel's main recommendation was so inconclusive. By telling women in their forties to make their own decision about mammography, the conference did nothing to clear up the confusion about whether they should have regular mammograms.

Although the panel did say that insurance companies should pay for mammograms for women who want the test, I am concerned that without a strong recommendation for mammography, insurance companies will interpret the panel's decision as a decision against mammography and stop paying for it. Many women might then decide not to have a mammogram simply because they cannot afford it. The ironic end result of the panel's decision would then be not to let women in their forties make up their own minds, but to have financial constraints make that decision for them.

What I find most disturbing about the panel's conclusions was the apparent disregard of much of the new data supporting mammography that was presented at the conference. Having heard the new evidence, I was impressed with the strength of the case in favor of it. It is clear that routine mammography is effective, beyond any reasonable doubt, at reducing breast cancer deaths for women in their forties. The pertinent question is no longer, Does mammography save lives? but rather, How many lives does mammography save?

The eight research studies that looked at this question showed that women in their forties who were offered mammography have, on average, 18 percent fewer breast cancer deaths than those who were not offered the test. For various reasons, the 18-percent figure actually underestimates the real benefit that women who have yearly mammograms can expect. When the limitations of the studies are taken into account, the benefit is estimated to be around 30 to 40 percent.

Contrary to what some have implied, breast cancer is relatively common in this age group. In fact, in 1996, there were more breast cancers diagnosed in women in their forties than in their fifties. At

Magee-Women's Hospital, the 40- to 49-age group accounts for 36 percent of all patients and 24 percent of all breast cancers.

Just looking at these statistics, however, really does not do justice to the real life consequences of breast cancer in younger women. In terms of the number of years of life lost to breast cancer, the 40- to 49-age group is affected far more than any other decade. What makes breast cancer even more tragic for younger women is that many of them die while they still have young children. Because of the profound effect breast cancer has on these women and their families, early detection with mammography is imperative.

Some critics argue that too many women in their forties with benign conditions have to have additional tests and biopsies for every cancer that is detected. Whenever I bring up this topic with my patients, they almost always say that finding a cancer early is much more important to them than the drawbacks associated with any additional tests or biopsies. They realize that the earlier a cancer is found, the better the chances of survival. Although it is true that women in their forties have extra tests and biopsies than older women, I disagree with the objections that there are too many. When it comes to breast cancer, women would rather be safe than sorry.

Senator SPECTER. Dr. Chang, could you summarize the balance of your statement, please?

Dr. CHANG. I am sorry. OK. In conclusion, there is no doubt that mammography saves lives and is a medically effectively screening test for women in their forties. In terms of the cost per year of life expectancy gained, it is cost effective as well, costing less than tests that screen for osteoporosis or cervical cancer.

PREPARED STATEMENT

Based on all the available information, I advise all my patients aged 40 to 49 to have regular mammograms once a year. I strongly urge your committee to make the same recommendations and to ensure that financial barriers do not prevent women of any age from having a mammogram whenever it is necessary. Thank you.

Senator SPECTER. Thank you very much, Dr. Chang.

[The statement follows:]

PREPARED STATEMENT OF THOMAS S. CHANG, M.D.

Senator Specter, I appreciate your interest in the controversy over breast cancer screening for women ages 40–49. We in the field of women's health care thank you for the positions you have taken in the past to promote women's health issues and thank you now for convening this timely hearing.

I am a radiologist specializing in women's imaging, with a significant portion of my practice devoted to breast radiology, including mammography, breast ultrasound, and needle biopsies of the breast. I am an active member of the breast care team at the University of Pittsburgh Medical Center and at Magee-Women's Hospital, one of only several specialty women's hospitals in the country.

For the past few years, I have closely followed the debate that Newsweek magazine, just last week, dubbed "The Mammogram War." I had the opportunity to attend the National Institutes of Health (NIH) conference on mammography last month and left the meeting with several thoughts and observations.

First, I was disappointed that the panel's main recommendation was so inconclusive. By telling women in their 40's to make their own decision about mammography, the conference did nothing to clear up the confusion about whether they should have regular mammograms.

Although the panel did say that insurance companies should pay for mammograms for women who want the test, I am concerned that without a strong recommendation for mammography, insurance companies will interpret the panel's decision as a decision against mammography and stop paying for it. Many women might then decide not to have a mammogram simply because they cannot afford it. The ironic end result of the panel's decision would then be not to let women in their 40's make up their own minds, but to have financial constraints make the decision for them.

What I found most disturbing about the panel's conclusions was the apparent disregard of much of the new data supporting mammography that was presented at the conference. Having heard the new evidence, I was impressed with the strength of the case in favor of it. It is clear that routine mammography is effective—beyond any reasonable doubt—at reducing breast cancer deaths for women in their 40's. The pertinent question is no longer, "Does mammography save lives?" but rather, "How many lives does mammography save?"

The eight research studies that have looked at this question showed that women in their 40's who were offered mammography had, on average, 18 percent fewer breast cancer deaths than those who were not offered the test (23 percent if the flawed Canadian study is excluded). For various reasons, the 18 percent figure actually underestimates the real benefit that women who have yearly mammograms can expect. When the limitations of the studies are taken into account, the benefit is estimated to be around 30–40 percent.

Contrary to what some have implied, breast cancer is relatively common in the 40–49 age group. In fact, in 1996, there were more breast cancers diagnosed in women in their 40's (33,400 or 18 percent of all breast cancers) than in women in their 50's (30,900 or 17 percent of all breast cancers). At Magee-Women's Hospital, the 40–49 group accounts for 36 percent of all patients and 24 percent of all breast cancers.

Just looking at these statistics, however, really does not do justice to the real-life consequences of breast cancer in younger women. In terms of the number of years of life lost to breast cancer, the 40–49 age group is affected far more than any other decade. What makes breast cancer even more tragic for younger women is that many of them die while they still have young children. Because of the profound effect breast cancer has on these women and their families, early detection with mammography is imperative.

Some critics argue that too many women in their 40's with benign conditions have to have additional tests and biopsies for every cancer that is detected. Whenever I bring up this topic, my patients almost always say that finding a cancer early is much more important to them than the drawbacks associated with having additional tests and biopsies. They realize that the earlier a cancer is found, the better the chances of survival. Although it is true that more women in their 40's have extra tests and biopsies than older women, I disagree with the objections that there are "too many." When it comes to breast cancer, women would rather be safe than sorry.

Some contend that mammography is not effective in the 40–49 age group because it saves "only" one or two lives out of every 1,000 women who have mammograms. My job as a health care professional is to help save lives, including those one or two lives, not to trivialize them.

Critics also charge that too many of these women are diagnosed with what they call "pseudodisease" or "precancer." While many of these cases of ductal carcinoma in situ (DCIS) never become lethal, others eventually kill. Unfortunately, there is no way of telling, at present, which of them will be the inactive ones that can be left alone. Until the time comes when it is possible to separate the inactive cases from the deadly ones, we owe it to all women to detect and treat DCIS before it spreads into surrounding breast tissue or other parts of the body.

In conclusion, there is no doubt that mammography saves lives and is a medically effective screening test for women in their 40's. In terms of the "cost per year of life expectancy gained," it is cost-effective as well, costing less than tests that screen for osteoporosis or cervical cancer.

In accordance with the established guidelines from the American Cancer Society, all women in their 40's should have regular mammograms. Although current guidelines suggest an interval of 1–2 years between mammograms, recent studies show that if screening is to be done at all, it should be done yearly to achieve maximal benefit. In part, this is because cancers in this age group tend to be faster growing and more likely to spread.

Based on all the available information, I advise all my patients aged 40–49 to have regular mammograms once a year. I strongly urge your committee to make the

same recommendation and to ensure that financial barriers do not prevent women of any age from having a mammogram whenever one is necessary.

SUMMARY STATEMENT OF DR. VICTOR G. VOGEL

Senator SPECTER. We now turn to Dr. Victor G. Vogel, professor of medicine and epidemiology and director of the Comprehensive Breast Cancer Program at the University of Pittsburgh Cancer Institute and Women's Hospital.

Prior to the current appointment, Dr. Vogel was associate professor and deputy chairman of the Department of Clinical Cancer Prevention at the University of Texas. He did his undergraduate work at Johns Hopkins and is a graduate of the Temple University Medical School.

I was scanning the morning paper on the turn sheet to see how extensively Dr. Vogel was quoted on the turn sheet before coming to his testimony. I did not want to miss anything.

But what appears to have been your prepared statement for today has already given significant currency to your views, Dr. Vogel. We welcome you here and look forward to your testimony.

Dr. VOGEL. Thank you, Mr. Chairman. Thank you for the opportunity to present my views to the committee.

There are approximately 16 million white women and more than 3 million women of color between the ages of 40 and 49 in the United States. Each year, 18 percent of all breast cancer cases occur in these women. Collectively, they will develop more than 33,000 cases of breast cancer this year, or more than 330,000 cases during this decade. Importantly, incidence among African American women between the ages of 40 and 44 is 9 percent greater than in white women.

Mammographic screening holds the promise of early detection of breast cancer in a curable stage. Eight prospective, randomized, controlled comparison studies are available in the world's medical literature that examine whether screening reduces a woman's chance of dying from breast cancer.

These studies show unequivocally that mammographic screening reduces the chance of dying from breast cancer by approximately 30 percent among women aged 50 to 69 years.

Unfortunately, only one study was designed specifically to investigate the efficacy of screening in women between the ages of 40 and 49, and that study was seriously flawed by methodological deficiencies. Nevertheless, and in spite of the limitations of the data, meta-analysis of all studies demonstrates a 24-percent reduction in breast cancer mortality attributable to screening for women in their forties.

Because of the faster growth rates of breast cancer in younger women, screening should be done annually rather than every 1 to 2 years as suggested by some experts.

There are nearly 1 million women in Pennsylvania between the ages of 40 and 49, and almost 2,000 will be diagnosed with breast cancer this year. Tragically, as many as 1,000 of these women may die. It is my opinion that we could reduce that number by approximately 250 deaths if women between the ages of 40 and 49 years were screened annually.

Available data also indicate that the risk of inducing breast cancer by mammographic radiation in younger women is exceedingly small, if it exists at all.

Not all experts believe that we should screen women during their forties, and they offer various justifications for their position. Opponents of screening claim that only 2 lives will be saved among a hypothetical group of 10,000 women screened for a decade. Yet, for all the women in that age group in the United States, as many as 35,000 lives can be saved each decade.

It is difficult for me as a clinician to withhold screening mammography from my patients in this age group in light of the very probable, although modest, benefit. Furthermore, the cost per year of life saved by screening is estimated to be approximately $20,000. This is comparable to published median costs of $19,000 per year of life saved for chemotherapy given to premenopausal women after a diagnosis of breast cancer.

The NIH Consensus Panel recommended that each woman make her own decision about screening on the advice of her physician. In my clinical experience, this will lead to a selective screening strategy in which only women with risk factors for breast cancer will seek screening, and half of the cases of breast cancer occur in women with no identifiable risk factors for the disease.

In a 1994 publication of the Journal of the National Cancer Institute Monographs, I estimated that a selective screening strategy conducted only among women who are at increased risk of breast cancer or about 20 percent of the population might prevent 3,000 deaths annually but would miss the opportunity to prevent at least 2,000 deaths each year among women without risk factors.

My recommendation at that time was to reject a screening strategy based on risk alone because of the large number of deaths that such a strategy would fail to prevent. I am unwilling to change that recommendation now. If we had treatment that reduced the death rate of breast cancer by 24 percent as screening mammography appears to do, it would be hailed as a significant achievement. Indeed, a hypothetical 30-percent reduction in the number of deaths due to breast cancer by the drug tamoxifen was considered ample justification for initiation of the breast cancer prevention trial by the National Cancer Institute. Why, then, is a similar 24-percent reduction in mortality by screening viewed as unconvincing?

When treatment can cure all women with breast cancer, screening may become unnecessary. It is my hope that practical and efficient preventive strategies may obviate the need for screening in the future. For now, however, primary prevention remains investigational, it is expensive, and available strategies are neither 100 percent effective nor completely safe.

To conclude, there is some concern that the sensitivity of screening mammography needs to be improved in younger women.

Senator SPECTER. Excuse me, Dr. Vogel. Did you say you were concluding?

Dr. VOGEL. Yes; I did.

Senator SPECTER. Thank you.

PREPARED STATEMENT

Dr. VOGEL. There is some concern that the sensitivity of mammography needs to be improved in younger women with dense, difficult to image breasts, and there is no doubt that we need improved screening methods. Those solutions will be found with continued funding support for basic and clinical research. In the interim, to do nothing while we can do something, albeit imperfect, is to deny thousands of women each decade the opportunity to be spared the tragedy of dying from breast cancer. Thank you.

Senator SPECTER. Thank you very much, Dr. Vogel.

We will come to the dialog and the questions. These are very profound statements by both Dr. Vogel and Dr. Chang, and we will pick up some of the specifics.

[The statement follows:]

PREPARED STATEMENT OF VICTOR G. VOGEL, M.D., MHS

There are approximately 16 million white women and more than 3 million women of color between the ages of 40 and 49 in the United States. Each year, 18.1 percent of all breast cancer cases occur in women of these ages. Collectively, these women will develop more than 33,000 cases of breast cancer this year, or more than 330,000 cases during this decade. Incidence is rising each year, but we do not yet understand the reason for this increase. Importantly, incidence among African-American women between the ages of 40 and 44 is 9 percent greater than in white women.

Mammographic screening holds the promise of early detection of breast cancer in a curable stage. Eight prospective, randomized, controlled, comparison studies are available in the world's medical literature that examine whether mammographic screening reduces a woman's chance of dying from breast cancer. These studies show unequivocally that between the ages of 50 and 69 years, mammographic screening reduces the chance of dying from breast cancer by approximately 30 percent. Unfortunately, only one study was designed specifically to investigate the efficacy of screening in women between the ages of 40 and 49, and that study was seriously flawed by methodological deficiencies. Nevertheless, meta-analysis of available data, from all the screening studies demonstrates a 24-percent reduction in breast cancer mortality attributable to screening when women in their forties are compared with women of the same age who are not screened.

There are nearly 1 million women in Pennsylvania between the ages of 40 and 49, and nearly 2,000 will be diagnosed with breast cancer this year. Tragically, as many as 1,000 of these women may die. It is my opinion that we could reduce that number by approximately 250 deaths if women between the ages of 40 and 49 years were screened annually with mammography.

Not all experts believe that we should screen women during their forties, and they offer various justifications for their position. Opponents of screening claim that only 2 lives will be saved among a hypothetical group of 10,000 women screened for a decade. Yet, for all the women in that age group in the United States, as many as 35,000 lives can be saved each decade. Yet, for all the women in that age group in the United States, as many as 35,000 lives can be saved each decade. Even though it is true that only 2 women of every 1,000 in their forties will develop breast cancer in a single year. It is difficult for me as a clinician to withhold screening mammography from my patients in this age group in light of the very probable, although modest, benefit. Furthermore, the cost per year of life saved (YLS) by screening is estimated to be approximately $20,000. This is comparable to published median costs of $19,000 per YLS for chemotherapy given to premenopausal women after a diagnosis of breast cancer.

The NIH Consensus Panel recommended that each woman make her own decision about screening on the advice of her physician. In my clinical experience, this will lead to a selective screening strategy in which only women with risk factors for breast cancer will seek screening, and half the cases of breast cancer occur in women with no identifiable risk factors for the disease. In a 1994 publication in the Journal of the National Cancer Institute Monographs, I estimated that a selective screening strategy conducted only among women who are at least at 3-fold increased risk of breast cancer (about 20 percent of the population) might prevent 3,000 deaths annually but would miss the opportunity to prevent at least 2,000 deaths each year among women without risk factors. My recommendation at that time was

to reject a screening strategy based on risk alone because of the large number of deaths that such a strategy would fail to prevent. I am unwilling to change that recommendation now even in light of newly available genetic methods to identify women at highest risk, again for the reason that those genetic risk factors are found in only 1 to 2 percent of the general population and in only 5 to 10 percent of breast cancer patients.

If we had treatment that reduced the death rate of breast cancer by 24 percent (as screening mammography appears to do), it would be hailed as a significant achievement. Indeed, a hypothetical 30 percent reduction in the number of deaths due to breast cancer by the drug tamoxifen was considered ample justification for initiation of the Breast Cancer Prevention Trial by the National Cancer Institute. Why, then, is a similar 24 percent reduction in mortality by screening viewed as unconvincing?

When treatment can cure all women with breast cancer, screening may become unnecessary. It is also my hope that practical and efficient preventive strategies may obviate the need for screening in the future. For now, however, primary prevention remains investigational, it is expensive, and available strategies are neither 100 percent effective nor completely safe.

There can be no doubt that we need improved screening methods, better treatment, and novel preventive strategies for breast cancer. Those solutions will be found with continued funding support for basic and clinical research. In the interim, to do nothing while we can do something, albeit imperfect, is to deny thousands of women each decade the opportunity to be spared the tragedy of dying from breast cancer.

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2. Tengs, TO, et al. Five-hundred life-saving interventions and their cost-effectiveness. Risk Analysis 15:369–384, 1995.

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SUMMARY STATEMENT OF DR. HOWARD A. ZAREN

Senator SPECTER. We now turn to Dr. Howard A. Zaren, director of the Mercy Breast Cancer Center, Mercy Cancer Institute. He is a surgical oncologist and chief of the Department of Surgery of the Pittsburgh Mercy Health System.

Dr. Zaren, we welcome you here, and the floor is yours.

Dr. ZAREN. Thank you, Doctor—Senator Specter.

Senator SPECTER. Thank you for the promotion.

Dr. ZAREN. I am not sure it is a promotion or a demotion. [Laughter.]

Before coming to Pittsburgh, I was chief of surgical oncology at the Medical College of Pennsylvania, which you know well, and used to be called the Women's Medical College.

Senator SPECTER. It was my neighborhood hospital. Now my neighborhood is expanded so much, they all are. [Laughter.]

Dr. ZAREN. Before that, I was a surgical oncology fellow at the N.D. Anderson University in Texas where I received my surgical oncology training.

The Pittsburgh Mercy Health System and the Mercy Breast Center appreciate the opportunity to address this important women's subject with you. My view is not much different than you have heard today, Senator Specter.

There will be almost 11,000 new cases of and 2,700 deaths from breast cancer in Pennsylvania in 1997. These figures place Pennsylvania within the top five States for highest incidence and mortality from breast cancer. It has been estimated that almost 20 percent of all breast cancer deaths and 34 percent of all breast cancer

deaths and 34 percent of all years of life expectancy lost result from cancers that are found among women younger than the age of 50 years.

During this period of life, the incidence of breast cancer will double from 1 in 50 at age 40 to about 1 in 25 at age 49. These facts make the detection and treatment of breast cancer in women aged 40 to 49 of paramount importance.

The NIH consensus statement on screening for breast cancer in this group of women received widespread publicity and may give women the general impression that there is no consensus opinion on this issue, or may be perceived as a change from current screening practice. Additionally, women may also interpret the statement to mean that they should now individually evaluate and act on scientific evidence that appears to have confounded scientific experts.

This unfortunate situation may be the result of a lack of foresight by those who should construct and plan screening studies to answer such specific questions. Only one of the eight randomized controlled trials that provides data on this problem was performed in the United States, and this was initiated in 1963. Unfortunately, more data on this issue will not be forthcoming from American sources, and we will have to wait on the maturity of these randomized clinical trials in less well financed and socialized health systems in Europe.

Epidemiologic studies in this country, however, show a shift toward diagnosing breast cancer at earlier stages in women 40 to 49, and this is regarded as indirect evidence of a possible benefit from screening these women.

No randomized clinical trial using mammography as the sole screening modality has by itself included enough women aged 40 to 49 years with sufficient number of years of followup to establish a statistically significant mortality reduction. The most recent meta-analysis by Smart et al., of the seven randomized clinical trials including women aged 40 to 49 with inclusion of the most recent and longest followup data, and the exclusion of data from the Canadian NBSS1 trial which was alluded by my colleague here because of the substantial differences from all other trials in terms of its design and implementation, showed a statistically significant mortality reduction of 24 percent from screening women in this younger age group.

This finding is not surprising when it is noted that the meta-analysis for these seven trials for the full age range, 40 to 74, or for the over 50 age group also show a statistically significant benefit for mammography.

The reasons for delayed demonstration of reduction in mortality in the 40 to 49 age group include lower instance of mortality rates for this age group as compared to women 50 and over.

Feig estimates—and this is my conclusion, Senator—Feig estimates that a mortality reduction of up to 35 percent can be expected if annual screening mammograms are performed in the 40 to 49 age group with current mammographic techniques and two views per breast. We at the Mercy Cancer Institute support this position. We also emphasize that at the present time, there is really no alternative modality for early detection of breast cancer.

The rapid evolution of new technology may improve the future accuracy of screening mammography and the application of new, minimally invasive surgical techniques may also help to reduce anxiety associated with surgical procedures.

Finally, it should be noted that screening mammography essentially only detects radiological differences, and mortality as a measure of success of screening is to a great part dependent on the results of treatment.

PREPARED STATEMENT

The randomized trials referred to above by colleagues and by myself were done between the years 1963 to 1982. Since then, significant advances in adjuvant therapy for breast cancer have been made, and this will have a positive effect in reducing mortality from screen detected breast cancers in the future. Thank you, Senator.

Senator SPECTER. Thank you very much, Dr. Zaren, and we thank you all for observing the lights. The subcommittee is not quite as tough as the Supreme Court of the United States. They interrupt in midsyllable.

I had occasion to argue a case there in 1994, about 3 years ago this time, and they were a little more punctual with me than they were with others, since seven of them had been before the Judiciary Committee. [Laughter.]

But when you looked over at the light, Dr. Zaren, I noted your attentiveness, and thought about being interrupted in midsyllable.

Dr. ZAREN. Oh, I am a surgeon, Senator, so my approach is slightly different. [Laughter.]

Senator SPECTER. Well, I doubt that Chief Justice Rehnquist would treat you any different.

Dr. ZAREN. I am sure of that.

[The statement follows:]

PREPARED STATEMENT OF HOWARD A. ZAREN, M.D.

Senator Specter, there will be almost 11,000 new cases of and 2,700 deaths from breast cancer in Pennsylvania in 1997. These figures place Pennsylvania within the top five states for highest incidence and mortality from breast cancer. It has been estimated that almost 20 percent of all breast cancer deaths, and 34 percent of all years of life expectancy lost, result from cancers that are found among women younger than the age of 50 years. During this period of life, the incidence of breast cancer will double, from about 1 to 50 at age 40, to about 1 to 25 at age 49. These facts make the detection and treatment of breast cancer in women aged 40–49 of paramount importance.

The NIH consensus statement on screening for breast cancer in this group of women received widespread publicity and may give women the general impression that there is no consensus opinion on the issue, or may be perceived as a change from current screening practice. Additionally, women may also interpret the statement to mean that they should now individually evaluate and act on scientific evidence that appears to have confounded scientific experts.

This unfortunate situation may be the result of a lack of foresight by those who should construct and plan screening studies to answer such specific questions. Only 1 of the 8 randomized controlled trials (RCT's) that provides data on this problem was performed in the United States, and this was initiated in 1963. Unfortunately, more data on this issue will not be forthcoming from American sources, and we will have to wait on the maturity of RCT's, in less well financed and socialized health systems in Europe.

Epidemiologic studies in this country however, show a shift toward diagnosing breast cancer at earlier stages in women 40–49, and this is regarded as indirect evidence of a possible benefit from screening these women. No RCT using mammog-

raphy as the sole screening modality has, by itself, included enough women aged 40–49 years with a sufficient number of years of follow up to establish a statistically significant mortality reduction. The most recent meta-analysis by Smart et. al., of the seven RCT's including women aged 40–49, with inclusion of the most recent and longest follow-up data, and exclusion of data from the Canadian NBSS 1 trial because of substantial differences from all other trials in terms of its design and implementation, shows a statistically significant mortality reduction of 24 percent from screening women in this age group. This finding is not surprising when it is noted that the meta-analyses for these seven trials for the full age range (40–74), or for the over 50 age group also show statistically significant benefits for mammography. The reasons for delayed demonstration of reduction in mortality in the 40–49 age groups include lower incidence and mortality rates for this age group as compared to women 50 and over, a deficient number of women in this age group included in trials, shorter lead time, lower sensitivity of mammography, higher rates of ductal carcinoma in situ with concomitant slower rates of clinical progression and fewer women with positive lymph nodes.

These trials indicate that stringent conditions must be met for successful future screening trials in this age group. These conditions include larger study populations with longer follow up, two view mammography with high technical quality and optimal interpretation, shorter screening integrals and aggressive biopsy policy, and low tolerance for non-compliance in study groups since this is a confounding factor. Tabar et. al estimated that the Swedish Two-County Trial could have resulted in a 19 percent mortality reduction as opposed to the 12 percent actually observed if for example women 40–49 had annual mammograms. A 24 percent mortality reduction for the active study group in the Ostergotland arm of the Two-County trial would also have been seen as opposed to a 2 percent increase, because death from breast cancer among women refusing screening was a confounding factor.

Feig estimates that a mortality reduction of up to 35 percent can be expected if annual screening mammograms are performed in the 40–49 age group with current mammographic techniques and two-views per breast. We at the Mercy Cancer Institute support this position. We also emphasize that at the present time there is really no alternative modality for early detection of breast cancer. The rapid evolution of new technology may improve the future accuracy of screening mammography, and the application of new minimally invasive surgical techniques may also help reduce anxiety associated with surgical procedures. Finally, it should be noted that screening mammography essentially only detects radiological differences, and mortality as a measure of success of screening is to a great part dependent on results of treatment. The randomized trials referred to above were done between 1963–82. Since then significant advances in adjuvant therapy for breast cancer have been made and this will have a positive effect in reducing mortality from screen detected breast cancers in the future.

SUMMARY STATEMENT OF DR. LAWRENCE WICKERHAM

Senator SPECTER. We now turn to Dr. Lawrence Wickerham, associate chairman and director of operations for the National Surgical Adjuvant Breast and Bowel Project, a project to evaluate new therapies in the treatment and prevention of breast and bowel cancers.

He graduated from Washington and Jefferson College and the University of Pittsburgh School of Medicine, and he serves as a faculty member in the Department of Human Oncology at the Allegheny University of the Health Sciences.

Welcome, Dr. Wickerham, and the floor is yours.

Dr. WICKERHAM. Thank you, Senator. I appreciate the opportunity to testify before you today.

The National Surgical Adjuvant Breast and Bowel Project is indeed a cancer research group that is funded primarily by the National Cancer Institute. The group's headquarters are located here in Pittsburgh at both Allegheny University and the University of Pittsburgh. Our membership includes more than 6,000 medical professionals, physicians, nurses and related health professionals lo-

cated in more than 200 medical centers throughout the United States and Canada.

Since 1958, the NSABP has entered more than 40,000 women in studies that have dramatically altered the ways that we treat breast cancers today. Perhaps the most visible result was that demonstrating that lumpectomy plus radiation therapy was an effective option in the surgical management of breast cancer.

Today's topic relates to screening mammograms in women 40 to 49. We know from randomized clinical trials that mammograms in women 50 and older reduce the risk of dying from breast cancer by as much as one-third. Unfortunately, despite this established benefit, there are still women 50 and older who have never had a mammogram. There are probably multiple reasons for this, including fear, costs and access to care, but my hope is that this recent consensus statement will not be added to that list. In addition, we are only talking about screening mammograms today, not diagnostic mammograms which are done to evaluate breast lumps or other breast abnormalities.

The consensus panel of experts reviewed a substantial body of data regarding the use of screening mammograms in women 40 to 49 and reached a conclusion. Other experts reviewing the same data have differing views, and I do not think we are going to resolve all those differences here today.

It is not unusual in science for knowledgeable individuals to disagree. I am not aware of data that demonstrates screening mammograms inflict physical harm. The discussions surround the magnitude of benefit if any that can be obtained by the use of mammograms in this group.

In the absence of clear, unequivocal data, as judged by the consensus panel, they chose to not make a single recommendation for mammograms for all women in their forties. The consensus statement directs women to decide for themselves whether or not to undergo mammography, and I do not disagree with that goal.

In order to make an informed choice, women and their health care providers need to have the best possible educational materials to aid them in those decisions. I would hope that such educational materials would include information documenting that the vast majority of mammographically detected breast cancers allow that woman the option of choosing a lumpectomy.

The consensus panel focused on the conventional measures of benefit, that is reduction in breast cancer mortality. An expanded definition of benefit is likely to be important in the individual woman, however.

There is nothing magical about turning 50, and just having a birthday certainly does not result in a benefit from screening mammograms. There is likely to be a sliding scale of benefit during the forties, and the potential benefit can be assessed by the woman in consultation with her health care providers based on her individual circumstances.

PREPARED STATEMENT

My greatest concern is that the consensus statement not be used by the insurance carriers as a reason to deny coverage for mammograms. I would hope that Congress can prevent a controversial con-

sensus statement from being used as a rationale for improving the balance sheet of the insurance industry.

Thank you for the opportunity to discuss this with you today.

Senator SPECTER. Thank you very much, Dr. Wickerham, for your testimony. Thank you all.

[The statement follows:]

PREPARED STATEMENT OF D. LAWRENCE WICKERHAM, M.D.

Mr. Chairman and members of the Committee, I am D. Lawrence Wickerham, M.D., Associate Chairman and Director of Operations for the National Surgical Adjuvant Breast and Bowel Project. I am also a faculty member in the Department of Human Oncology at Allegheny University of the Health Sciences. I appreciate the opportunity to testify before you today.

The National Surgical Adjuvant Breast and Bowel Project is a cancer research group funded primarily by the National Cancer Institute. The group's headquarters are located in Pittsburgh at Allegheny University. Our membership includes more than 6,000 physicians, nurses, and other medical professionals located in more than 200 medical centers throughout the United States and Canada.

Since 1958, the NSABP has entered more than 40,000 women on studies which have dramatically altered the ways in which breast cancer is treated today. Perhaps the most visible result was the demonstration that lumpectomy plus radiation therapy was an effective option in the surgical management of breast cancer.

Today's topic relates to the use of screening mammograms in women 40–49. We know from randomized clinical trials that mammograms in women 50 and older can reduce the risk of dying from breast cancer by as much as one-third. Unfortunately, despite this established benefit, too many women who are 50 or older have never had a mammogram. There are multiple reasons for this including fear, costs, and access to care, but I would hope the confusion surrounding this recent Consensus Statement would not be added to that list. We are also talking only about screening mammograms, not about diagnostic mammograms which are done to evaluate a breast lump or other breast abnormalities.

The Consensus Panel of Experts reviewed a substantial body of data regarding the use of screening mammograms in women 40–49 and reached a conclusion. Other experts reviewing the same data have differing views and we are not going to fully resolve these differences today. It is not unusual in science for knowledgeable individuals to disagree. I am not aware of data that demonstrates screening mammograms inflict physical harm. The discussions surround the magnitude of benefit, if any that can be obtained by the use of mammograms in this age group.

In the absence of clear unequivocal benefit the Consensus Panel chose to not make a single recommendation for mammography for all women in their forties. The Consensus Statement directs women to decide for themselves whether to undergo mammography, and I do not disagree with that goal. In order to make an informed choice, women and their health care providers need to have the best possible educational materials to aid them in these decisions. I would hope that such educational materials would include information documenting that the vast majority of mammographically detected breast cancers allow the woman the option of choosing a lumpectomy. The Consensus Panel focused on the conventional measure of benefit, i.e., mortality reduction. An expanded definition of benefit is likely to be important to individual women. There is nothing magical about turning 50. A woman doesn't have a birthday and suddenly develop a benefit from screening mammograms. There is likely to be a sliding scale of benefit during the 40's. This potential benefit can be assessed by a woman in consultation with her health care providers based on her individual circumstances.

My greatest concern is that this Consensus Statement not be used by insurance carriers as a reason to deny coverage for mammograms. I would hope that Congress can prevent a controversial Consensus Statement from being used as a rationale for improving the balance sheet of the insurance industry.

Thank you for the opportunity to appear before you today. This concludes my prepared statement. I would be happy to answer any questions you may have.

NATIONAL CANCER INSTITUTE

Senator SPECTER. When you talk about the lack of magic of a birthday, I am reminded of Senator Glenn's statement last week when he announced he was not running again, and I think we have

lost a great Senator. He has been a colleague of mine for the past 16 years plus and an outstanding man.

He said—and this is something which even the mighty medical profession cannot solve—he said, "There is no cure for the common birthday." [Laughter.]

And Senator Glenn commented about how old he would be at the end of his next term and decided not to run again, which I think is a loss for the country.

Let me begin at the core issue as to how many lives would be saved. And as I hear the testimony of this panel, and we had a similar hearing in Philadelphia last Thursday and we are going to have a similar hearing next Monday in Harrisburg, all in advance of the testimony of Dr. Shalala—Secretary Shalala, I just about promoted her, too.

We are going to file a report—this is news to Bettilou Taylor, who is my key staffer on this—of what you have testified here to. We will put it in the Congressional Record and make a floor statement of it, because I think that the information which I heard last week and what I am hearing today warrants broader circulation, really, to the country as a whole and for the focus of Secretary Shalala.

I am concerned that the National Cancer Institute may not take prompt action to contradict what the NIH consensus panel has done here, as I listen to the testimony and have read on the subject generally.

But the question is how many women are saved. And Dr. Vogel, as you have outlined the statistics, when you talk about 2,000 Pennsylvania women being diagnosed with breast cancer this year and that 1,000 will die, and that 250 could be saved with prompt mammography, to what extent, Dr. Vogel, would that impact be felt by mammography in the 40-to-49 age category?

Dr. VOGEL. Those figures, Mr. Senator, refer totally to that age group.

Senator SPECTER. So when you say 2,000 will be diagnosed this year——

Dr. VOGEL. Between the ages of 40 and 49.

Senator SPECTER. In the category of 40 to 49 alone?

Dr. VOGEL. Yes; now, that represents only 18 percent of the cases. It is true that breast cancer is largely a disease of older women. The average age is in the sixties. But 2,000 Pennsylvanians will be diagnosed this year while they are in their forties.

Senator SPECTER. Why do we see the statistics published as they are present in the morning press about saving the lives of only 2 women out of 10,000, then?

Dr. VOGEL. It is a little bit complex. It is based on the assumption that approximately 2 in a 1,000 per year will develop the disease, so in a decade, there would be, if you had a hypothetical group of 10,000 women, you would have 20 deaths that perhaps would be reduced by 10 percent by mammographic screening.

The problem with that is, it is a very pessimistic estimate of the benefit of screening mammography. And as Dr. Wickerham said, it is likely that the benefit is a sliding scale.

Senator SPECTER. It somewhat underestimates or significantly underestimates or enormously underestimates the number of women who will die out of that 10,000, does it not?

Dr. VOGEL. I think it does, and I think one has to be careful in how one mixes the picture. Now, we want to remain optimistic about a woman's chances of surviving breast cancer, but there is no doubt that breast cancer detected late, particularly breast cancer detected with symptoms, has a far worse outcome and a much greater chance of mortality than does breast cancer that is mammographically detected.

And as I and the others tried to point out, even though every single study is flawed and unable to answer the question, the meta-analysis, that is when you combine all the data together, I think a very reasonable estimate of the benefit in this group of women is a 25- to 30-percent reduction in mortality.

And that benefit is not insignificant, and it is comparable to the benefits we achieve with other things that are accepted as standard practice such as chemotherapy.

Senator SPECTER. Well, that is a very large swath of women who will die who could be saved.

Dr. Chang, in your testimony, you characterized the mammograms for women 40 to 49 as cost effective. That runs counter to a good bit of the literature in the field and, again, the morning press reports.

Dr. Vogel has testified in absolute numbers to the women who would die as a result of breast cancer if undiagnosed and untreated. Dr. Chang, how do you draw the conclusion about cost effectiveness which you testified about?

Dr. CHANG. Clearly, the definition of cost effectiveness can be debated left and right. What you really have to do is, as Dr. Vogel did, weigh what is the absolute cost. That is one way of looking at it.

Another way is the way Dr. Feig in Philadelphia has looked at it, which is looking at the cost per year of life expectancy saved. And that is actually a common method of assessing cost effectiveness.

The fact of the matter is, for women in their forties, breast cancer affects their lives profoundly because they have many decades of life that they lose as opposed to, for example, prostate cancer where the vast majority of men who die are elderly and do not have as many years of life that they lose.

Senator SPECTER. Let us not undercut the importance of diagnosis prostate cancer.

Dr. CHANG. Absolutely not. But I think I would like to emphasize that this is a very important goal, to try to prevent cancer in younger people because they are at the peaks of their lives. They have younger families. The effect on them and their families is very great.

Senator SPECTER. Dr. Zaren, let me take up with you the issue of what harm comes to women. The consensus panel of NIH emphasized the problem of false readings and then unnecessary biopsies.

Is there any factor beside that one which is harmful from having a mammogram for women 40 to 49?

Dr. ZAREN. Let us just talk about the radiation harm. This occasionally gets raised. The harm from that is minuscule compared to the harm in not making the diagnosis early in breast cancer.

Senator SPECTER. When you are on the issue of radiation, let me digress for just a moment to the MRI. The MRI does not use radiation. Is there any problem with repeated MRI exams?

Dr. ZAREN. We at this point do not use MRI's in a screening situation in the breast.

Senator SPECTER. I know you do not, but some other people do.

Dr. ZAREN. I realize they do, and there is no radiation difficulty.

Senator SPECTER. Any harm that you know of from MRI's?

Dr. ZAREN. Not that I am aware of.

Dr. CHANG. Could I address that point, please?

Senator SPECTER. Sure.

Dr. CHANG. As far as we know, MRI does not cause any untoward effects. I would like to make one correction. MRI does use radiation, but it is not ionizing radiation, which is what x rays are.

Senator SPECTER. What kind of radiation does it use?

Dr. CHANG. It is a magnetic sort of radiation.

Senator SPECTER. So that is not the kind that is a problem, that dentists put the big lead shield on you?

Dr. CHANG. No lead shield. In fact, that would be contraindicated. The kind of radiation that is used is magnetic, which is the kind that has been debated, actually, in neighborhoods where they have power lines.

Senator SPECTER. There is some feeling about power lines, that they do cause cancer.

Dr. CHANG. Right.

Senator SPECTER. A lot of people think that in Scranton, for example.

Dr. CHANG. Exactly. That is another controversial issue where there is tremendous debate.

Senator SPECTER. So there may be some debate as to whether the MRI has some quality which could cause medical problems?

Dr. CHANG. There is always that chance for debate.

Senator SPECTER. I do not want to know about a chance for debate. I want to know about—[Laughter.]

I am serious, now. I want to know about any evidence, any evidence.

Dr. CHANG. None so far.

Senator SPECTER. Dr. Zaren, back to you, and the question is on problems. You discounted radiation?

Dr. ZAREN. Yes.

Senator SPECTER. Go ahead.

Dr. ZAREN. I think, Senator, if you look at problems encountered in radiation, second malignancies or causing problems with radiation, it is minuscule compared to missing the early diagnosis of breast cancer.

As it turns out, we at least in Pennsylvania have dedicated breast centers with equipment that is the state of the art now for detection, minimizing the amount of radiation given to a patient during mammography, a two-view mammogram.

As far as biopsy is concerned, I alluded to newer techniques that we are looking at in order to minimize biopsy, open biopsy, open surgical biopsy.

Senator SPECTER. Well, you do not have to have a biopsy simply because the mammogram shows you something.

Dr. ZAREN. Well, if the mammogram does show you an abnormality or a change from the last mammogram and has specific changes that look like there may be an abnormality there, there are ways to do biopsies now that do not require open surgical techniques.

Senator SPECTER. So are you saying that the biopsy issue is not a real problem, just like the radiation issue is not a real problem?

Dr. ZAREN. I am saying that as we develop these newer techniques for minimally accessing breast masses——

Senator SPECTER. How about right now, aside from developing newer techniques? How about right now?

Dr. ZAREN. The approach right now is, again, a biopsy can be done through a small needle, mammographically detected, to take a core biopsy of a piece of tissue.

Senator SPECTER. So is that a significant risk?

Dr. ZAREN. It is a much less risk than open surgical biopsy, much less discomfort.

Senator SPECTER. And how do you compare that as a potential harm? It has been identified in the consensus panel as a harm. Is it really a harm?

Dr. ZAREN. Well, any surgery, that requires general anesthesia. Most of these procedures require local anesthesia.

Senator SPECTER. So you are saying in effect that it is some harm, but what you are saying is it is minimal, again, like radiation, contrasted with the benefits?

Dr. ZAREN. I think it is minimal harm.

Senator SPECTER. Let me turn to the issue which you brought up, Dr. Wickerham, of discouraging women from having mammograms. That is one of the things that really concerns me about the NIH consensus panel.

If people have any reason not to have an examination, they will follow that reason. People, understandably, do not like examinations or tests because they may show that there is something wrong with you.

When you have this headline, "Mammograms Unnecessary, Age 40–49," many people, most people do not read the fine print. To what extent do you think it is dissuading women generally from having mammograms?

Dr. WICKERHAM. My greatest concern was in the group 50 and older where we know this test to be of value, that they not misinterpret the headlines as well and avoid mammograms.

I have been warning patients that I see each week for several months that this consensus panel was coming down the road, and that they should be aware of it, read it carefully, and I would be happy to answer any questions that they might have.

I was very concerned that this information might be misinterpreted not only by the medical community but also by the lay public.

Senator SPECTER. On the issue of cost effectiveness, that really is a public policy judgment, a political judgment, much more so, it

seems to me, than a medical judgment, although obviously the medical inputs are important on cost effectiveness. But that is something which we all have to make a determination as to how to deliver medical services.

But with respect to the availability of mammograph machines, is there any shortage, any reason why every woman in the 40 age bracket up could not have one mammography a year, that is with respect to the available physical equipment? Anybody?

Dr. VOGEL. Perhaps I can address that. There have been studies to examine the number of machines available in the country. Larry Kessler and others at the NCI have done those studies, and to my satisfaction they have answered that question that the access to mammography is not limited by the availability of machines.

And the FDA program with the Mammography Quality Standards Act has assured that those machines that are available are up to technical standards.

I think the problems are those that have been alluded to by Drs. Wickerham and Zaren and Chang, and that is that the message be confused. And when our studies done 10 years ago and others looked at the reasons why women did not get mammograms, the two reasons they cited most often were that their physician did not tell them to have one, and they cost too much. And I think those are my concerns.

Senator SPECTER. How much does a mammogram cost?

Dr. VOGEL. They are variable, but $60, $70 in round numbers.

Senator SPECTER. Are they available free of charge?

Dr. VOGEL. To some women, they are, and there are many programs in the city that make mammography available.

Senator SPECTER. We are getting a lot of nods from the audience. We may have to take some more sworn testimony here.

One thought which occurred to me on the MRI, which is a good deal more expensive, is that MRI's might be given in the middle of the night. The marginal cost for doing one at 3 a.m., would not be high, and it would be a lot cheaper at 3 a.m. And I think a lot of people would be well advised to have one any time they can get one in some situations. So that on the issue of availability of medical resources, we do have them.

Dr. ZAREN. Senator, just one more point. You raise an excellent point here about the cost and cost benefit, but we cannot forget—and again, my colleagues have said it—we cannot forget that if you do not diagnose breast cancer early, the cost of treating that patient is monumentally increased.

Senator SPECTER. I am thinking about our report here. Bettilou is writing ferociously. Can you give me a ballpark analysis as to the cost of diagnosis contrasted with the cost saving once diagnosed?

Dr. ZAREN. If a patient needs to have not just a needle aspirated biopsy but go on to have a surgical removal of a breast lesion and then is found to have a cancer that needs to be treated with chemotherapy, I cannot give you a direct cost for that. We can determine that. We do it every day.

Senator SPECTER. Would you please do that, Dr. Zaren? I would be interested to know that, when you talk about cost effectiveness,

a lot of my colleagues are more impressed with that factor than any other, so I would like to be able to lay that on the line.

Dr. ZAREN. It is something we can do.

Senator SPECTER. May I ask all of you on the panel to study that issue for me and supplement your testimony? We will put it in the record.

There have been some concerns expressed that, on a comparison as to where we ought to be spending our money, that much more of the money ought to be spent on research as opposed to screening. My response to that is we do not have to limit as to one or the other.

We have a Federal budget of $1,700,000,000,000, which is a staggering sum of money that people cannot comprehend. And I am personally convinced that if we established priorities, we could cover the needs of our nation and have a balanced budget.

Senator Harkin and I cut out some 134 programs for our subcommittee, enabling us to reallocate $1,500,000,000 to what we consider to be the high value items like NIH research and like scholarships and like worker safety.

We have in our subcommittee three departments, not only Health and Human Services, but also the Department of Education and the Department of Labor.

I would be interested in your research. I asked the head of the NCI, how much money would he like to have. And I know this is not your field. We now appropriate more than $400,000,000 a year for cancer research. The NIH makes that allocation.

I would be interested in any sense any of you may have as to what the right figure is. You may be more competent than either Senator Harkin or I in determining that.

Dr. ZAREN. That is a dangerous question.

Dr. VOGEL. Yes, Mr. Senator. The answer is always more.

Senator SPECTER. I know it is a dangerous question, but I am only two spots from being chairman of the full Appropriations Committee, and I need to know things like that. There is a lot of danger to my job. [Laughter.]

Go ahead, doctor.

Dr. VOGEL. The pay line at the NCI over the last several years has been as low as the 10th percentile. That means that as many as 90 percent of approved grants go unfunded.

Dr. Klausner has done a yeoman's job at improving that somewhat, but the pay line is still only in the vicinity of the 20th percentile.

It is particularly difficult to get new investigators started because of the limited funds available for them. And I have no data, but I have the impression that a number of capable young physicians are leaving the sphere of medical research because of the difficulty in securing funding.

There has been a welcomed increase in attention toward funding of breast cancer specifically with the Department of Defense initiatives and those increases at the NCI.

Senator SPECTER. Let me ask the four of you to study this question for you and give me a figure as to what you would like to see done here, bearing in mind the debate that cancer takes more than

it ought to in the overall budget from Alzheimer's and heart disease, AIDS, et cetera.

Dr. ZAREN. Just before you move on, Senator, I think it is important, and Dr. Vogel put it very well. In fact, Dr. Vogel says the 10th percentile, but at times it has been as low as the 4th percentile in research dollars.

Senator SPECTER. Well, would you fund them all, Dr. Zaren?

Dr. ZAREN. I would love to fund them all, but I would not want to pay for it and neither would the rest.

I think it is important to know that there are two aspects to the research. One, represented here at this table, is very important and that is the clinical trial expertise and support of that kind of research.

The clinical trials I alluded to here, most of the clinical trials that have looked at this question have been done outside of the United States of America. They have been done in England and Sweden and other areas.

Senator SPECTER. Why is that? Why are those tests not done in the United States?

Dr. ZAREN. Well, first is the accrual of patients for clinical trials. It is much more difficult in the States than it is out of the States.

Senator SPECTER. Why?

Dr. ZAREN. Because of our legal system and because of the need for informed consent and not the need for informed consent in other situations.

Senator SPECTER. Wait a minute. What about our legal system impacts on this issue?

Dr. ZAREN. We have very stringent rules and regulations for accrual of patients in clinical trials.

Senator SPECTER. Why? Informed consent I understand. That is something you could get.

Dr. ZAREN. Yes.

Senator SPECTER. How many women turn down a request to have their cases studied with a view to helping other women?

Dr. ZAREN. Not so much turn down their case's study, but when you present to women whether they can participate in a clinical trial or not, we very fully explain, "we" meaning the U.S. of A., clinical trials, very fully explain to the *n*th degree the dangers as well as the benefits of participating in a clinical trial.

And for a patient to make that decision sometimes is very difficult from the information we need to give them, because we give them both sides of the coin very thoroughly.

Senator SPECTER. Do you talk them out of it?

Dr. ZAREN. I beg your pardon.

Senator SPECTER. Do you talk them out of it?

Dr. ZAREN. Not talk them out of it, but very, very, very, very, very carefully explain the risk-benefit of being involved in a clinical trial.

Senator SPECTER. Are there risks in being involved in a clinical trial?

Dr. ZAREN. There are risks in being involved in a clinical trial depending on that clinical trial, yes. But more importantly, Senator, it is not just the funding of basic research in cancer, but we need to fund clinical trials and we need to fund clinical trials be-

cause that is where the answers lie, at multiple phases of clinical trials, from phase 1 to phase 3. That is the only point I wanted to make.

Senator SPECTER. There are a couple of other subjects I want to move to, and we are running late on the panel. But I would like you to address this subject as well. If there is some problem on informed consent or if there is some problem with the legal system, that is something we can legislate about.

It is a little distressing to me to see all the tests coming out of Sweden. I mean, more power to them, but considering our budgets, why do we not have more clinical information on this question? One test on women 40 to 49 since 1963 is hardly where we ought to be.

Let me move on to another subject, and that is this issue of gene research. The research and what your profession has done has been so astounding that there is so much sentiment in the Congress to increase the funding.

And we hear a lot about gene research, identifying the gene which predisposes a woman to cancer. One of the items we are giving consideration to now is to legislation which would protect privacy, because you have a curious situation.

If a woman takes a test and finds she has a gene which predisposes her to cancer, she may rule herself out as being insurable.

And if she knows about it and is asked a question and does not tell the insurance company, the insurance policy will not cover her if that is determined as fraud in the inducement.

So it is worse than catch-22. It is a catch-44 situation. People do not want to find out what their medical problems are because they will be barred from getting insurance coverage on it.

So I think we can legislate at the Federal level to provide privacy, but that raises the question that I have not heard a good answer to yet as to, what will you be able to do for the woman if you find out that she has a predisposition from the gene beyond, say, more mammograms at an early age? What kind of treatment can you give, if any, once there is a determination that a woman has a predisposition from a gene test?

Dr. WICKERHAM. Senator, the group that I work for, the NSABP since 1992 has been conducting a very large breast cancer prevention trial, and one of the goals is to do just what you have described, give an option for women at risk for this disease beyond watchful waiting and mammograms and physical exams and the other extreme, prophylactic mastectomies, removal of the breast prior to the onset of the disease.

Senator SPECTER. A pretty tough procedure, pretty tough remedy.

Dr. WICKERHAM. We have over 12,700 women who have volunteered.

Senator SPECTER. For prophylactic mastectomies?

Dr. WICKERHAM. Who have entered this prevention trial.

Senator SPECTER. Oh, pardon me, OK.

Dr. WICKERHAM. All of them at increased risk for developing the disease.

Senator SPECTER. What is the incidence of women who will undertake a prophylactic mastectomy, if you can comment on that?

Dr. WICKERHAM. I cannot.

Senator SPECTER. One of the things that concerns me is, is it desirable to have a determination on gene predisposition if there is nothing you can really do with it?

You are going to worry a lot of people in our society if you tell them they have a predisposition to it.

Dr. WICKERHAM. In addition to searching for potential benefits from the particular therapy we are looking at, it would also allow for those individuals to be targeted for structured evaluations, so that they would be certain to comply with the screening procedures that we do have in place.

Are those perfect? Far from it, nor is the genetic testing perfect at this point in time.

Senator SPECTER. May I ask you all to give me a supplementary answer on that point, as to what you think about pursuing the gene research determination and what you expect to do with it, and your evaluation as to how hard we ought to push it?

Let me raise one final question with you, which is not within the purview of our hearing today, but I would be interested in your views, with the disclosure in the news in the last day or two about cloning of the mammals and the ethical issues which are posed by that, and that is something which we might be taking a look at for a hearing in Washington.

When I have four distinguished researchers, although it is not exactly your field, Dr. Chang, does this raise any questions in your mind that the Senate ought to be studying?

Dr. CHANG. As you point out, that is not one of my areas of expertise. In terms of cloning, what exactly are you referring to?

Senator SPECTER. I am not sure. That is what I am asking you. What I am referring to, according to the news report, is that you have had the first mammal cloned, sheep, an exact replica.

What would you say about the consequences of cloning another Dr. Chang? You make quite a contribution to our society, Dr. Chang. Should we clone you?

Dr. CHANG. That is difficult to say.

Senator SPECTER. Dr. Zaren, should we clone Dr. Chang?

Dr. ZAREN. We should definitely clone Dr. Chang, but not Dr. Zaren. He has got enough of his own problems. [Laughter.]

Senator SPECTER. Wait a minute. Will Dr. Zaren have problems if he is cloned? The clone may have a problem.

Dr. ZAREN. The world may have, Senator Specter, if you clone another Dr. Zaren. [Laughter.]

Senator SPECTER. What are the problems? One is enough?

Dr. ZAREN. One causes enough problems.

But let me say this, Senator. Again, I am not an expert in this area, but anything that would forward gene research in any aspect may help us change what happens in breast cancer and cancer in general.

So it is very frightening to think that you actually can do this now, but it should not be any great surprise that we are able to do this.

We are moving at lightning speed in certain areas, and one of the areas is gene research. Now, at the University of Pittsburgh, this

is a major area of research for them. I am not speaking for them, but it is a major area that they have been in the forefront of.

I am sure Dr. Vogel will have something to say about this, but I am not an expert in this area.

Senator SPECTER. Well, this is a subject which comes up when you talk about genes and you talk about the research. Now you talk about cloning, and this is a breathtaking conclusion on cloning of mammals.

Dr. Vogel is next. Would you care to comment, Dr. Vogel, on this issue?

Dr. VOGEL. Well, as you know, Mr. Senator, we could be here a long time talking about this, but very briefly——

Senator SPECTER. Do you think the Senate, and our subcommittee ought to be inquiring into any aspect of this issue?

Dr. VOGEL. With great respect for the Senate, I think we run the risk here of trying to control scientific inquiry. Now, I hope I am as moral and as ethical as the next person, and I would certainly want to seriously examine all the ethical ramifications of cloning experiments that would involve human beings.

On the other hand, as a scientist, I would be very reluctant for any legislation that would impede substantially scientific inquiry. But in my own mind, that is a tension. There will be great difficulty in resolving scientific freedom and ethical appropriateness in this area, but I think we should move very slowly and have very open deliberations about this so that scientific inquiry is not impeded.

The sheep cloning that was reported in the New York Times and the Pittsburgh Post-Gazette yesterday was initiated in the hope that sheep mammary gland, a curious irony with our topic today, sheep mammary gland would produce large quantities of proteins beneficial to human beings.

I would not want to see ethical concerns that may be initially appropriate in protecting humans from research that might ultimately benefit human beings.

Senator SPECTER. Well, how about the Congress establishing priorities? We are only funding 10 percent of the grants. One thing we are supposed to do is establish priorities. I keep hearing all the time, just give us one B–2 bomber for my project, just one B–2.

Dr. VOGEL. I only need a wing, Senator. [Laughter.]

Senator SPECTER. Dr. Wickerham? I am not going to get into that one. Do you want to make a comment on this last irrelevant question? [Laughter.]

Dr. WICKERHAM. With all due respect, not really. [Laughter.]

Senator SPECTER. OK. I am only joking that it is irrelevant, because it is not irrelevant. The ethical questions will be analyzed at every level of our society, but when it comes to the question of priorities, that is a fair question for our subcommittee as to where we put the money. We recently had a hearing on Ebonics, because there is a question. We give a lot of money for education.

Dr. Chang, you have the last word. I see you straining forward in your chair. Maybe you want to answer that question about whether Dr. Chang should be cloned.

Dr. CHANG. I think it is fine and good that we are talking about gene research and cloning, but I think we really have to get back

to the central question of what can we do for women now in terms of preventing and treating breast cancer so that we can save lives.

The only proven method right now is mammography that we can offer to help in that goal, and I think that is where we have to concentrate at the present time.

Senator SPECTER. Well, it has broad ramifications to the gene issues, to the mammillary issues that Dr. Vogel raised on what has turned into cloning.

This has been a very, very useful panel. I have given you some extra work to do which I would appreciate it if you could let us have responses by the end of the week, because I do want to try to file a report sometime next week so that our colleagues can have the benefit of the thinking.

We have found out too much in the brief hearings we have had, perhaps comparable or at least supplemental to what the consensus panel had done. So we thank you very much.

We are going to take a 5 minute recess before the next panel.

[A brief recess was taken.]

PANEL 2

STATEMENTS OF:

DIANE F. CLAYTON, BREAST CANCER SURVIVOR

YVONNE D. DURHAM, PROGRAM COORDINATOR, AMERICAN CANCER SOCIETY, MAMMOGRAM VOUCHER PROGRAM

LAURIE S. MOSER, EXECUTIVE DIRECTOR, THE SUSAN G. KOMEN BREAST CANCER FOUNDATION, PITTSBURGH RACE FOR THE CURE

JUDY POTTGEN, VOLUNTEER, AMERICAN CANCER SOCIETY

OPENING REMARKS OF SENATOR SPECTER

Senator SPECTER. We will proceed with our hearing.

We have a very distinguished panel of witnesses: Ms. Diane F. Clayton, Ms. Yvonne D. Durham, Ms. Laurie Moser, and Ms. Judy Pottgen.

We thank you very much for being with us. If I may make just a brief comment about the 5 minute recess, we lost a camera, which was going to leave us in any event.

I said I was reluctant to take a break and lose a camera, and I was told they were leaving in any event to make the noon news, and that they had already interviewed some of you ladies.

And I told them the reason I did not like to break was I did not want them to miss any of this second panel, although I do not control what they do, obviously.

But I think one of the real benefits from these hearings is that it sensitizes the public as to the issues, so they reach more people by breaking at this point, and they said they had already interviewed some and would interview others. But I wanted to make that brief word of explanation.

We now turn to this very distinguished panel, and in alphabetical order, we will hear first from Ms. Diane F. Clayton, a strong advocate for mammography screening and early detection.

She was diagnosed with breast cancer at the age of 46, which obviously puts Ms. Clayton in a category affected by this precise issue.

She is the mother of a 13-year-old son and resides in Wexford where she lives with her husband who is a decorated Vietnam veteran.

SUMMARY STATEMENT OF DIANE F. CLAYTON

We welcome you here, Ms. Clayton, and look forward to your testimony. We have, as I think you heard, a 5-minute light. Green is 5 minutes, yellow is 1 and red is stop to the extent that you can, leaving the maximum amount of time for dialog, questions and answers. So, the floor is yours, Ms. Clayton.

Ms. CLAYTON. Thank you, Senator Specter.

I appreciate this opportunity to speak on behalf of American women who I believe have been sent a confusing message by the National Institutes of Health. It is a special privilege for me to be here this morning to share my story with you and its relationship to the debate surrounding mammography for women in their forties. I am here with no ax to grind and I represent no professional or other special interest group. I am here only as an ordinary citizen.

I am a breast cancer survivor mainly due to early detection. My breast cancer was found during a routine mammogram almost 4 years ago. I was 46 years old and never had the first lump to indicate anything was wrong, nor was I aware of any family history of breast cancer. The ductile carcinoma in situ was discovered only by mammography. It was described to me as if someone had thrown pebbles in a pond throughout my duct.

I was told by the radiologist who looked at my mammogram that I had cancer and probably needed chemotherapy. A biopsy followed several days later and cancer was confirmed. The bad news was that I had cancer. The good news was that if I had to have cancer, mine was the best kind to have, especially since it was at such an early stage.

The next weeks were spent taking what little control I had and running with it, becoming educated on the subject, obtaining second and third opinions and determining the best procedure for me for the best possible outcome. Rational decisions needed to be made in a totally emotional and irrational situation. I likened it to standing on my tongue.

After a grueling 5 weeks of waiting, a total mastectomy was performed and lymph nodes were taken. Fortunately, there was no lymph node involvement and, therefore, I did not have to suffer the ravages of radiation and/or chemotherapy. I was, indeed, very fortunate.

I have read the NIH consensus statement, but I do not understand how they could have reached their conclusions. If I might, let me quote from their statement relating to my type of breast cancer: "Because some cases of ductile carcinoma in situ may not progress to invasive cancer, a risk of overtreatment exists."

May not progress? Would you want to take the chance that it may not progress? What is the risk of no treatment? Their findings defy logic, common sense and simple observation. I am offended by them. When I joined a breast cancer survivor's group called Looking Ahead, I was one of the very few members who did not have invasive cancer. Of the approximately 100 victims in my group,

over 90 percent of them were under the age of 50. Even more distressing, many were in their twenties and their thirties. Some of those special women have since died.

I have tried to assess the committee's motives. Was it money driving their direction? It does not seem logical, since early detection and aggressive treatment have been shown to reduce the total costs of treating this horrible disease.

Was it ignorance? This hardly seems likely when you examine the outstanding credentials and backgrounds of those members.

Was it politics? Who could be against preserving and extending the lives of mom, sis, Aunt Mary, and grandma? No; it could not have been politics.

Could it have just simply been a big mistake, a wrong conclusion, an honest effort that just went bad? I hope so. I cannot fathom that an organization known as the National Institutes of Health could have maliciously concluded that women's health is not important. It really must have been a big mistake. Let us simply admit it and go forward by doing the right thing, advise and counsel women in their forties to have routine mammograms, even if they do not feel a worrisome lump. Ignorance is not bliss in this situation. I thank the Senate for attempting to rectify this egregious error.

I am living, breathing proof that early detection can save lives. If it had not been for my routine mammogram, again, let me stress, at the age of 46, I believe I might not have been able to share my story with you today.

I know that mammography is not a perfect science, but I also know that it probably saved my life. I am happy to tell you that I had cancer, although I will always belong to what I call the C club. I also do not mind telling you that 3 days ago, I joyfully celebrated my 50th birthday.

PREPARED STATEMENT

Thank you for letting me share my thoughts with you and why I am a proponent of early mammography. It worked for me and will continue to work for women like me if focus on early detection is promoted and maintained. My simply being here is proof.

[The statement follows:]

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NIH PANEL CONSENSUS

Senator SPECTER. Well, Ms. Clayton, that is powerful, powerful testimony. You are precisely the kind of person who would not be getting a mammogram under the NIH panel consensus, because you would have no reason to. You had no lump, you had no family history, you had no indication.

And as you testified, you had a total mastectomy.

Ms. CLAYTON. That is correct.

Senator SPECTER. You made a very forceful comment about not wanting to hear about the risk of overtreatment. You wanted to be sure.

Ms. CLAYTON. At that stage, there was no choice for me because it was the type of cancer that it was, the ductile carcinoma in situ, as if someone had thrown pebbles in a pond.

Senator SPECTER. As I understand it, aided by staff here, what you had is an early form of breast cancer in which the cancer cells

are still located in the ducts and have not spread into the surrounding breast tissue or other parts of the body.

But what you are saying is, the kind of breast cancer you had was susceptible to spreading to the rest of the body.

Ms. CLAYTON. It was maintained within the breast.

Senator SPECTER. Yes; but had you not had the mastectomy, it was the kind that would have spread?

Ms. CLAYTON. Correct. As far as my understanding is, that is correct.

Senator SPECTER. Well, you are, as I say, a powerful story on this subject.

Ms. CLAYTON. Thank you, Senator.

SUMMARY STATEMENT OF YVONNE D. DURHAM

Senator SPECTER. I would like to turn now to Ms. Yvonne Durham, program coordinator for the Mammogram Voucher Program for the American Cancer Society, affiliated with the African-American Cancer Awareness Coalition sponsored by the University of Pittsburgh Cancer Institute, active in numerous organizations which increase cancer awareness, promoting cancer screening and early detection, providing community based breast health education.

Welcome, Ms. Durham, and the floor is yours.

Ms. DURHAM. To the Honorable Arlen Specter and subcommittee members: First and foremost, I would like to thank you for extending to me the opportunity to participate in this special hearing to discuss the problems of the NIH Consensus Development Conference on Breast Cancer Screening in Women Ages 40–49.

As an African-American breast cancer survivor, diagnosed at age 46, I was deeply troubled by the consensus panel's decision not to recommend regular mammogram screening for women beginning at age 40.

The consensus statement that each woman should decide for herself whether to undergo mammography sends a confusing message to the public.

As the coordinator of the American Cancer Society's mammogram voucher program and the YWCA ENCOREplus program, I have witness that women unfortunately cannot always make informed decisions about health issues. This is evidenced by information reported in Healthy People 2000, citing findings that only 25 percent of women age 50 and above reported having had a mammogram in the preceding 2 years, even though it is widely accepted that mammography can reduce breast cancer deaths by 30 percent in this age group.

My work in the African-American community has made me more aware of the uniqueness of breast cancer disease among black women. I have personally met and spoken with several black women who were diagnosed with breast cancer between the ages of 27 and 35.

Published research findings also support that breast cancer occurs in black women at an earlier age. Based on data from 1987, African-American women ages 35 to 44 had a breast cancer mortality rate two times that of white women of the same age. Yet Afri-

can-Americans as well as Hispanic Americans have some of the lowest mammogram screening rates in the United States.

As an outreach worker, one of my goals is to educate women about the importance of mammography in detecting breast cancer. A clear statement by NIH is important in giving credibility to our outreach efforts. While I understand that mammography is not 100 percent reliable, I can say that I personally would prefer to have the information provided by this screening test when being faced with making a decision about my breast health.

It has been estimated that 25 percent of breast cancers are missed by mammography. I was one of those women in that 25 percent category. However, my treatment was not based solely on mammography results. Because I had had a screening mammogram at age 38, I was fortunate to have been taught breast self-examination [BSE]. My breast cancer was detected by BSE, and I credit that to my exposure to BSE technique during a screening mammogram. No; mammography did not directly contribute to my early diagnosis, but it did play an important role in my survivorship.

The clinical importance of mammography for all women starting at age 40 may not be clear at this time, but what is clear is that we still have an underutilization of this most effective screening tool. We still continue to see women with advanced disease at diagnosis, and we are still losing our mothers, sisters, grandmothers, aunts, and friends to the disease of breast cancer.

No; a mammogram will not detect all breast cancers, but it will detect many. Instead of limiting its availability, we need to look at ways for making this screening test more reliable. For many women, even those women under age 40, mammography has provided the opportunity for early diagnosis, less extensive surgical procedures and an added sense of control over our breast health. The risk of discomfort or inconvenience certainly pales in comparison to the benefits realized.

PREPARED STATEMENT

I urge you to reconsider your position in regards to this matter. Recommend mammography starting at age 40 until there is conclusive evidence of no benefit. I also urge you to support research efforts that may offer a clearer understanding of how breast cancer disease affects minority populations. By failing to support mammography starting at age 40, you will jeopardize our ability to obtain this screening test. This is especially true for women who are uninsured or underinsured.

In conclusion, I would like to say that the benefit of mammography far outweighs any risk associated with this screening test. Please continue to make this test available to all women beginning at age 40. Thank you.

[The statement follows:]

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not to recommend regular mammogram screening for women beginning at age 40. The consensus statement that, "Each woman should decide for herself whether to undergo mammography", sends a confusing message to the public. As the coordinator of the American Cancer Society mammogram voucher program and the YWCA ENCOREplus program, I have witnessed that women unfortunately cannot always make informed decisions about health issues. This is evidenced by information reported in Healthy People 2000 citing findings that only 25 percent of women, age 50 and above, reported having had a mammogram in the preceding 2 years. Even though it is widely accepted that mammography can reduce breast cancer deaths by 30 percent in this age group.

My work in the African American community has made me more aware of the, uniqueness of breast cancer disease among black women. I have personally met and spoken with several black women who were diagnosed with breast cancer between the ages of 27 and 35. Published research findings also support that breast cancer occurs in black women at an earlier age. Based on data from 1987, African American Women, age 35–44, had a breast cancer mortality rate 2 times that of (30 per 100,000 vs 16 per 100,000) white women of the same age.[1] Yet African Americans, as well as Hispanic Americans, have some of the lowest mammogram screening rates in the United States.

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MAMMOGRAPHY

Senator SPECTER. Ms. Durham, did I understand you to urge me to reconsider my position?

Ms. DURHAM. Yes.

Senator SPECTER. Because my position is that women 40 to 49 ought to have mammography. You do not want me to reconsider that position, do you?

Ms. DURHAM. No.

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[1] National Center for Health Statistics. Prevention profile. Hyattsville, MD: Public Health Service, 1990:135.

Senator SPECTER. The testimony this morning by the panel of experts was in line with what you had said, Ms. Durham, about greater susceptibility for African-American women. Do you have any idea why that is the case?

Ms. DURHAM. No; other than by the time the disease is detected, that the prognosis is so poor and the disease is advanced so.

Senator SPECTER. Well, you have testified that you know women of the age category 27 to 35. May I ask you how many women you know in that age category who have had breast cancer?

Ms. DURHAM. Those several women between 27 and 35 were women that were diagnosed with breast cancer, that had breast cancer.

Senator SPECTER. Well, the issue which you raise, which I had not heard about, the 27 to 35 category, would suggest there ought to be some special tests for African-American women where there are some indications, the doctors have already testified, that more African-American women have breast cancer, to see if that incidence also impacts at an earlier age category.

We really have not talked about mammograms for women 30 to 39. We are talking now about mammograms for women 40 to 49. Now, women do have mammograms where there is an indication in an earlier category, in an earlier age category, but what you are suggesting is that there ought to be some surveys made to see if any special group of people have a greater susceptibility which ought to lead to different screening procedures.

Ms. DURHAM. Well, one of the things I wanted to say was, you pointed out that African-American women have a higher rate, the incidence of breast cancer is higher than in the Caucasian population, but the mortality rate is higher in the African-American community.

Senator SPECTER. You would think that would follow, if the incidence is higher.

You had the mammography, did you say, at the age of 38?

Ms. DURHAM. Yes.

Senator SPECTER. But you were not diagnosed until 46.

Ms. DURHAM. I insisted to my doctor to have the mammogram.

Senator SPECTER. Did you have another mammogram at 46?

Ms. DURHAM. Oh, yes, I had it every 2 years after that.

Senator SPECTER. But you detected it with your own breast screening examination?

Ms. DURHAM. Yes; eventually I did.

Senator SPECTER. Thank you very much, Ms. Durham.

SUMMARY STATEMENT OF LAURIE MOSER

We now turn to Ms. Laurie Moser, executive director of the Susan G. Komen Breast Cancer Foundation, Pittsburgh Race for the Cure.

She is a middle school teacher at the Hillel Academy here in Pittsburgh, a member of the board of directors for the American Cancer Society's Greater Pittsburgh unit, affiliated with the United Jewish Federation of Greater Pittsburgh and past director of the National Council of Jewish Women for Pittsburgh.

Welcome, Ms. Moser, and the floor is yours.

Ms. MOSER. Thank you.

Thank you, Senator, for the opportunity to testify today. The Pittsburgh Susan G. Komen Breast Cancer Foundation Race for the Cure is an annual race, a 5–K walk and run on Mother's Day, that raises awareness about breast cancer and provides mammograms and followup diagnostic services to medically underserved women in 22 counties of western Pennsylvania and supports the Komen National Research Program.

In 4 years, we have raised $1.25 million and have provided over 7,600 vouchers to underinsured women. Fifty-six cancers have been diagnosed. While the race is a once a year event, our education and our early detection programs continue throughout the year, reaching out to the African-American community, senior citizens, new Americans, native Americans, and breast cancer survivors.

We at the Komen Foundation strongly disagree with the latest decision from the NIH Consensus Development Conference on Breast Cancer Screening for Women Ages 40 to 49 that stated that: "The available data does not warrant a single recommendation for mammography for all women in their forties."

It is estimated that in 1996, women in their forties accounted for 18 percent of newly diagnosed invasive breast cancers, while women in their fifties were estimated to make up 16.8 percent of these new cases.

Significant data has been presented that indicates regular mammography screening of women in their forties, when combined with appropriate intervention, leads to a significant decrease in mortality.

We firmly believe that the panel's position overstated potential risks and understated the benefits of mammography. Although imperfect, mammography screening is presently the most reliable tool for detection of breast cancer. Mammography facilitates early detection and intervention which decrease mortality and can lead as well to an improved quality of life for those diagnosed by allowing for breast conservation surgery and less aggressive treatment options.

My personal story twice underlines the importance of mammography and early detection. In 1987, for my fortieth birthday, I treated myself to a mammogram. I had no history of breast cancer in my family. I was in great shape. I ran 7 to 8 miles a day.

To my great surprise, the doctor called and told me that there were signs of calcification, that 85 percent of them were benign, and that I should come back in 6 months.

I was not satisfied with that report, and I insisted on a biopsy. The biopsy turned out to be malignant. I had ductile carcinoma in situ, DCIS, and I had to have a lumpectomy. The lymph nodes were removed and they found that they were not involved, and thankfully I just needed to have 30 radiation treatments, no chemotherapy.

I had a mammogram every single year after that, and last September I was diagnosed once again with breast cancer in the same breast. The DCIS had returned. I knew more about breast cancer then than I did 9 years ago and I was not frightened by the diagnosis, but I was very saddened by it.

I had a mastectomy at that point. I did not need any chemo or any radiation, and I am now recovering from reconstruction.

I strongly feel that all women in their forties should have full information in order to make informed personal decisions about mammography. Many consumers, however, look to the opinion of a body of experts such as the consensus panel to interpret data and provide recommendations which they can weigh as they make decisions. The present NIH statement does nothing more than confuse the public about an extremely important issue. A strong consensus would also help to guarantee women in their forties the necessary insurance coverage for mammography.

PREPARED STATEMENT

When the Race for the Cure began in Pittsburgh in 1993, a woman died every 11 minutes from breast cancer. Today, a woman dies every 12 minutes. Over 2,000 additional lives are saved each year with early detection. Our mutual goal should be to add 1 minute each year in the hope that more and more women will survive breast cancer. Mammography can help.

Thank you, Senator.

[The statement follows:]

PREPARED STATEMENT OF LAURIE S. MOSER

My name is Laurie S. Moser, and I am Executive Director of the Pittsburgh Susan G. Komen Breast Cancer Foundation Race for the Cure®. The annual race, a 5–K walk and run on Mother's Day, raises awareness about breast cancer, provides mammograms and follow-up diagnostic services to medically underserved women in 22 counties of western Pennsylvania and supports the Komen National Research Program. In 4 short years we have raised over $1.25 million and provided 7,600 vouchers; 56 cancers have been diagnosed. The RACE is a once-a-year event, but our education and early detection programs continue throughout the year, reaching out to the African-American community, senior citizens, new Americans, Native Americans and breast cancer survivors.

We at the Komen Foundation strongly disagree with the latest decision from the NIH Consensus Development Conference on Breast Cancer Screening for Women Ages 40–49 that stated that: "the available data does not warrant a single recommendation for mammography for all women in their forties." It is estimated that in 1996, women in their forties accounted for 18.1 percent of newly diagnosed invasive breast cancers, while women in their fifties were estimated to make up 16.8 percent of the new cases. Significant data was presented that indicates regular mammography screening of women in their forties, when combined with appropriate intervention, leads to a significant decrease in mortality. We firmly believe that the panel's position overstated potential risks and understated the benefits of mammography. Although imperfect, mammography screening is presently the most reliable tool for detection of breast cancer. Mammography facilitates early detection and intervention which decrease mortality and can lead, as well, to an improved quality of life for those diagnosed by allowing for breast conservation surgery and less aggressive treatment options.

My personal story twice underlines the importance of mammography and early detection. In 1987, for my fortieth birthday, I treated myself to a mammogram. This was an optional procedure after a physician casually recommended that I have a baseline. I had no symptoms; there was no history of breast cancer in my family and I was in perfect health. I ate well and ran seven to eight miles each day. To my great surprise the doctor called and told me I had calcifications in my left breast, but 85 percent of calcifications are benign, he assured me. He recommended that I come back in six months. I was not satisfied and called a surgeon, who told me the same statistics. At that point I was not interested in national numbers and requested a biopsy. He agreed and we found that the calcifications were malignant—ductal carcinoma in-situ (DCIS) and I had a lumpectomy. The margins were cleaned and, thankfully, there was no lymph node involvement. As follow-up I received 30 radiation treatments; no chemotherapy was necessary. Each year I returned for mammograms and sonograms; all was well until this past August (1996). Many calcifications had returned all over my left breast; even with my uneducated eye I could tell by looking at my mammogram that a mastectomy was necessary.

After a stereo-tactic biopsy it was confirmed the DCIS had returned and a mastectomy was indeed in order. The good news was the cancer had not spread and that it had been detected early, once again. The first time around my then 13-year-old son asked me if I was going to die. I replied, "Yes, but not from breast cancer and not for a very long time," was my reply. This summer, using the same information, I reassured him again. I firmly believe that my life has been saved twice by the benefits of early detection—and I am not yet 50 years of age.

In addition, because I was diagnosed at such an early age, my recovery was relatively quick and the cost of treatment was significantly less if the cancer had been more advanced.

I strongly feel that all women in their forties should have full information in order to make informed, personal decisions about mammography. Many consumers, however, look to the opinion of a body of experts, such as the consensus panel, to interpret data and provide recommendations which they can weigh as they make decisions. The present NIH statement does nothing more than confuse the public about an extremely important issue. A strong consensus would also help to guarantee women in their forties the necessary insurance coverage for mammography.

When the Race for the Cure® began in Pittsburgh in 1993, a woman died every 11 minutes from breast cancer. Today, a woman dies every 12 minutes. Over 2,000 additional lives are saved each year with early detection. Our mutual goal should be to add 1 minute each year in the hope that more and more women survive breast cancer.

With your help we can "race for the cure."

STATISTICS

Senator SPECTER. Thank you very much, Ms. Moser. When you cite the statistics about a women dying every 11 minutes, now every 12 minutes, is that a national figure?

Ms. MOSER. Yes; it is.

Senator SPECTER. The statistic which you cite about 18 percent being detected in the forties contrasted with between 15 and 16 percent in the fifties, what is the basis for that statistical study?

Ms. MOSER. That comes from the American Cancer Surveillance Statistics, 1995.

Senator SPECTER. One of the questions which we are going to put to the panel of the NIH is what they did with that kind of information. It looks like fairly persuasive evidence for screening in the forties.

You say that you had a mammogram at 40 and it showed signs of calcification. They told you to come back in 6 months?

Ms. MOSER. Yes.

Senator SPECTER. What did the doctor say to you when you went back sooner?

Ms. MOSER. Actually, I changed doctors.

Senator SPECTER. You changed doctors. I did, too.

Ms. MOSER. I am glad. It was good for both of us.

I decided to get a second opinion. The second doctor, I should say, also said 85 percent calcifications, we can do this in 6 months, and I said, "Why? So that it can get worse? Let us find out what it is now." And he was willing to play ball with me.

Senator SPECTER. And when did you have the later exam to show recurrence?

Ms. MOSER. Well, I had a yearly mammogram after that, yearly, and then this past September, the calcifications reappeared all over the breast.

Senator SPECTER. And may I ask you how old you were last September?

Ms. MOSER. I was 49.

Senator SPECTER. And may I ask you what you are doing about that? What sort of treatment are you having?

Ms. MOSER. I have had a mastectomy. I have had reconstruction since then as well, and I am racing for the cure every day.

Senator SPECTER. Well, at 40, how many miles did you run every day?

Ms. MOSER. Seven.

Senator SPECTER. How many miles are you running now?

Ms. MOSER. Eight. [Laughter.]

Senator SPECTER. Very impressive, Ms. Moser. Thank you very much. There are 7,600 vouchers that you have provided for women who could not afford mammography?

Ms. MOSER. Yes; that is through the mammogram voucher program. Some 75 percent of the money that the Race for the Cure raises stays in the Pittsburgh area and we provide the mammograms and followup diagnostic services to women who cannot afford them.

Senator SPECTER. And 56 detections from the 7,600?

Ms. MOSER. Yes.

Senator SPECTER. Do you have a breakdown as to how many of those women were in their forties?

Ms. MOSER. No; I do not. I certainly could get that.

Senator SPECTER. Could you? The subcommittee would be very interested in that. Now, 75 percent of the money stays in Pittsburgh. Where does the other 25 percent go?

Ms. MOSER. It goes to the Komen Foundation in Texas for national research. The Pittsburgh race is 1 of 77 that take place all over the country. There is a Mother's Day race in Philadelphia as well.

Senator SPECTER. I have been in it.

Ms. MOSER. I am sure you have.

SUMMARY STATEMENT OF JUDY POTTGEN

Senator SPECTER. We now turn to Ms. Judy Pottgen, an active volunteer with the American Cancer Society, a 4-year breast cancer survivor, mother of three daughters.

She was diagnosed with breast cancer when she was 43. She now tours high schools in Allegheny County teaching junior and senior class girls how to do self-breast examination.

Welcome, Ms. Pottgen, and the floor is yours.

Ms. POTTGEN. Thank you very much.

I am a 47-year-old woman who is a wife and mother of three wonderful daughters ages 23, 17, and 13. Other than my daughters, I feel my greatest accomplishment is having survived breast cancer for nearly 4 years.

In April 1993 when I was 43 years old, I found a lump in my right breast while doing self-breast exam. I had a mammogram and the radiologist referred me to my surgeon.

I was told I needed a biopsy, and when the results came back, my greatest fear became reality. It was cancer. I had a modified radical mastectomy in May of that year, and adjuvant chemotherapy that lasted for 3 months.

When my treatment was completed in August, I felt in my heart that it was the beginning of the rest of my life. What a wonderful

feeling, to know that you have been one of the lucky ones to have faced possible death and knocked it flat on its bottom.

Battling this disease has certainly given me a new outlook on life. I now appreciate all the wonderful things around me—my family, nature, especially a beautiful sunset—and I do not take any day for granted anymore.

There are three very important aspects to maintaining breast health. Breast self-exam is the first phase of breast health and should be taught to all teenage girls. No one knows their own bodies better than themselves.

I am very passionate about this because self-exams are every woman's first line of defense against breast cancer. Because I found a lump in my breast at a very early stage, it saved my life.

I have been very passionate also about educating my three daughters and educating other young women about breast health care. We have a wonderful program here in Pittsburgh called Check it Out. This is a 3-year-old project sponsored by the American Cancer Society of which, as you said, I am a very active volunteer; by Hadassah, which is a Jewish women's organization, and the Allegheny County Board of Health.

This program teaches junior and senior high school girls the proper way to do self-breast exam. We have visited almost 40 high schools so far. We are providing these young women with the knowledge and proper procedures they need to detect changes in their breasts and to seek medical attention, God forbid, should they later in life be faced with the same thing I was. The second aspect of good breast health is a clinic examination done by a physician. Through training and experience, doctors can tell what some lumps are just by touch. The last part of preventive breast care and arguably the best is the mammogram. Mammography can detect a lump long before a woman can feel it or even before her doctor can detect it. What is the best cure for breast cancer? Early detection. And early detection must include mammography.

For some reason, incidence of breast cancer is higher in Allegheny County than the national norm. As the mother of three daughters, I feel a woman should have her initial baseline mammogram taken at the age of 40 if not even at the age of 35. I know I will insist that my daughters have their baseline at the age of 30, then repeated at 35, and every year from the age of 40. Breast cancer used to be called a disease of older women, but I am aware of younger women in their twenties and thirties who are developing this terrible disease. I was only 43, and I really do not think of that as old.

PREPARED STATEMENT

Preventive medicine is a lot cheaper than therapeutic medicine. It is cheaper to have a mammogram than to have major surgery and radiation or chemotherapy. Years ago, the National Institute of Health concluded that a yearly pap smear was unnecessary. How many women unnecessarily developed cervical cancer and died because of this policy? Is it going to be the same story with a mammogram? Will more women have to lose their breasts or be disfigured or will they have to die from this dreaded disease before NIH realizes the tremendous diagnostic benefit to preventive care

they have with a mammogram? A mammogram cannot hurt us, but it can save our lives.

[The statement follows:]

PREPARED STATEMENT OF JUDY POTTGEN

My name is Judy Pottgen, I am a 47 year old woman who is a wife, and mother of three wonderful daughters ages 23, 17, and 13. Other than my daughters, my greatest accomplishment is having survived breast cancer for nearly 4 years. In April 1993, when I was 43 years old, I found a lump in my right breast while doing self-breast exam. I had a mammogram, and the radiologist referred me to my surgeon. I was told I needed a biopsy and when the results came back, my greatest fear became reality, it was cancer. I had a modified radical mastectomy in May of that year, and adjuvant chemotherapy that lasted for 3 months. When my treatment was completed in August, I felt in my heart that it was the beginning of the rest of my life. What a wonderful feeling to know that you have been one of the lucky ones to have faced possible death, and knocked it flat on its bottom. Battling this disease has certainly given me a new outlook on life. I now appreciate all the wonderful things around me, my family, nature, especially a beautiful sunset and I don't take any day for granted anymore.

There are three very important aspects to maintaining breast health. Breast self-exam is the first phase of breast health and should be taught to all teenage girls. No one knows their own bodies better than themselves. I am very passionate about this, because self-exams are every woman's first line of defense against breast cancer.

Because I found a lump in my breast at a very early stage, it saved my life. I have been very passionate about education my three daughters and education other young women about breast health care. We have a wonderful program in Pittsburgh called Check It Out. This is a 3-year-old project sponsored by the American Cancer Society, of which I am an active volunteer, Hadassah, a Jewish women's organization and the Allegheny County Board of Health. This program teaches Junior and Senior high school girls the proper way to do self-breast exam. We have visited 40 high schools so far.

We are providing these young women the knowledge and proper procedures they need to detect changes in their breasts and to seek medical attention. God forbid, should they later in life be faced with the same thing I was. The second aspect of good breast care is the clinical examination done by a physician. Through training and experience doctors can tell what some lumps are just by touch. The last part of preventive breast care, but arguably the best, is the mammogram. Mammography can detect a lump long before a woman can feel it, or even long before her doctor can detect it. What is the best cure for breast cancer? Early detection. And early detection must include mammography. For some reason, incidence of breast cancer is higher in Allegheny County than the national norm. As the mother of three daughters, I feel very strongly that a woman should have her initial base line mammogram taken at the age of 40, if not even at 35. I know I will insist that my daughters have their base line at the age of 30, and then repeal it at 35, and then every year from the age of 40. Breast cancer used to be a disease of "older women" but I am aware of younger women, in their twenties and thirties who are developing this terrible disease. I was only 43, and I certainly don't think of that as "old."

Preventive medicine is a lot cheaper than therapeutic medicine. It is cheaper to have a mammogram than to have major surgery and radiation or chemotherapy. Years ago, the National Institute of Health concluded that a yearly pap smear was unnecessary. How many women unnecessarily developed cervical cancer and died because of this policy? Is it going to be the same story with a mammogram? Will more women have to lose their breasts or be disfigured or will they have to die from this dreaded disease before NIH realizes the tremendous diagnostic benefit to preventive care they have with a mammogram? A mammogram can't hurt us, but it can save our lives.

SELF-EXAMINATION

Senator SPECTER. Thank you very much, Mrs. Pottgen, for that testimony. You found the lump through self-examination at the age of 43?

Ms. POTTGEN. Right.

Senator SPECTER. And when did you begin that self-examination?

Ms. POTTGEN. I started when I was 38. My obstetrician gynecologist taught me how to do it, and really that was very late. I should have been doing it from the age of 18, 19, or 20.

Senator SPECTER. Well, you are counseling high school young women about self-examination. What does the evidence show as to the incidence of breast cancer in women at that age?

Ms. POTTGEN. They are really not at a very high risk. The statistics that I have heard doing this program is maybe one in 25,000 girls between the ages of 18 and I guess 21, 22. It is not a high risk.

Senator SPECTER. How about earlier than 18? Because you are counseling young women who are younger than 18.

Ms. POTTGEN. I really do not think they are at a high risk at all. However, the sooner they become familiar with their bodies, the better off they will be able to determine, God forbid, that they do have a change in their breast, they would be able to determine it earlier.

Senator SPECTER. The thought crosses my mind as to whether they might be discouraged from maintaining it all their lives until they get to be at an age where it really becomes very germane.

Ms. POTTGEN. Hopefully, it becomes a habit like brushing your teeth every morning when you get out of bed. When these girls are due for their monthly self-exam, hopefully it will just become habit and it would be an automatic thing.

Senator SPECTER. I find your testimony interesting where you say you should have a baseline at 40 or maybe at 35.

Ms. POTTGEN. Yes.

Senator SPECTER. Your children at 30?

Ms. POTTGEN. Absolutely, because I had breast cancer, and I have three girls.

Senator SPECTER. Why not for everybody at 30?

Ms. POTTGEN. Oh, I am a full proponent of that, but I am just talking about my own children, and since they cannot decide that we really need it before the age of 50, I really do not believe that the NIH would make a proposal to bring it down to 30. That would be terrific.

Senator SPECTER. The question is, what would the cost be? Why not? If you can take them in off hours, we have enough mammogram machines, take them late at night, take them at a time when they are very low cost, marginal cost, why not?

Ms. POTTGEN. I agree.

Senator SPECTER. If we have the machines.

Ms. POTTGEN. I did hear you ask about the cost, if somebody would have breast cancer how much would it cost to have the followup therapy.

I did have a mastectomy and I did have chemotherapy, and I did see my doctor bills, and it was outrageous.

Senator SPECTER. Well, there you are as to the cost. If it is not detected early, the costs go up and up and up.

Ms. POTTGEN. Yes.

Senator SPECTER. Let me pose a question to the panel generally. There have been debates as to whether there ought to be a mammogram every year, even some challenges to a mammogram for women over 50.

How often do you think there ought to be a mammogram for women 50 and older, Ms. Clayton?

Ms. CLAYTON. For 50 and over, Senator?

Senator SPECTER. Yes.

Ms. CLAYTON. I think by the time a woman is 50 years old, a routine annual mammogram.

Senator SPECTER. Forty and over?

Ms. CLAYTON. Forty and over, absolutely.

Senator SPECTER. How often?

Ms. CLAYTON. I will give my own story. I had my first baseline when I was 40 years old. I had a mammogram the following year when I was 42. I didn't go back for 4 years. I cannot beat myself up about not having caught it even earlier, but there was a 4-year interim.

Senator SPECTER. Too long?

Ms. CLAYTON. Probably, although I advocate every year.

Senator SPECTER. How often do you think women over 40 should have it? Forty to fifty, how often?

Ms. CLAYTON. Every year.

Senator SPECTER. How about under 40? Should we have mammograms for women under 40 who are not with a family history?

Ms. CLAYTON. I did not have a family history.

Senator SPECTER. That is why I am asking you.

Ms. CLAYTON. I would and will encourage all my nieces to have their first baseline earlier than 40 if they can do that.

Senator SPECTER. Does anybody here disagree with Mrs. Clayton's testimony?

Ms. MOSER. I do not disagree with it, Senator. I would like just to reinforce what the American Cancer Society has said for years, that a woman 50 and older should have one every year, a woman 40 to 49 without risk should have it every 1 to 2 years, and then women younger than that if there is families at great risk.

Senator SPECTER. Do you think 1 to 2 years is often enough, Ms. Moser, for women 40 to 49?

Ms. MOSER. I think if a women is showing no risk, I think that that is ample. I think it is also interesting that the NIH used to follow those guidelines and has given them up, and that is what is causing so much confusion.

Senator SPECTER. I would like your sense on this gene therapy at the current stage of what can be done with it. You have heard the doctors' testimony that it leads to screening, but I would be interested in your evaluation.

Ms. Pottgen, what kind of anxiety do you think would be present for a woman who finds at the age of 15, she has a gene which shows a propensity for breast cancer?

Ms. POTTGEN. When I first heard about the gene and that they would probably be able to tell somebody if they would be at high risk, needless to say the first thing I thought about were my 3 girls, and I did debate the issue with my oldest daughter, who is now 23. She was maybe 20, 19 at the time.

Senator SPECTER. How did the debate turn out?

Ms. POTTGEN. Well, I said to her, "Would you want to know? Would you want to have this blood test done so you would know?" And she said, not really, because the fear of developing breast can-

cer, even though there's a good possibility that she would not, would be great.

Senator SPECTER. She has substantial concern, naturally, from your experience.

Ms. POTTGEN. Right, right. She still said that doing self-breast exam and having a mammogram, that that would be enough for her.

Senator SPECTER. Ms. Durham, what do you think about having young women told about positive genes, that a gene shows them positive for breast cancer?

Ms. DURHAM. If I was the young woman, it would be an overwhelming burden, worrisome trouble for me. I do not think that I would want to know beforehand. It would just cause me to be too anxious all the time.

Senator SPECTER. You would rather not know?

Ms. DURHAM. I would rather not know, yes.

Senator SPECTER. Ms. Clayton, you talked about ignorance not being bliss. What do you think about the gene detection for very young women?

Ms. CLAYTON. I think it is real tough.

Senator SPECTER. Excuse me?

Ms. CLAYTON. I think it is tough. I think it would be very difficult to know. I think it would be harder to know who has access to that information.

Senator SPECTER. Suppose we could guarantee the privacy? There are no absolutes, but suppose we had a Federal law which said insurance companies could not find it, and if they found it, they could not act on it, death penalty for anybody who invades your privacy or something more severe.

Ms. CLAYTON. Personally, I would want to know, having been through it. You do not know until you have been there. I personally would want to know.

Senator SPECTER. Ms. Moser, what do you think about that question?

Ms. MOSER. I would like to know so that I could follow myself more closely, yes.

Senator SPECTER. Well, thank you very much for your testimony. You are all survivors. I compliment you on your activism and on your battle.

We have a very major problem here. It is a little inconceivable to me on the face of the evidence how the consensus panel could make a public declaration that women 40 to 49 are not warranted for mammogram in that age category.

We have pursued why they made the disclosure, and they have tried to explain it, saying they did not really come to that conclusion, they only had a draft report. Why did they get it into the public domain? There is no good answer for that.

A press release had been prepared which should not have been disclosed and it was disclosed, and now we face a situation where apparently the National Cancer Institute is reluctant to overturn what the panel said, and a lot of people are saying, "Well, let us not pressure science."

Senator Snow introduced a sense of the Senate resolution, essentially calling for mammograms at 40 to 49, and there is an op-ed

piece in the Washington Post criticizing Senator Snow for trying to push scientists.

So it is quite an issue, and I find these hearings to be very informative as to what the doctors have to say and how women are feeling about it.

I know from before this issue came, how the terror is present from my own family, from my wife who was concerned about the issue going back for many, many, many, years.

And the medical profession has to do a better job in informing people as to what is going on. And I know, when I had my problem, I got bad information from a doctor, and it scares you to death when you get bad information.

Doctors have to know enough to perhaps defer a statement at least for a few days until they have a followup test before they give you false information. They cannot be faulted for giving false information under some circumstances, but giving it prematurely is a real problem.

So these are very, very big issues for sensitizing all of us, and the subcommittee will be pursuing it. We are going to have some more hearings.

Usually when we have these hearings, I say I want to find out what the facts are. I said at the outset of our hearing in Washington a couple of weeks ago that I had a fixed opinion. That is a legal expression, when jurors cannot serve if you have a fixed opinion, but I wanted to say at the outset that I did. Even a fixed opinion can be altered, but what I have heard just confirms the opinion that I started with.

Does anybody want to make a closing statement?

Ms. DURHAM. I just wanted to make a comment, Senator, because I spoke to your staff person, Sharon Wagner, a couple times. And I can assure you, I did know your position. I even asked her, was your wife a breast cancer survivor. So I got a little nervous. I do not want it to be thought that I did not know your position.

SUBCOMMITTEE RECESS

Senator SPECTER. Well, I appreciate that. Joan is not a survivor, but she was very concerned with one troubling incident. Back in 1971, I will never forget the day. It was a negative, but real terror. When you look at the statistics, there is cause for the concern.

Thank you, and that concludes our hearing, the subcommittee will recess and reconvene at the call of the Chair.

[Whereupon, at 11:30 a.m., Monday, February 24, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

MAMMOGRAPHY

MONDAY, MARCH 3, 1997

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Hershey, PA.

The subcommittee met at 10:30 a.m., in the Hershey Medical Center, Hershey, PA, Hon. Arlen Specter (chairman) presiding.

Present: Senator Specter.

NONDEPARTMENTAL WITNESSES

STATEMENTS OF:

JAMES F. EVANS, M.D., DIRECTOR, SURGICAL ONCOLOGY AND ASSISTANT DIRECTOR, GENERAL SURGERY, GEISINGER CLINIC

MARY A. SIMMONDS, M.D., CHIEF, DIVISION OF HEMATOLOGY AND MEDICAL ONCOLOGY, PINNACLE HEALTH SYSTEMS

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OPENING REMARKS OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The hearing of the Appropriations Subcommittee on Labor, Health and Human Services, and Education will now proceed. This hearing has been convened as an official subcommittee field hearing to inquire specifically into the issue of the advisability of having mammograms for women age 40 to 49.

This issue has come upon the scene as the result of a panel determination of an NIH panel, raising a question about the advisability of such mammograms. Immediately after the panel report was filed, Dr. Richard Klausner, Director of the National Cancer Institute, said that he was shocked by the findings of the NIH panel.

The subcommittee then convened a hearing in Washington, DC, this is the third of our field hearings. Earlier hearings having been held in Pittsburgh and Philadelphia.

The essential question is whether the mammograms are useful for women 40 to 49. The question has been raised as to whether cost is the determinant. My own view is that the U.S. medical profession has enough doctors, hospitals, mammogram machines, pharmaceutical equipment, MRI's, et cetera, to bring health care to all Americans and that it is a matter of delivering it and paying for it.

I chair the Subcommittee on Health and Human Services. And last year Senator Tom Harkin, who is the ranking Democrat, and I, worked together on a bipartisan basis. That is the way things get done in Washington, DC, when Democrats and Republicans work together.

Senator Harkin and I working together consolidated or eliminated some 134 programs so that we were able to reallocate $1½ billion to priority items, such as funding for the National Institute of Health and Pell grants and guaranteed student loans with our views being that two of the highest priorities, if not the highest priorities of America were education and NIH research.

I recently had a medical problem and after some travail got an MRI. The doctors said I did not need one. And I got one. I understand that I am in a little better position than many to get an MRI if I want one. The doctors did not think I should have one. And it disclosed an meningioma which was life threatening and it, in effect, saved my life. So, you can see my point of origin on this issue, that if we can save lives it is very important.

We have had statistical evidence produced which suggests that many women's lives can be saved in the age category 40 to 49. And we are here today to hear testimony from medical experts and also from women in the field.

Tomorrow in Washington, we will have a hearing where Secretary of Health and Human Services, Donna Shalala, will testify. It may be that there will be an administrative decision by the Secretary of Health and Human Services with coverage for women 40 to 49 in Medicaid and Medicare. And that would be an enormous step forward.

It is my hope that the legislation will not be necessary, we will not have Congress micromanaging the health care field, but if it is necessary we will consider it in due course.

With that introduction, I want to now turn to our distinguished panel, Dr. James F. Evans, Dr. Mary A. Simmonds, and Dr. David Van Hook. It is our practice with a panel of this caliber to go alphabetically and not to try to make any judgments among the panelists.

So, in alphabetical order, we turn to Dr. James F. Evans, who is director of surgical oncology at the Geisinger Clinic and an assistant professor of surgery at Jefferson Medical College. Dr. Evans received his medical degree from Columbia University's College of Physicians and Surgeons. He has been a fellow in surgical oncology at Memorial Sloane Kettering Cancer Center and is a principal investigator for the national surgical breast project. He is also past chairman of the American Cancer Society breast cancer detection task force.

SUMMARY STATEMENT OF DR. JAMES EVANS

We welcome you here, Dr. Evans. Your full statement will be made a part of the record as is our custom. And I ask also, as is our custom, that there be a limit to 5 minutes on opening statements to allow the maximum opportunity for dialog, questions and answers as we proceed. Dr. Evans, the floor is yours.

Dr. EVANS. Thank you. Mr. Chairman, members of the committee, members of the Pennsylvania Breast Cancer Coalition and

guests, I am honored to have the opportunity to provide my personal opinion to the subcommittee today.

I believe you all have my written comments and I have tried several times to read them aloud to myself within 5 minutes. I could never get under 15. So, therefore, I will summarize them and hope that there will be questions which will provide the chance to correct the misconceptions that I have created with 5 minutes of testimony.

These comments are my personal opinion and do not represent any official position of Geisinger. I have studied the issues over the past 20 years. I am familiar with the data. I am familiar with the policy statements of the National Institutes of Health and the American Cancer Society. My comments are not intended to reflect the position of either organization. However, I am amused by the disclaimer of the NIH consensus panel that their statement, "does not provide recommendations for public policy or personal action." Of course, we all understand that the statement will be used for both of these purposes.

We, as advisers to women and to policymakers, cannot just throw up our hands and say, decide for yourselves, as the panel seemed to do. Most women and most of their primary care providers do not have the time or background to analyze the data that the medical community has been debating for decades. It is right to express our uncertainty, but we must provide our opinion.

The panel stated: "the available data do not warrant a single recommendation for mammography for all women in their forties." If I were to write my own consensus statement, it would state that the available data does warrant a single guideline recommendation for women between the ages of 40 and 70 years, namely annual screening. In fact, this is the only firm conclusion to be drawn from the randomized clinical trials.

However, guidelines are not recommendations for individual women. And this is a point to be stressed. Before I give you my abbreviated views of the randomized trials, there are a few caveats that will be more important perhaps than the actual data from the trials.

No. 1, policy decisions, guidelines and personal decisions should be based on science, not on rhetoric. In the press and even in announcements of hearings such as this one, there is frequently more heat than light. Trying to influence the thinking of policymakers with emotional arguments and polarizing one liners rather than with data may be effective in the short run but ultimately detracts from credibility.

Careful analysis of randomized clinical trials data is the best hope for progress. I must parenthetically note that of the eight randomized trials conducted on the question of breast cancer screening, only one, the first one, was conducted in the United States. Perhaps we can explore this issue during questions, but this is not a record of which we should be proud.

No. 2, data are not available to answer all the questions about breast cancer screening. Uncertainty is omnipresent. Therefore, experts may legitimately disagree. Experts must, however, explicitly acknowledge the areas of uncertainty and emphasize that what we conclude today may be altered in the future by new data.

No. 3, setting public policy and writing clinical guidelines is a very different activity from making a recommendation to an individual patient with her unique risk profile and personal life history. Guidelines should derive from clinical trial data. No clinical trial, however, can account for the number of variables and special circumstances which must be accounted for in a decision for an individual.

To re-emphasize this point, what we conclude about the effectiveness of screening for a population, in this case women between the ages of 40 and 70, will not apply equally to all subsets or individuals within the population. Subsets based on age, which is our current focus, is only one such example. This large population could also be divided by family history, personal history, genetic profiles, or characteristics that we have not yet considered. Such subsets may benefit more or less from the recommended generic screening policy.

Turning to the clinical trials, I would make the following points. No. 1, all except one of the randomized clinical trials in breast cancer screening have been designed to answer a very specific question and the question is, does breast cancer screening result in lower death rates from breast cancer for women aged 40 to 70 years. The answer from all the trials is "yes."

I would emphasize that the trials consistently show survival benefit for screening beginning at age 40. When we try to get trial data to answer a question for which the trial is not designed, such as does breast cancer screening result in lower death rates for breast cancer for women 40 to 49, the conclusions are less secure.

No. 2, retrospective subset analysis, for example, going back to look at the benefit in women 40 to 49 from a trial that was designed to study women 40 to 70 is too tempting to avoid. It is also useful. However, subset analysis of the data can be appropriately used or it can be abused. Unfortunately it has been used——

Senator SPECTER. Dr. Evans, would you seek to summarize, please?

Dr. EVANS. I certainly will. No. 3, the only randomized clinical trial that was designed to answer the question about women 40 to 49, as you know, was a negative trial. In fact, the screened women did a little worse. The trial has been severely criticized for design and execution flaws. And these flaws as well as the meta-analysis support those that claim a benefit in women 40 to 49.

My written testimony includes more data on these points and several additional points, but given the time constraints, I will conclude that, No. 1, guidelines for screening mammography should include women 40 to 70 years for annual screening.

No. 2, clinicians and women must adjust these guidelines based on personal characteristics and circumstances. We must recognize these adjustments are based upon best guesses until future clinical trials allow a more precise definition of the correlation between breast cancer risk and screening benefit.

And, No. 3, health care funding should support clinical research, especially randomized clinical trials.

PREPARED STATEMENT

Again, I would like to thank the committee and the Pennsylvania Breast Cancer Coalition for the opportunity to express my opinion. I welcome the opportunity to answer questions and discuss the issues.

Senator SPECTER. Thank you, Dr. Evans. During the questions and answers, we will pick up some of the points you have referred to.

[The statement follows:]

PREPARED STATEMENT OF JAMES F. EVANS, M.D., FACS

Mr. Chairman and members of the Committee, I am honored to have the opportunity to provide my personal opinion to the subcommittee today. Geisinger Clinic and Medical Center has not taken an official position on the subject we are discussing today or on the recent National Institutes of Health Consensus Development Conference Statement. The opinions expressed are strictly my own. I have studied the clinical research data on this subject over the last twenty years. I have reviewed the randomized clinical trial (RCT) data numerous times. I have reviewed the abstracts of the testimony recently presented to the NIH and have read the consensus statement. As co-chair of a consensus development conference sponsored several years ago by the Pennsylvania Department of Health and the Pennsylvania and Philadelphia Divisions of the American Cancer Society, I am familiar with the position of the Cancer Society. My comments are not intended to specifically support the position of either of these organizations.

Every week in the clinical setting, I must advise women on this subject. My recommendations have not changed as a result of the NIH Consensus Statement. I was amused by the conclusion the Consensus Statement that stated, "This consensus statement * * * does not provide recommendations for public policy or personal action." Of course, we all understand that it will be used for both of those purposes. The statement goes on to state that "the available data do not warrant a single recommendation for mammography for all women in their forties. Each woman should decide for herself whether to undergo mammography." Of course, women will decide for themselves. That is inherent in our system of informed consent. However, many of them are not well positioned to understand the nuances of randomized clinical trials, meta analysis, subset analyses and surrogate markers.

In all honesty, neither are their primary health care providers. It is asking too much of women and their providers to evaluate and weigh the data themselves when the "experts" themselves cannot reach consensus. Those women and their providers who do not have the time or expertise to make independent assessments are legitimately asking the NIH, the ACS, and other experts for guidance and specific recommendations. We must provide our opinion even while we admit that there are areas of uncertainty. If I were to write my own consensus statement, it would say that the available data specifically does warrant a single guideline recommendation for women between the ages of 40 and 70 years, namely annual screening.

However, guidelines are not recommendations for individual women. This is a point I will stress. We would all like to have enough data to make specific recommendations for each individual based on personal profiles and highly specific and reliable research data. We must be honest and admit that this sort of data does not exist. The best data that we have comes from randomized clinical trials and that data supports a guideline recommendation for annual screening beginning at age 40. Clinicians and women themselves should then use additional but less reliable data that we have to make decisions for individuals. Ongoing and future research has the potential to refine these recommendations.

Before I complete my testimony, I will give you my abbreviated views of the randomized clinical trials and I will tell you again what I would currently recommend. Before that, however, several caveats are important:

1. Policy decisions, guidelines, and personal decisions should be based on science, not on rhetoric. Clinical research, particularly randomized clinical trials, are invaluable source of information. As incomplete as the data is at the present, the randomized clinical trials that have been conducted over the past thirty years have provided most of what we know about breast cancer screening. Only one of these eight trials has been performed in the U.S., the country with the best and most extensive systems for breast imaging in the world. Support for clinical research is the best hope for answering the remaining questions about breast cancer screening. It is

worrisome that consensus conferences sometimes stifle new creative approaches. If we claim to know what we really do not know, the ethical conduct of clinical research is hampered. It is more worrisome that most managed care organizations have not made clear commitments to clinical research.

2. If we increase our commitment to clinical research and randomized clinical trials, new data will accrue. New clinical trials, longer follow-up of older trials, and new technology all contribute new data. Therefore, what we conclude today will require alteration in the future.

3. Data are not available to answer all of the questions about breast cancer screening. Decisions, therefore, must be made on less than complete and perfect data. This has always been true in medicine and will always remain true. There is always some uncertainty and "experts" may legitimately disagree, recognizing that they are sometimes making their "best guess". It is important, however, to be explicit about which conclusions are secure and which are uncertain, and which justify further research. It is also important to try to quantify the degree of uncertainty.

4. Setting public policy and writing clinical guidelines are very different activities from making a recommendation to an individual patient with her unique risk profile and personal life history. The current changes in health care delivery systems are tending to blend these activities for better or for worse. For the purposes of understanding the issues that we are discussing today, they should be kept distinct. I think you will hear two kinds of testimony today. You will hear from three breast cancer clinicians. I believe they will provide testimony that tries to interpret the data that has accrued from clinical trials, to put this data in perspective, and to give a personal opinion and recommendation. This sort of testimony is useful for setting policy and writing guidelines. You will also hear from three women who are equally dedicated to influencing the outcomes for women with breast cancer. I believe that they have personal or family experiences with breast cancer. I suspect that their testimony will add some narrative that will demonstrate the clear limitations of the use of policy and guidelines as the sole instrument for making decisions for individuals. The personal risk profile and personal life story of a woman in her forties who has cared for a mother or sister dying of breast cancer should not and cannot be ignored in making her choices.

To re-emphasize the point, what we conclude about the effectiveness of screening for a population (e.g., women between the ages of 40 and 70) will not apply equally to all subgroups in the population (e.g., women 40 to 49, or women with strong family histories) and certainly not equally to all individuals. I will come back to this point.

5. The emphasis on mortality data and survival benefits may make us forget that there are other benefits to early breast cancer diagnosis even if the survival benefit is marginal or non-existent. Earlier diagnosis correlates with a greater potential for breast conservation.

Turning to the clinical trials, I would like to make the following points:

1. Six or seven (depending on whether the Swedish Two County Trial is counted as one or two) randomized trials have been conducted to test the effectiveness of breast cancer screening in women between the ages of 40 and 70 years. Some of the trials included women over 45 and others only included those under 65. All of these trials were designed to answer a specific question. The question was, "Does breast cancer screening result in lower death rates from breast cancer for women ages 40 to 70?" The answer from all the trials was and continues to be "yes". I would emphasize that the trials show a survival benefit for screening beginning at age forty. This is the most secure conclusion that we can draw from the randomized clinical trials. Admittedly, it is incomplete. But it is the only one that should, in my opinion, be part of a clinical guideline.

2. So called "subset analysis" is too much of a temptation to avoid during the analysis of data from a randomized trial. It is an attempt to provide evidence for adding to the conclusions for which the trial was initially designed. Once we have determined that the group of women between 40 and 70 years, benefit from screening, we want to know whether subsets of women within the total group benefit more or less. Those subsets could be based on age, family history, prior biopsies, the presence of the BRCA gene, etc., etc. Because subset analysis was begun based on age, we have been arguing that point for the past 15 years.

Subset analysis can be used properly or it can be abused. The results of subset analysis are never as secure as the analysis of the question for which the trial was originally designed. Subset analysis introduces bias that may lead to erroneous conclusions. Subset analysis is best used to get ideas for further research. These trials were not designed to answer thee question of whether breast cancer screening is effective in the specific age group of 40 to 49.

3. Only one randomized trial was specifically designed to answer the question, "Does breast cancer screening in women 40 to 49 years of age result in fewer breast cancer death?" NBSS trial conducted in Canada was specifically designed based on the results of subset analysis of HIP and Swedish trials. As you know, it did not show a benefit. However, it did not settle the debate for two reasons (leaving out the political ones). First, a single trial is rarely enough to provide a definitive answer and usually requires confirmation (witness the number of trials done for women 40 to 70). Second, the trial has been a target of severe criticism based on design and execution flaws.

4. Although drawing conclusions from subset analysis entails greater risk of being wrong, subset analysis from multiple trials that shows similar trends provides additional credence to subset analysis results. The meta-analysis of the 40 to 90 age subsets from multiple trials suggest a survival benefit in this group. Each of the trials individually have "confidence intervals" that include a relative risk of "1". Translated, this means that the improved survival seen has a 5-percent probability of being due to "chance". However, all of the trials show a benefit. If the differences between screened and non-screened populations were non-existent, we would expect to see some individual trials showing a small benefit (by chance) and some a small worsening of survival (by chance). The fact that the "trend" in every trial is toward benefit suggests that the relatively small differences are real. It appears to be smaller than the benefit for women age 50 to 70 and it appears to be delayed. This would not be unexpected given the lower incidence of breast cancer in the 40 to 49 year age group. The question of whether the benefit in women 40 to 49 years is a result of screening after the age of fifty is a legitimate question. However it is not definitively answered by these trials. I suspect the answer will be: "partially". This is a legitimate question for future research. A survival benefit is also supported by the use of "surrogate markers" (tumor size and nodal status) from non-randomized trials. This data demonstrates that mammography seems to diagnose small and node negative breast cancers as well in women 40 to 49 as in older women. Although not as strong as data from randomized trials, it adds to the weight of evidence.

5. We must not forget that subset analysis based on age is only one of several subset analyses that could be done. Women could also be divided based on family history, personal history, genetic markers, etc. Age just happens to be the one chosen first and, therefore, began this controversy through the misuse of subset analysis. There are probably subsets of women in their forties who based on other subset criteria (e.g., family history) derive more benefit from screening than some women in older age groups.

6. Little analysis and discussion has been based on "potential years of life lost" (PYLL). A woman in her forties who avoids a premature death from breast cancer may derive a large benefit than a woman cured of breast cancer at the age of eighty five. Therefore, although the number of deaths avoided per 1,000 women screened in the 40 to 49 age group may be smaller, the years of additional life per individual will probably be larger.

7. Given a survival benefit, the risks of mammography (radiation, false positives, anxiety, pain) are real but justifiable. These risks provide justification for research to find more accurate, less painful, and less anxiety producing methods, but do not provide justification for abandoning an effective diagnostic test.

Conclusions

1. Guidelines for screening mammography should include women ages 40 to 70 for screening. The screening interval in the guideline should be annual.

2. Clinicians and women will need to adjust the guidelines based on personal characteristics. Clinicians and women must recognize that the adjustments are based on "best guesses" until research allows a more defined correlation between breast cancer risk and screening benefit.

3. Health care funding should support clinical research, especially randomized clinical trials.

Again, I wish to thank the committee for the opportunity to express my opinion and welcome the opportunity to answer questions.

SUMMARY STATEMENT OF DR. MARY SIMMONDS

Senator SPECTER. We turn now to Dr. Mary Simmonds, chief of the division of hematology and medical oncology with Pinnacle Health Systems and a clinical associate professor of medicine with Penn State University. She is a member of the board of trustees

for the Pennsylvania Breast Cancer Coalition and serves on the national board of directors for the American Cancer Society, former chair of its Pennsylvania Division's Breast Cancer Detection Awareness Task Force. We welcome you here, Dr. Simmonds. The floor is yours. Your full statement is a part of the record. And we ask for your similar summary within the 5-minute time period.

Dr. SIMMONDS. Thank you. Mr. Chairman, I am grateful to have the privilege to be here today to speak as a practicing oncologist and as a woman in her forties. I support the American Cancer Society recommendations that women in their forties should undergo screening mammography every 1 to 2 years.

A perfect screening tool is accurate, acceptable as a procedure, safe, widely available, and inexpensive. Such a tool should be applied to detect a prevalent disease when early detection will avoid suffering and costs if not found until a more advanced stage.

As medicine is practiced, decisions must be made on an individual basis. The perspective of relative risk factors and incidence of disease within the population must somehow be integrated into an individual health plan. Thus, practice guidelines play an important role in guiding the practitioner and the individual consumer.

Unfortunately, no screening tool is perfect. Mammography included. You have already heard expert testimony analyzing the scientific data, so I will not reiterate these points in my limited time today. Rather, I would speak about the need to accept these limitations, and to endorse a more liberal recommendation to screen women in their forties for the early detection of breast cancer.

Breast cancer is a serious health problem for this age group and the potential impact in suffering and premature death is relatively greater for a younger woman and her family.

The economics of health care are an important and undeniable aspect of this debate. Policymakers are struggling with the issue of the cost effectiveness of mammography. Dr. William Kissick, a leading health economist and professor of public health and preventive medicine at the University of Pennsylvania captures the essence of this issue, I believe, in the title of his book, it is, "Medicine's Dilemma: Infinite Needs versus Finite Resources." In other words, if there were infinite resources, then there would be no debate.

Where the guideline is drawn in the real world is a value judgment. Rational individuals will disagree even with conclusive data. I would argue that the standard needs to be more inclusive, hoping to capture the detection of breast cancer in those women who develop the disease in their forties.

The incidence of the disease is great enough in this age group and furthermore the application of mammography as a screening tool fits the standard criteria. That is, it is accurate, an acceptable procedure to most women, it is safe, widely available and relatively inexpensive compared to the costs of treatment of advanced disease.

Finally, as part of my testimony, I would like to share with you a copy of recommendations for a Statewide plan for the early detection of breast cancer. And your staff already has the booklet.

This was formulated in October 1991 as a result of deliberations of a Pennsylvania Breast Cancer Awareness Consensus Conference.

This conference was convened by the Pennsylvania and Philadelphia divisions of the American Cancer Society and the Pennsylvania Department of Health.

Expert testimony was heard about the benefits and limitations of screening for breast cancer. With this background, invitations were issued to organizations and individuals who represent all aspects of the implementation of screening procedures, such as consumers, government agencies and legislators, insurers, and professional groups.

While some of the statistics in this publication might be updated, many of the recommendations are indeed still relevant. A list is included with this report.

One recommendation stands out. And that is four simple unambiguous consistent messages should be communicated to all women concerning mammography. That is, first, mammography saves lives. Second, you should get mammograms even if you do not have symptoms. Third, ask your doctor for information about mammography and for access to mammography. And finally, follow the American Cancer Society guidelines for the frequency of mammography and physical examination.

PREPARED STATEMENT

This recommendation underscores the need for guidelines. These guidelines must be clear for the sake of both the provider and the consumer. It is time to see this debate for what it is, and to stop sending mixed messages to women who may develop breast cancer.

Thank you for the opportunity to present this statement. And I will be glad to answer any questions.

Senator SPECTER. Thank you very much, Dr. Simmonds. And we will have some questions for you on this very impressive publication.

[The statement follows:]

PREPARED STATEMENT OF MARY SIMMONDS, M.D.

Mr. Chairman and Members of the Committee, I am grateful for the privilege to be here today to speak as a practicing oncologist and as a woman in her forties. I support the American Cancer Society recommendations that women in their forties should undergo screening mammography every 1 to 2 years.

A perfect screening tool is: accurate; acceptable as a procedure; safe; widely available; and inexpensive.

Such a tool should be applied to detect a prevalent disease when early detection will avoid suffering and costs if found at a more advanced stage.

As medicine is practiced, decisions must be made on an individual basis. The perspective of relative risk factors and incidence of disease within the population must somehow be integrated into an individual health plan. Thus practice guidelines play an important role in guiding the practitioner and the individual consumer.

Unfortunately, no screening tool is perfect, mammography included. You have already heard expert testimony analyzing the scientific data, so I will not re-iterate these points in my limited time today. Rather, I would speak about the need to accept these limitations and to endorse a more liberal recommendation to screen women in their forties for the early detection of breast cancer. Breast cancer is a serious health problem for this age group, and the potential impact in suffering and premature death is relatively greater for a younger woman and her family.

The economics of health care are an important and undeniable aspect of this debate. Policy makers are struggling with the issue of cost-effectiveness of mammography. Dr. William Kissick, a leading health economist and Professor of Public Health and Preventive Medicine at the University of Pennsylvania captures the essence of the issue, I believe, in the title of his book Medicine's Dilemma: Infinite

Needs vs. Finite Resources. In other words, if there were infinite resources, then this debate would be resolved.

Where the guide-line is drawn is, in the real world, is a value judgment. Rational individuals will disagree, even with conclusive data. I would argue that the standard needs to be more inclusive, hoping to capture the detection of breast cancer in those women who develop this disease in their forties. The incidence of the disease is great enough in this age group. Furthermore, the application of mammography as a screening tool fits the standard criteria. That is, it is accurate, an acceptable procedure to most women, safe, widely available, and relatively inexpensive compared to the costs of treatment of advanced disease.

Finally, as part of my testimony, I would like to share with you a copy of Recommendations for a Statewide Plan for the Early Detection of Breast Cancer formulated in October, 1991 as a result of deliberations of a Pennsylvania Breast Cancer Awareness Consensus Conference. This conference was convened by the Pennsylvania and Philadelphia Divisions of the American Cancer Society and the Pennsylvania Department of Health. Expert testimony was heard about the benefits and limitations of screening for breast cancer. With this background, invitations were issued to organizations and individuals who represent all aspects of the implementation of screening procedures such as consumers, government agencies and legislators, insurers, and professional groups. While some of the statistics in this publication can be updated, many of the recommended actions are indeed still relevant. The list of these recommendations is attached to this report.

One recommendation stands out; four simple, unambiguous, consistent messages should be communicated to all women concerning mammography:

—mammography saves lives;
—you should get mammograms even if you don't have symptoms;
—ask your doctor for information about mammography and for access to mammography; and
—follow the American Cancer Society guidelines for the frequency of mammography and physical examination of the breast as well as the performance of breast self examinations.

This recommendation underscores the need for guidelines These guidelines must be clear for the sake of both the provider and the consumer. It is time to see the debate for what it is, and to stop sending mixed messages to women who may develop breast cancer.

RECOMMENDATIONS FOR A STATEWIDE PLAN FOR THE EARLY DETECTION OF BREAST CANCER

[Pennsylvania breast cancer consensus conference—action groups]

Recommended actions	Consumers	Department of Health and Government agencies	Legislators	Insurers	Media	Professional associations and American Cancer Society	Primary care physicians	Radiologists	Health services and radiology facilities
Review and, if necessary, change regulations and legislation to insure uniformly high quality mammography services throughout the State		X	X						
Introduce into the legislature, legislation to improve quality assurance		X	X						
Encourage mammography facilities throughout the Commonwealth to obtain American College of Radiology accreditation and to comply with State regulations for radiation protection		X				X			
Distribute an updated list of American College of Radiology accredited facilities to referring physicians and the general public		X				X			
Develop and promulgate a standardized classification format for screening mammograms		X				X			
Promote continuing education programs for radiologists and technicians involved in mammography		X				X		X	X
Encourage regional consortia of mammography providers in which community facilities have close, supportive relationships with cancer centers		X							X
Communicate the four, simple, unambiguous, consistent messages to all women concerning mammography		X			X	X	X	X	X
Develop educational programs and messages that target older and minority women and other groups who are less likely to receive mammograms or breast examinations or to do breast self-examination						X			
Develop a clearinghouse for breast health education materials		X				X			
Include presentations concerning the need for and conduct of regular breast screening in medical school, residency, and fellowship training of physicians						X			

RECOMMENDATIONS FOR A STATEWIDE PLAN FOR THE EARLY DETECTION OF BREAST CANCER—Continued

[Pennsylvania breast cancer consensus conference—action groups]

Recommended actions	Consumers	Department of Health and Government agencies	Legislators	Insurers	Media	Professional associations and American Cancer Society	Primary care physicians	Radiologists	Health services and radiology facilities
Promote continuing medical education programs in breast cancer education, screening, and detection for all health professionals		X				X			X
Encourage innovative programs which utilize the best available technology						X			
Disseminate information about the value of breast cancer screening and mammography through physician, American Cancer Society and/or radiologist generated newsletters						X			
Develop a standardized reporting system for results of screening mammograms		X				X	X	X	
Encourage mammography facilities to offer flexible hours, mobile technology, reasonable costs, sliding fee scales, child care, acceptance of self referrals, and offering free mammograms periodically	X				X	X		X	X
Institute dedicated mammography programs at radiology facilities that are designed to provide services to a maximum number of patients both for initial mammograms and for periodic re-examinations as recommended by the American Cancer Society		X				X		X	X
Encourage employers to subsidize worksite screening programs	X			X	X				
Lobby State and Federal legislators to extend coverage, using public funds, to pay for mammograms for uninsured and underinsured women	X		X	X	X	X		X	X
Review Medicare reimbursement schedules periodically to ensure they reflect the latest scientific data and the best standards of practice at the lowest-possible cost		X	X			X			

Compute trends in cancer incidence, stage at diagnosis and deaths from the Pennsylvania Cancer Registry and the Pennsylvania Vital Statistics files to permit effective epidemiological surveillance		X							
Study breast cancer screening practices among residents of Pennsylvania in order to determine the characteristics of women who are and are not receiving screening mammograms as well as reasons for their behaviors		X							
Study the distribution and characteristics of mammography equipment in the Commonwealth to determine the quantity, quality, and location of mammography services available		X							
Develop ongoing data collection systems that would permit an evaluation of screening results and accuracy		X				X	X	X	X

SUMMARY STATEMENT OF DR. DAVID VAN HOOK

Senator SPECTER. We turn now to Dr. David Van Hook, assistant professor of radiology and chief of mammography here at the Hershey Medical Center, graduate of the University of Missouri School of Medicine and a member of the Radiological Society of North America and the Society for Breast Imaging. Welcome, Dr. Van Hook. Your full statement will be made a part of the record, and you are aware of our time limitations, so the floor is yours.

Dr. VAN HOOK. Thank you, Senator Specter, members of the panel and members of the Pennsylvania Breast Cancer Coalition.

Breast cancer is a terrible disease. Today in the United States breast cancer is the single most common malignancy in women ages 40 to 49. It is the leading cause of death in women ages 40 to 49. In the United States today, more than 10,000 deaths per year occur among women who develop breast cancer between the ages of 40 and 49.

Population screening for breast cancer is a good thing if early intervention leads to overall benefit to the population as measured by reduced mortality or by overall savings for the health care system or both.

For women over the age of 50, there seems to be little doubt that these benefits can be achieved by screening with mammography. In 1995, the National Cancer Institute reported for the first time ever a 5-percent reduction in breast cancer mortality which occurred from 1989 to 1992. They acknowledge that to some degree this reduction was likely due in part to the increased utilization of screening mammography.

But in January 1997, the NIH announced that there was insufficient scientific evidence to justify a recommendation for breast cancer screening for women under the age of 50. Although an analysis of combined data from seven population-based randomized control trials which included over 170,000 women in their forties and published in 1995 demonstrated a statistically-significant benefit in reducing mortality from breast cancer, and data from several other nonrandomized screening studies also support a benefit to women ages 40 to 49, the problem seems to be that thus far there has been no single randomized control trial which has shown statistically significant proof of benefit of mammography screening for women ages 40 to 49.

It seems intuitive that a screening test designed to minimize the impact of a disease on members of a population by early detection and treatment would benefit that population. But the process of determining the most appropriate strategy for screening is enormously complex and expensive. And it should be equally intuitive that not every screening test will be beneficial or cost effective for all members of the population in all cases.

It may be, in fact, that there really is no such thing as the perfect study to assess the benefits of screening to the satisfaction of everyone, especially in this age of cost containment. If this is true, then is it right to ignore the significance of the accumulated evidence that does support the benefit from screening? Do we say, well, this is prevention, we are not forced to act when many, if not

most, of the decisions that are made in daily medical practice are not made on the basis of statistically significant scientific proof?

The controversy over screening mammography has continued for 20 years and seems no closer to resolution today. But if anything is clear as a result of this latest random debate, it is that there is far more at stake here than just dollars spent to save lives, that there is far more involved here than just having to try to make some sense of the statistical mumbo-jumbo required for scientific proof of something.

PREPARED STATEMENT

The decisions regarding health care and intervention which affects our society perhaps involve not only science but should also take into account the willingness of those most affected by those decisions to accept some degree of uncertainty, especially when there is controversy or less than scientific proof of benefit. The beneficiaries of breast cancer screening, those who stand to gain or lose the most from it, our mothers, wives and daughters, are willing to do just that.

We the remainder of society should respect that and act accordingly. Thank you.

Senator SPECTER. Thank you very much, Dr. Van Hook.

[The statement follows:]

PREPARED STATEMENT OF DAVID VAN HOOK

1. Today, in the United States, breast cancer is:
—the single most common malignancy in women ages 40–49; and
—the leading cause of death in women ages 40–49.

2. In the United States, more than 10,000 deaths per year occur among women who develop breast cancer between the ages of 40–49.

3. Population screening for breast cancer is a good thing if early intervention leads to overall benefit to the population, as measured by reduced mortality, or by overall savings for the health care system, or both. For women over the age of 50 there seems to be little doubt that these benefits can be achieved by screening with mammography.

4. In 1995, the National Cancer Institute reported, for the first time ever, a 5-percent reduction in breast cancer mortality, which occurred from 1989 to 1992. They acknowledge that to some degree this reduction was likely due in part to the increased utilization of screening mammography.

5. But, in January 1997, the NIH announced that there was insufficient scientific evidence to justify a recommendation for breast cancer screening for women under age 50.

6. Although an analysis of combined data from seven population-based randomized-controlled-trials, which included over 170,000 women in their forties, published in 1995, demonstrated a statistically significant benefit in reducing mortality from breast cancer, and data from several other non-randomized screening studies also support a benefit to women 40–49. The problem seems to be that thus far there has been no single randomized-controlled trial which has showed statistically-significant "proof" of benefit from mammography screening for women ages 40–49.

7. It seems intuitive that a screening test designed to minimize the impacts of disease on members of a population by early detection and treatment would benefit that population.

But, the process of determining the most appropriate strategy for screening is enormously complex and expensive, and, it should be equally intuitive that not every screening test will be beneficial or cost-effective for all members of a population in all cases.

8. It may be, in fact, that there really is no such thing as the "perfect" study to assess the benefits of screening to the satisfaction of everyone, especially in this age of cost containment.

9. If this is true, then is it right to ignore the significance of the accumulated evidence that does support a benefit from screening?

Do we say, "ah, well, this is prevention, we are not forced to act", when many, if not most of the decisions that are made daily in medical practice are-not-made on the basis of statistically-significant-scientific-proof.

10. The controversy over screening mammography has continued for over 20 years, and seems no closer to resolution today.

11. But, if anything is clear as a result of this latest round of debate, it is that there is far more at stake here than just dollars spent to save lives, that there is far more involved here than just having to try to make some sense of the statistical "mumbo-jumbo" required for scientific proof of something.

12. The decisions regarding a health care intervention which affects our society should, perhaps, involve not only science, but should also take into account the willingness of those most affected by those decisions to accept some degree of uncertainty, especially when there is controversy or less than scientific "proof" of benefit.

13. The beneficiaries of breast cancer screening, those who stand to gain or lose the most from it, our mothers, wives, and daughters are willing to do just that.

14. We, the remainder of society, should respect that and act accordingly.

IMPACT OF MAMMOGRAPHY

Senator SPECTER. Let me begin with the question as to the impact of mammography. We had some very impressive testimony in Pittsburgh on this subject from a number of doctors, including Dr. Victor Vogel, who said this, there are nearly 1,000,000 women in Pennsylvania between the ages of 40 and 49. And nearly 2,000 will be diagnosed with breast cancer this year. As many as 1,000 of these women may die. It is my opinion that we could reduce the number by approximately 250 deaths if women between the ages of 40 and 49 were screened annually with mammography.

Now, I realize that you do not have any scientific data, but starting with you, Dr. Evans, would you say that that was within the ballpark figure as to what your expectation would be?

Dr. EVANS. Yes; I think it is. The randomized trials suggest there is no proof but certainly strongly suggest a benefit for women in this age group. And it may be smaller than the benefit for women in the older age groups, but the data would suggest that perhaps 1 or 2 lives per 1,000 women screened might be a ballpark figure in terms of the expected benefit from screening in this age group.

Senator SPECTER. Dr. Vogel is suggesting substantially more, suggesting that if you have 1 million women you may save as many as 250 lives. Dr. Simmonds, what would your sense be as to Dr. Vogel's statement?

Dr. SIMMONDS. I would agree with his statistics. I trust the numbers on the population of Pennsylvania and then the fact that he quoted that one-half the women will die of breast cancer. One point that I wanted to make to you, Senator, is that——

Senator SPECTER. One-half the women who are diagnosed with breast cancer will die?

Dr. SIMMONDS. Will die——

Senator SPECTER. Yes.

Dr. SIMMONDS. While we are making great strides in the treatment of this disease once it is diagnosed, we have a long way to go. The best thing we can do at this point is to catch it in its earliest possible stage.

Senator SPECTER. Dr. Simmonds, let me ask you a question which may be unduly personal, and if it is, you do not have to answer. Do you have mammograms?

Dr. SIMMONDS. Absolutely, every year.

Senator SPECTER. And another question which goes to what Dr. Van Hook has testified to about having mammograms, whether or not there is any indication. Is there any specific warrant or indication for you to have the mammograms?

Dr. SIMMONDS. Are you asking?

Senator SPECTER. Yes; I am asking you.

Dr. SIMMONDS. The indication for my mammograms?

Senator SPECTER. Do you have a history in your family of breast cancer? Any special reason for you to have the mammograms?

Dr. SIMMONDS. I do, in fact, have an aunt who died of breast cancer. But I would get the mammograms regardless of that. I believe that any woman in her forties is at risk.

The other point that I want to make, Senator, a point that I do not hear made very often, but medically we know. We have this label, is what I tell my patients, called breast cancer. That is what it is. It is a name. And, you know, as a disease entity, it is really a spectrum. It is maybe various diseases, maybe of various causes. And so some of them are very aggressive and some of them are very indolent. And that goes into the mixture of what we are picking up with mammography.

As a general rule, the disease in a woman in her forties might be more aggressive. So that is another factor that bears in screening women at that age. In other words, if you did not pick it up early, they would surely die.

Senator SPECTER. Now, Dr. Van Hook, let me shift the ground slightly to the question about how often on mammograms. There has been some controversy as to whether even women 50 and over should have annual mammograms. What is your evaluation as to the frequency of mammograms in women 40 and up?

Dr. VAN HOOK. My recommendation for every woman over the age of 40 is annually.

Senator SPECTER. When we talk about the issue of, as you characterize it, Dr. Simmonds, from the book "Infinite Need: Finite Resources," how expensive is it to get a mammogram, Dr. Simmonds?

Dr. SIMMONDS. That is a very good question. There is a variable cost. In a true screening procedure, you can cut the cost to maybe $50 in that you streamline the procedure. You have a facility that does not have a lot of fancy overhead. You have a radiologist that can batch the reading of this, so that there is a limited amount of time of the professional involved. That gets very confused sometimes with what are diagnostic mammograms, which Dr. Van Hook can answer as well, where the radiologist must be there one-on-one with the patient.

But a true screening mammography, we could cut the costs somewhat.

Senator SPECTER. Could the costs be cut by having mammograms given at inconvenient hours? When I had my MRI, it was very expensive to do during the day. There have been some suggestions, you might run MRI's around the clock. Would it be less expensive on the marginal cost to do a mammogram, say, at 10 o'clock at night or even 1 a.m., in the morning to reduce the cost? Dr. Evans, what do you think about that?

Dr. EVANS. I really would defer that one to Dr. Van Hook as the radiologist.

Senator SPECTER. OK. Dr. Van Hook?

Dr. VAN HOOK. The way you achieve economy in screening is by volume of patients seen. Here at the Hershey Medical Center, we do what we call online reading, which means that virtually every woman who comes in for a mammogram, her examination is read at that time and the interpretation, the results of the exam, is given to the patient directly by the interpreting radiologist.

This is not terribly cost effective, but it is a good service for the patients. I think most of our patients really appreciate that.

The way to make it economical is to have patients come in in volume, do their exams, have them leave and read the examinations at a later time, perhaps even at another site. And then those women who need to be recalled for more workup would be notified.

Senator SPECTER. Let me shift ground back to a more primary question about more research. We have added enormous funds to breast cancer research. And this has come regardless of who the chairman has been, whether it is Senator Weicker in the early 1980's, later Governor Weicker, Senator Lawton Chiles of Florida, later Governor Chiles. Senator Harkin chaired the committee. I have chaired the committee. We have added funds all the time on NIH research.

And this year, I laid down a marker of a 7½-percent increase of $952,000,000 for extra breast cancer research. And I did that at the outset of the session, because I wanted my colleagues to know what I thought about it and what we were going to be looking for.

The question is, if you doctors can shed some light on a collateral—a corollary question as to whether more can be done on research to find the causes of breast cancer. Dr. Simmonds, what do you think?

Dr. SIMMONDS. That is absolutely what needs to be done and we have made progress. I think there is a demonstrated track record. As you probably know, we are on the verge of some very exciting understanding through the genetic markers. Then there are advances in the various medical oncology treatments of the disease, new drugs.

Senator SPECTER. Dr. Evans, what do you think about the adequacy of funding on research for breast cancer, if you care to express an opinion?

Dr. EVANS. Absolutely. I do not think there is any doubt about the fact that research will add to our knowledge and improve outcomes. Research into basic causes is one area of research. I suspect that in the short run, that sort of research, we are going to see less result in the short-term than we will from research, for example, in mammography, how to make it more accurate, how to make it less anxiety-producing, how to make it less painful for women so that compliance rates go up. All those are important components.

My concern is that with the increasing pressures on the Federal and State budgets that there has not been a clear commitment from managed care organizations to support clinical research. And I think we need to see that.

Senator SPECTER. Well, you raised a very good question as to managed care organizations, as to the cost of medical education, which is a big issue here at Hershey, big issue across the country, research, what is—this is a complicated question. Let me ask you

to supplement your testimony, if any of you can give us a hand on how we structure managed care to make a contribution. I would be very interested in your thinking on that.

Dr. Van Hook, let me move over to this issue as to tests. Although this was Dr. Evans' testimony, let me ask you the question. Why is it that, considering our NIH budget, there are so few tests? With eight tests having been conducted in this field, only one in the United States?

Dr. VAN HOOK. I really do not know.

Senator SPECTER. Are the recipients or are the grantees spending their money wisely?

Dr. VAN HOOK. I am not an expert in that area. I am really not qualified to answer that.

Senator SPECTER. OK. Dr. Simmonds, I appreciate your making this very interesting booklet available to us. It looks like an impressive study which was undertaken here.

Dr. SIMMONDS. Yes; right here in Pennsylvania.

Senator SPECTER. In 1991. What have the benefits been on this, if any?

Dr. SIMMONDS. In the center are the recommended actions. Some of them are indeed hard to measure, but the Department of Health has in particular, used the results of the consensus conference. I picked out the one message about communicating the simple message and then corollaries of that, are educational programs, a clearinghouse for breast health education, and indeed the Pennsylvania Breast Cancer Coalition has made a lot of progress in some of these aspects.

Senator SPECTER. Let me shift ground—were you finished, Dr. Simmonds?

Dr. SIMMONDS. Yes; I was.

Senator SPECTER. Let me shift ground here again to a somewhat related subject. And that is, I have heard from a number of constituents that Medicare has sent out notices about reduction in payments, some projected to be lower than Medicaid payments, some reduced as much as 35 to 40 percent. We are trying to contain the costs of rises in Medicare costs, not to cut Medicare, but to restrain the rate of growth, say, to 7 percent instead of 10 percent, which is somewhat more than twice the inflation rate.

Have any of you doctors received such notification about Medicare reductions in payments to you? Proposed cuts? Dr. Evans?

Dr. EVANS. I personally have not.

Senator SPECTER. Dr. Van Hook.

Dr. VAN HOOK. No.

Senator SPECTER. Dr. Simmonds.

Dr. SIMMONDS. No; I have not.

Senator SPECTER. OK. Let me turn to an avant-garde question, which is not directly related but one which I would like your opinions on with respect to the cloning which was disclosed just last week. This may be the subject of a hearing in Washington. It brings more animation than any of my other questions. What do you think about it, Dr. Van Hook? Would you care to get involved in that deep philosophical issue?

Dr. VAN HOOK. No; not at all. [Laughter.]

Senator SPECTER. OK. Dr. Evans, would you care to?

Dr. EVANS. Well, I think, my guess is that this came like a lightning bolt to the public, but I suspect it did not come as a lightning bolt to the scientific community. And I am not part of the scientific community in cloning, so it came perhaps as much of a surprise to me as it did to the public.

I think, though, the scientific community was a little bit behind the eight ball in setting out, discussing, dialoging some of the ethical implications that would derive from cloning of animals or ultimately humans.

The most recent news release would suggest that we are even closer and that the technology is perhaps closer than we thought.

Senator SPECTER. Dr. Simmonds.

Dr. SIMMONDS. Senator, I would like to bridge your question back to breast cancer, actually, to pick up on the genetic aspects, which is not quite cloning. I recognize, a concern that a lot of people have, and I alluded to this in the questions as far as the breast cancer genes. And imminently this test will be widely available, that a woman may find out if she is carrying this gene, was born with this gene, or not.

There are a number of ethical questions that I do not believe we are fully prepared in our society to deal with. Just one example would be, what is an insurance company going to do with that individual? Are they going to deny her insurance, because she is now at risk for a disease? I would like to highlight that.

Senator SPECTER. Well, I was about to move to that next. That is a much more restricted question than cloning. We have commented about that in our hearings. I believe that legislation is necessary to protect the privacy of women, so that they can get the benefits from an identification of a gene which predisposes to breast cancer without losing insurance. Because if you know you have a preexisting condition, and do not disclose it to the insurance company, they can cancel your insurance policy on what the lawyers call fraudulent inducement.

So, we ought not to preclude people from finding out about predisposition which could help in the medical care. That is on our agenda to work on.

Well, this is only the beginning. We have another panel which we wish to hear from, but I would very much appreciate your staying in touch on additional suggestions that you may have. The question of how to get a fair share contribution on research from managed care facilities and also on graduate medicine and also education and also on caring for the poor is something that if you care to give some supplemental testimony, we would be pleased to have it.

OK. Thank you very much, Dr. Evans, Dr. Simmonds and Dr. Van Hook. I appreciate your being here.

PANEL 2

STATEMENTS OF:

LOIS A. ANDERSON, COFACILITATOR AND FOUNDER, SURVIVING BREAST CANCER SUPPORT GROUP AND COCAPTAIN, PENNSYLVANIA BREAST CANCER COALITION, YORK, PA

LORENE KNIGHT, PENNSYLVANIA BREAST CANCER COALITION

HON. KATIE TRUE, STATE REPRESENTATIVE, 37TH LEGISLATIVE DISTRICT

INTRODUCTION OF WITNESSES

Senator SPECTER. I would now like to turn to our next panel of Ms. Lois Anderson, Ms. Lorene Knight, and Representative Katie True. If you ladies would step forward.

Again, in alphabetical order, we will turn to Ms. Lois Anderson medical technologist at Mercy Medical Center in Baltimore. She has served as a medical technologist at Memorial Hospital and the Hillcrest Women's Medical Center in York and at Columbia Hospital in Columbia, PA. She is York County cocaptain of the Pennsylvania Breast Cancer Coalition and is a member of the surviving breast cancer support group for breast cancer survivors. Her breast cancer was diagnosed when she was 39 years old.

Welcome, Ms. Anderson. We would like, again, to limit opening statements to 5 minutes. And any written statements will be made a part of the record in full. The floor is yours.

SUMMARY STATEMENT OF LOIS ANDERSON

Ms. ANDERSON. Thank you, Senator Specter. The Honorable Arlen Specter and subcommittee members, I would like to thank you for extending an opportunity to testify at this special hearing on the NIH Consensus Conference's decision on mammography for women between the ages of 40 and 49.

As a breast cancer survivor, I was outraged by their decision to not recommend screening mammography for all women in this age group. My own breast cancer experience began October 12, 1992, just 6 days after my 40th birthday; 3½ months earlier, I received a blow to my right breast while roughhousing with my then 12-year-old son.

After the initial injury, the bruise would come and go at a specific point in my menstrual cycle. Because I was turning 40 in the fall, I had a doctor's order for a baseline mammogram. That mammogram, done on September 14, 1992, was reported as: "benign mammographic findings of dense fibrocystic change," meaning that I had dense breast tissue.

However, because of my experience and savvy as a medical technologist and my husband's work as a registered nurse, I knew the bruise needed treatment. The radiologist who spoke with me after the mammogram strongly suggested I return to my gynecologist for an exam.

The night before this scheduled appointment, I decided to do a self-breast exam which I previously practiced monthly, and I found a lump. I saw the gynecologist and was referred to a surgeon for an excisional biopsy of the lump, which revealed a poorly differentiated infiltrating ductal carcinoma with osteoclast-like giant cells,

an extensive ductal carcinoma in situ of comedo and cribriform subtypes.

A right mastectomy was performed 1 month later and macrometastasis were found in 5 of 11 lymph nodes. These findings made me a stage III breast cancer patient with less than a 40-percent chance of surviving 5 years.

At 39 going on 40, no woman is expected to have breast cancer and this diagnosis devastated me. It took me several weeks to work my way through my emotions and decide what I had to do. I went through 6 months of chemotherapy, 6 weeks of radiation therapy and all the while continued physical therapy for a frozen shoulder that occurred after surgery.

I am now on tamoxifen for the rest of my life or until I develop a recurrence. Some 2 years after this initial experience, a lesion was found on the mammogram of my remaining breast, which was removed and turned out to be a benign cystic lesion. From this, you can see how my own breast tissue changed mammographically in only 2 short years.

The incidence of breast cancer in younger women is increasing. And the NIH's decision to not recommend mammograms for women below 50 years of age will certainly cause an increase in the death rate from breast cancer. As a breast cancer support group founder and facilitator, I have watched as several younger group members struggled in vain with this disease and eventually succumbed to it.

Premenopausal breast cancer is usually more aggressive than breast cancer in older women. To deny mammograms to younger women is handing them a death sentence. This decision comes at a time when statistics are showing us a slight decrease in the overall rate of breast cancer, partially attributed to early screening mammograms.

Mammography is our only tool other than self-breast exams and professional breast exams to combat this disease. No other technology has proven itself as reliable as a mammogram. The mammogram is not a perfect test. No test is ever perfect. No test will detect disease 100 percent of the time. However, in the hands of a practicing, skilled radiologist who consistently reads mammograms day in and day out, mammography becomes our best tool for early detection when breast cancer is in its nonpalpable stages.

As a Pennsylvania Breast Cancer Coalition member, I have collected over 226 stories from women under the age of 50 who have been diagnosed with breast cancer through the use of a mammogram. And I would like these stories entered into the record. They are here.

Senator SPECTER. They will be admitted into the record in full. Thank you.

Ms. ANDERSON. These stories continue to flood my mail, my e-mail, and my fax. Copies were sent to Dr. Alan Rabson and Dr. Richard Klausner, Deputy Director and Director respectively of the National Cancer Institute for presentation at the NCI's Advisory Board meeting February 25 and 26 of this month in the hopes that this anecdotal evidence would persuade the NCI to change its mammogram recommendations.

Since women represent 52 percent of the population in the United States, I think we as younger women deserve better direction

in our breast health care. Specific guidelines for the use of mammography, especially in women 40 to 49 years of age, need to be set down and followed. Women need to be told that a mammogram is not perfect, but it is the best tool we have for detecting breast cancer early.

Deadly confusion over screening mammography will result from the NIH's decision if these guidelines are not changed.

Senator SPECTER. Thank you very much, Ms. Anderson. We will come to the questions and answers later, but let me just ask you preliminarily now how are you feeling?

Ms. ANDERSON. As far as the NIH's decision or my health or what?

Senator SPECTER. That is a very good——

Ms. ANDERSON. My health is great right now.

Senator SPECTER [continuing]. That is a very good request for specification on the question. I usually am sufficiently specific not to do that.

PREPARED STATEMENT

Ms. ANDERSON. I am still very upset about the NIH's decision.

Senator SPECTER. OK. But your personal health is fine?

Ms. ANDERSON. My personal health is good, very good.

Senator SPECTER. It is important how you feel about the NIH. It is more important how your health is.

[The statement follows:]

PREPARED STATEMENT OF LOIS A. ANDERSON

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I saw the gynecologist and was referred to a surgeon for an excisional biopsy of the lump, which revealed a poorly differentiated Infiltrating Ductal Carcinoma with Osteoclast-like Giant Cells and extensive Ductal Carcinoma In Situ of comedo and cribiform subtypes. A right mastectomy was performed one month later and macrometastasis were found in 5 of 11 lymph nodes. These findings made me a Stage III breast cancer patient with a less than 40 percent chance of surviving 5 years. At 39 going on 40 no woman is expected to have breast cancer and this diagnosis devastated me. It took me several weeks to work my way through my emotions and decide what I had to do. I went through 6 months of chemotherapy, 6 weeks of radiation therapy and all the while continued physical therapy for a frozen shoulder that occurred after surgery. I am now on Tamoxifen for the rest of my life or until I develop a recurrence. Two years after this initial experience a lesion was found on the mammogram of my remaining breast, which was removed and turned out to be a benign cystic lesion. From this you can see how my own breast tissue changed mammographically in only two short years.

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Since women represent 52 percent of the population in the United States, I think we, as younger women deserve better direction in our breast health care. Specific guidelines for the use of mammography, especially in women 40–49 years of age need to be set down and followed. Women need to be told that a mammogram is not perfect, but it is the best tool we have for detecting breast cancer early. Deadly confusion over screening mammography will result from the NIH's decision if these guidelines are not changed.

SUMMARY STATEMENT OF LORENE KNIGHT

Senator SPECTER. OK. We now turn to Ms. Lorene Knight, logistics distribution analyst for the New Holland North American Inc., a member of the NAACP of Lancaster County, the Urban League of Lancaster County and a volunteer for the American Cancer Society's Reach to Recovery Program and a member of the Pennsylvania Breast Cancer Coalition. Ms. Knight was diagnosed with breast cancer when she was 47 years old.

We welcome you here, Ms. Knight, and look forward to your testimony.

Ms. KNIGHT. Thank you. My name is Lorene Knight. I am a 54-year-old African-American single woman, no children, and I am a 7-year breast cancer survivor as of Wednesday, March 19. I am a member of the Pennsylvania Breast Cancer Coalition and a very active volunteer with the American Cancer Society.

I found a lump in my breast through self-breast examination, followed by a mammogram and a sonogram. It turned out to be breast cancer. At the age of 47, I had a modified radical mastectomy on my right breast followed by 6 months of chemotherapy and 5 years of hormone therapy by the way of the drug tamoxifen.

Had I not had a mammogram that verified my suspicion of breast cancer, I may not have had the opportunity to be here today and participate in this special hearing. I had my first mammogram at the age of 36 because of the presence of fibrocystic tissue in my breast and because of my family history with breast cancer and my sister's death at age 43, just 9 years ago, due to complications from this disease, it was never a question that my mother, my three sis-

ters and I would have yearly mammograms. And my mother, by the way, is a 5-year breast cancer survivor.

I am most disturbed by the findings of the NIH's consensus development program that the available data do not warrant a single recommendation for mammography for women in their forties. Therefore, the burden of decision for a woman in her forties is hers alone. This kind of statement would no doubt lure entirely too many women of all races and in their forties into a false sense of security about the odds that breast cancer would not likely happen to them during this decade of their lives.

Because I am an African-American woman, I know how private my race is about certain illnesses and how reluctant we all too often are, to seek medical attention because of fear of the unknown and economics. The NIH's statement is only sending a negative message to these women that will reinforce these feelings.

I am living proof that breast cancer does happen to African-American women in their forties and that we can survive it when it is found early. As a member of the Breast Cancer Detection CORE Team at the Lancaster County unit of the American Cancer Society, I know how busy this team of volunteers is with numerous patient service, early detection, education and advocacy projects with regards to the issue of breast cancer.

I am very proud to share with you today a portion of some new statistics that our CORE Team is currently compiling for Lancaster County. There are four hospitals in Lancaster County and two of them to date have pulled figures that show us details about recent breast cancer patients. At one hospital during the 1995–96 fiscal year, 104 women underwent breast cancer surgery. Nearly 36 percent of these were under the age of 50.

At a second Lancaster County hospital during the same fiscal year, 21 women underwent breast cancer surgery; 8 of the 21 women were under 50 years of age, and 1 of the 8 was in her thirties.

We are working with other hospitals to get similar figures that will enable us to soon have a complete Lancaster County percentage of the 40 to 49 age group for the 1995–96 fiscal year.

Also for 2 years, I have been a volunteer with the American Cancer Society's Reach to Recovery Visitation Program. I have yet to visit one recovering breast cancer patient that is African-American. Why is this? In my heart, I believe it is because not enough African-American women are having early detection procedures such as mammograms at an early enough age to detect the breast cancer at an early enough stage to survive it.

In fact, the American Cancer Society's Breast Cancer "Facts and Figures 1996" clearly states, and I am now quoting from that publication, from 1973 to 1988 breast cancer mortality rates increased 1.1 percent among white women and 19.4 percent among African-American women. Between 1989 and 1992, mortality rates among whites declined approximately 5.2 percent, while rates among African-American women increased 2.6 percent.

So, while a decline in deaths from breast cancer is wonderful news, we must keep these numbers going down until we hit zero. Conversely in my mind, any increase in deaths from breast cancer is just not acceptable. This year an estimated 180,200 new invasive

cases of breast cancer are expected among women in the United States. An estimated 43,900 of these women will die from it. This is too many lives lost.

Every woman of every race in every community should have access to earliest possible detection methods, such as mammograms combined with monthly self-breast exams and regular physician's exam. And every woman of every race in every community should have it available to her at age forty if that is what she determines to be necessary for her, dictated by family history, her physician's recommendation and any other personal health factors pertinent to her well-being and longevity in this world.

PREPARED STATEMENT

Thank you for allowing me this time today to share my story and to personally request that you do not lend your support to the NIH's recent findings and public statement. Thank you.

Senator SPECTER. Ms. Knight, you may be sure I will not lend my support to the NIH's recent findings. May I ask you the status of your health now?

Ms. KNIGHT. I am doing wonderfully well. I am fine.

Senator SPECTER. OK. Thank you. We will get more questions and answers later.

[The statement follows:]

PREPARED STATEMENT OF LORENE KNIGHT

My name is Lorene Knight. I am a 54-year-old African-American single woman—no children—and I am a 7-year breast cancer survivor as of Wednesday, March 19, 1997. I am a member of the Pennsylvania Breast Cancer Coalition, and a very active volunteer with the American Cancer Society.

I found a lump in my own breast through Breast Self Examination (or BSE), followed by a mammogram and a sonogram. It turned out to be breast cancer. At the age of 47, I had a modified radical mastectomy on my right breast, followed by 6 months of chemotherapy and 5 years of hormone therapy by way of the drug Tamoxifin. Had I not had the mammogram that verified my suspicion of breast cancer, I may not have had the opportunity to be here today and participate in this special hearing.

I had my first mammogram at the age of 36 because of the presence of fibrocystic tissue in my breasts. And because of my family history with breast cancer and my sister's death, at age 43 (just 9 years ago) due to complications from this disease. It was NEVER a question that my mother, my three sisters and I would have yearly mammograms. And my mother, by the way, is a 5-year breast cancer survivor.

I am most disturbed by the findings of the NIH's Consensus Development Program "that the available data do not warrant a single recommendation for mammography for all women in their forties. Therefore, the burden of decision for a woman in her forties is her alone." This kind of statement will no doubt lure entirely too many woman—of all races and in their forties—into a false sense of security about the odds that breast cancer will not likely happen to them during this decade of their lives. And because I am an African-American woman, I know how private my race is about certain illnesses and how reluctant we, all to often are, to seek medical attention because of fear of the unknown and economics. The NIH's statement is only sending a negative message to those women that will reinforce these feeling, and I am living proof that breast cancer does happen to African-American women in their forties, and that we can survive it when it's found early.

As a member of the Breast Cancer Detection CORE Team at the Lancaster County Unit of the American Cancer Society, I know how busy this Team of volunteers is with numerous patient service, early detection, education, and advocacy projects with regard to the issue of breast cancer. And I'm proud to share with you today a portion of some new statistics that our CORE Team is currently compiling for Lancaster County.

There are four hospitals in Lancaster County and two of them, to date, have pulled figures that show us details about recent breast cancer patients. At one hos-

pital, during the 1995–96 fiscal year, 104 women underwent breast cancer surgery nearly 36 percent of them were under the age of 50. At a second Lancaster County hospital, during the same fiscal year, 21 women underwent breast cancer surgery—8 of the 21 women were under 50 years of age, and 1 of the 8 was in her 30's. We are working with the other hospitals to get similar figures that will enable us to soon have a complete Lancaster County percentage of the 40–49 age group, for the 1995–96 fiscal year.

Also, for 2 years, I have been a volunteer with the American Cancer Society's Reach To Recovery visitation program. I have yet to visit one recovering breast cancer patient that is African-American. Why is this? In my heart, I believe it is because not enough African-American women are having early detection procedures such as mammograms at an early enough age to detect the breast cancer at an early enough stage to survive it. And in fact, the American Cancer Society's Breast Cancer Facts & Figures 1996 clearly states that, I am now quoting from that publication.

"From 1973 to 1988, breast cancer mortality rates increased 1.1 percent among white women and 19.4 percent among African-American women. Between 1989 and 1992, mortality rates among whites declined approximately 5.5 percent, while rates among African-American women increased 2.6 percent."

So, while any decline in deaths from breast cancer is wonderful news, we must keep these numbers going down until we hit "zero." Conversely, in my mind, any increase in deaths from breast cancer is just not acceptable.

This year, an estimated 180,200 new invasive cases of breast cancer are expected among women in the United States. An estimated 43,900 of these women will die from it.[1] This is too many lives lost.

Every woman of every race, in every community should have access to the earliest possible detection methods such as mammograms, combined with monthly Breast Self Exams and regular physician's exams. And every woman, of every race, in every community should have it available to her at age 40 if that is what she determines to be necessary for her, dictated by family history, her physician's recommendations and any other personal health factors pertinent to her well-being and longevity in this world.

Thank you for allowing me this time today to share my story, and to personally request that you do not lend your support to the NIH's recent findings and public statement.

SUMMARY STATEMENT OF STATE REPRESENTATIVE KATIE TRUE

Senator SPECTER. Now turning to the Honorable Katie True, Representative of the Pennsylvania State Legislature having been elected in 1992, representing the 37th legislative district. She currently chairs the Subcommittee on Drugs and Alcohol and has founded several drug and alcohol programs for children and parents.

She is a strong supporter of cancer research and someone whose family has been affected by breast cancer. Representative True introduced legislation to provide a State income tax refund checkoff for breast and cervical cancer research. The legislation has already passed the House and is currently pending in the Senate.

Welcome, Representative True, and the floor is yours.

Ms. TRUE. Thank you, Senator. I appreciate being asked to participate in this hearing. And I thank you for the opportunity to lend my voice to the findings of the NIH Consensus Development Conference on Breast Cancer Screening in Women Ages 40 to 49. As a legislator, I am proud to be an active participant in the fight against breast cancer. As a woman, wife, mother, grandmother, and daughter, I feel it is my responsibility to pick up the gauntlet.

I fight for the women who suffer mental anguish and physical pain when they lose their breasts, for the women who endure major medical procedures, chemotherapy and radiology, and the women

[1] American Cancer Society Cancer Facts and Figures—1997.

who have died from this dreadful disease. One of the weapons I have chosen to battle breast cancer is House bill 134, the State income tax checkoff for breast cancer research. Research requires money.

This bill that I have prime sponsored will help provide some of the funds needed for cancer research. I feel very strongly that a second weapon used to battle breast cancer is education. We are making great strides in getting the word out that breast self-exams combined with mammograms can save many lives.

Women still hesitate to look after themselves first, usually putting others and their needs before their own. Sadly, the findings of the NIH Consensus Development Conference on Breast Cancer Screening takes us a step backward instead of moving us forward.

Until we find a cure, women need to understand that it is imperative that they have a mammogram early on and not wait until after age 50. They need to have encouragement through education that mammography is not harmful and can save their life. This is a case where good far outweighs the bad.

I would like to digress just for a moment from my written remarks to say I read the proposal that was faxed to me from the NIH, and noticed that one of their concerns was minimal radiation and discomfort. And I think what mammograms can do far outweighs those concerns.

The recommendation of the NIH Consensus Development Conference on Breast Cancer Screening Panel in my opinion is irresponsible. And I question, I really question, the motives behind such a recommendation. Plain and simple, their message is wrong. And I think it is deadly.

PREPARED STATEMENT

We need to stop this disease. We need to join forces, support research and make others aware of how devastating breast cancer is. And we need to battle for all those women who lost the fight and for all those fighting the battle now.

Thank you, Senator.

Senator SPECTER. Thank you very much, Representative True.

[The statement follows:]

PREPARED STATEMENT OF STATE REPRESENTATIVE KATIE TRUE

I appreciate being asked to participate in this special hearing of the Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies. Thank you for the opportunity to lend my voice to the findings of the NIH Consensus Development Conference on Breast Cancer Screening in Women Ages 40–49.

As a legislator I am proud to be an active participant in the fight against breast cancer. As a woman, wife, mother, grandmother, and daughter, I feel it is my responsibility to pick up the gauntlet. I fight for the women who suffer mental anguish and physical pain when they lose their breasts, for the women who endure major procedures, chemotherapy and radiology, and the women who have died from this dreadful disease.

One of the weapons I have chosen to battle cancer is House Bill 134, the State income tax "checkoff" for breast cancer research. Research requires money. This bill that I have prime-sponsored will help provide some of the funds needed for cancer research. The donation is deducted from the tax refund to which an individual is entitled and does not constitute a charge against the income tax revenue's due to the State.

I feel very strongly that a second weapon used to battle breast cancer is education. We are making great strides in getting the word out that breast self-exams

combined with mammograms can save many lives. Women still hesitate to look after themselves first, usually putting others and their needs before their own. Sadly the findings of the NIH Consensus Development Conference on Breast Cancer Screening takes us a step backward instead of moving us forward.

Until we find a cure, women need to understand that it is imperative that they have a mammogram early on and not wait until after age 50. They need to have encouragement through education—that mammography is not harmful and can save their life. This is a case where Good far outweighs the Bad. The recommendation of the NIH Consensus Development Conference on Breast Cancer Screening panel is irresponsible, and I question the motives behind such a recommendation. Plain and simple—their message is wrong and deadly.

We need to stop this disease. We need to join forces, support research and make others aware of how devastating breast cancer is. We need to battle for all those women who lost the fight and for all those fighting the battle right now.

MOTIVE OF MONEY

Senator SPECTER. Let me begin and ask you what you think their motive is?

Ms. TRUE. Money. I think the motive has to come somewhere, somehow from finances and how a lot of this is going to be paid for. Again, this is my opinion. I really do not believe a group of people wake up one day and decide to have a hearing on a panel like this and come up with recommendations like that if there is not a real driving force behind it.

And the only thing in political life I can think of, it must have something to do with finances.

Senator SPECTER. Well, Representative True, the money, of course, is a matter of assessing priorities. My own sense is that with a Federal budget of $1,700,000,000,000, if we allocate the funding properly, we can find the money and still candidly have a balanced budget. As I said earlier, Senator Harkin and I found 134 programs we could either consolidate or eliminate as a matter of priority. It is not that we did not like them, but they just were not as important as other programs.

And we have not come to grips really with what these mammograms cost. But my sense is that we can find the money for them.

Let me just ask you women one after another, how high a priority do you put here? I know what the answer is, but let me put it on the record. Representative True, start with you.

Ms. TRUE. Well, I think it is a very high priority and I would agree with you, that is, the whole ballgame is putting priorities on it. I do not know if you could put a dollar amount on a woman's life. And so, I would feel that compared to what we spend our money on, and I certainly know on a State level where a lot of the money goes, I think we could find a way to make this work.

Senator SPECTER. Ms. Knight, what is your sense of that?

Ms. KNIGHT. I think it is a big priority. And the thing that I wish I could really get out into the African-American community is how important it is that they do go once a year for a mammogram or every other year. And I wish we could be more open with it, because I do think that mammograms can save lives.

Senator SPECTER. Ms. Knight, certainly the statistics and you referenced this very accurately show that African-American women currently experience 32.2 deaths per 1,000 women compared to 26 per 100,000 for white women. And what do we need to do? Do we

need more publicity in the African-American community on the availability and importance of mammograms?

Ms. KNIGHT. Yes; I think that would probably be one step. And we need to make sure that mixed messages are not sent out into the community that it is not necessary to have a mammogram. For a woman that is faced with an illness and she suspected a lump in her breast and she is already fearful of going in because she has many fears. She may not have the money to pay for it, and sometimes you just do not want to know that there is something there. And we need to educate the people to go in and to have it done. A mammogram does not hurt. You know, it only takes a few minutes and what is a few minutes when it can be for the rest of your life, to save your life.

Senator SPECTER. Well, I said at the hearing in Washington that the report by the NIH panel set this back a long way, not only for women 40 to 49 but for women generally. People do not like to take tests——

Ms. KNIGHT. Right.

Senator SPECTER [continuing]. Because we are all fearful of what they are going to show. We are going to make some more inquiries into this issue about availability of mammograms to women who cannot afford them. I think this is something that has to rank very, very high on our scale of values.

Mrs. Anderson, I know from your answer to my first question, inartfully phrased, what your temperature level is here. These hearings are very important not only for facts but for temperature. I get a very good reading on temperature when I have these hearings or open house town meetings. The other elected official here, Representative True, can confirm that, I am sure.

And I congratulate you for assembling those statements to send to the Director and Deputy Director. Let me ask you what you think we can do to raise the level of awareness of the National Cancer Institute and the panel of NIH on this subject, how women feel about it?

Ms. ANDERSON. More public meetings, committee hearings such as this. I hate to get the politicians involved in health issues, but if that is what it takes then we have to do it. That is all there is to it. It is just to put it out in front of the public eye and keep it in front of the public eye. The whole issue of breast cancer itself has been kept in a closet for too long, way too long.

And it has only been until, I would say, my generation has come along that it has come out of the closet. There are women that I speak to, and I am a reach to recovery volunteer also, who are 60, 70 years old who want to deny that they have breast cancer.

Senator SPECTER. Well, the statistics are overwhelming that breast cancer is the No. 1 killer of women ages 40 to 49. Some 184,000 women, and you recited this, Ms. Knight, were diagnosed with this disease last year and nearly 44,000 of them will die from breast cancer.

This is something very high on the radar screen of our subcommittee, I can assure you of that.

One final question for you, Representative True. Bettilou Taylor advises me that your mother has—this is Bettilou, who is our chief

architect, advises me that your mother has breast cancer. How is she?

Ms. TRUE. My mother was diagnosed and had surgery 20 years ago. She is now 83 years old and she is doing very well, but I would like to add my voice again. The fact my mother would not come with me today. My mother did not tell any of the people that we live near. She went to Baltimore to have her surgery done, which is our hometown. And she did not want to share it with her friends. She was embarrassed. And she literally went through—what little I could do, I had three small children, running back and forth to Baltimore, she went through it alone for that very reason.

And she is absolutely fine, I am very happy to say now. But what a devastating thing to have to go through by yourself without ever telling her neighbors, which is why she would not come. I begged her to come with me today, but she would not do it.

If I could just add one other thing.

Senator SPECTER. Looks like we may have to issue a subpoena for her. [Laughter.]

Ms. TRUE. Yes; I do not know. She is 83. I do not know if it would work. If I could just add one other thing, Senator.

Senator SPECTER. Please do.

Ms. TRUE. My whole background on the drug issue deals with prevention. And on that issue, I know how cost affordable prevention is. And what we are talking about today, particularly when we get into the cost of mammograms and preliminary findings, it cannot match what we spend on health care if someone has been diagnosed or they have waited too long.

So, I really, in our quest as political people as we go down the road and talk in town meetings, to emphasize prevention. I mean, that is where you save money. It might take money, but you save a great deal more and that is my message.

Senator SPECTER. Well, thank you very much, Representative True, for your leadership and for your presence here today.

Ms. TRUE. My pleasure.

Senator SPECTER. And give our records to your mother.

Ms. TRUE. Thank you.

Senator SPECTER. Ms. Knight, do you have anything you want to say in conclusion?

Ms. KNIGHT. No; but I think I mentioned earlier that my mother is also a 5-year breast cancer survivor. My mother is 76 years old.

Senator SPECTER. How does she react to what Representative True says about her mother's embarrassment?

Ms. KNIGHT. My mother is an Alzheimer's patient. So, when my mother had her breast cancer, it is because we took her in to be examined. My mother had 6 months of chemotherapy treatment. She is still on the pill tamoxifen. And her prognoses were not as good as mine. Out of 14 lymph nodes, 13 were positive. So, for the average woman, she would have died many years ago.

But my mother being an Alzheimer's has no stress. She does not know that she has had breast cancer or that she has it. So, there is no worry. And she will probably live for a very long time. And she is doing well, even being with Alzheimer's.

Senator SPECTER. Well, that is a remarkable concurrence, I would say, on that. Mrs. Anderson, anything further you would care to say?

Ms. ANDERSON. Let me say one fact to get it on the record. When I heard the NIH's decision, I started crying, because I knew what this meant to women. My husband also wrote a letter to the editor of the York Dispatch. And when that letter to the editor appeared in the Dispatch, there was this political cartoon depicting the deadly confusion of women ages 40 through 49 regarding having a mammogram. Do you have it? Do you not have it? Do you do this? Do you do that? Whatever. It was just so poignant that that came out at that point in time.

It is just this whole decision has just set medical history back so far. And we are trying our best to come forward with this disease and we are not. Unless women 40 through 49 are able to have screening mammograms on a yearly basis, we will not be detecting breast cancer early. And there is no way that you can tell me that by not having these mammograms, you are going to detect it early.

CONCLUSION OF HEARINGS

Senator SPECTER. Well, thank you very much, Ms. Anderson, Ms. Knight, Representative True. This is very helpful. Your testimony is part of our record for the full subcommittee to see and for all of Congress to see. I believe that we will be successful in having mammograms available to women 40 to 49. That is the preponderant weight of the testimony. And my sense is we will get there.

So, thank you all very much.

Ms. TRUE. Thank you.

Ms. KNIGHT. Thank you.

Ms. ANDERSON. Thank you.

Senator SPECTER. That concludes our hearing, the subcommittee will recess and reconvene at the call of the Chair.

[Whereupon, at 11:30 a.m., Monday, March 3, the hearings were concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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