

**H.R. 1157, BREAST CANCER AND
ENVIRONMENTAL RESEARCH ACT
OF 2007 AND H.R. 758, BREAST
CANCER PATIENT PROTECTION
ACT OF 2007**

HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED TENTH CONGRESS
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H.R. 1157, BREAST CANCER AND ENVIRONMENTAL RESEARCH ACT OF 2007 AND H.R. 758, BREAST CANCER PATIENT PROTECTION ACT OF 2007

WEDNESDAY, MAY 21, 2008

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 11:07 a.m., in room 2123 of the Rayburn House Office Building, Hon. Frank Pallone (chairman) presiding.

Members present: Representatives Pallone, Waxman, Towns, Eshoo, Green, Capps, Baldwin, Engel, Schakowsky, Solis, Hooley, Matheson, Deal, Shadegg, Pitts, Rogers, Myrick, Murphy, Burgess, Blackburn, and Barton (ex officio).

Staff present: Ryan Long, Chad Grant, Brandon Clerk, Amy Hall, Jessica McNiece, Bobby Clark, Melissa Sidman, Hason Sarsour, Lauren Bloomberg, Brin Frazier, and Jodi Seth.

Mr. PALLONE. The meeting of the subcommittee is called to order.

Today we are having a hearing on two bills, H.R. 1157, "The Breast Cancer and Environmental Research Act of 2007," and H.R. 758, "The Breast Cancer Patient Protection Act of 2007."

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. I will recognize myself initially for an opening statement.

These bills obviously are very important. According to the Centers for Disease Control and Prevention, or the CDC, breast cancer is the second most common form of cancer in women. Each year in America approximately 182,000 women are diagnosed with breast cancer, of which 41,000 lose their lives. Undoubtedly, many of us know some of these women. They are our mothers, our grandmothers, wives, sisters, daughters, co-workers, and friends. Families across the country are confronted with this terrible disease every day. In fact, breast cancer has hit close to home for me and my family after my mother-in-law was recently diagnosed with the disease. So I can personally attest to the struggle these families have to face. And as a son, a husband, and the father of two girls

I want to ensure that we are doing everything we can to beat back this terrible disease.

While improved access to screening and treatment services have helped reduce breast cancer death rates over the past couple of decades, significant challenges still remain.

For example, we are still unsure about what causes breast cancer or how to prevent it. While there have been a number of studies that have looked at various risk factors, we have not been able to draw a solid conclusion about what specifically causes breast cancer. H.R. 1157, "The Breast Cancer and Environmental Research Act of 2007," introduced by Congresswoman Nita Lowey, is intended to address the need for more research in the hopes of discovering the causes, possible preventative measures, and one day a cure. Let me also acknowledge the work of my colleagues on the Committee, Ms. Capps and Ms. Myrick, who have also been tireless advocates on behalf of this legislation.

H.R. 1157 would authorize a research program at the National Institutes of Health to study the potential links between breast cancer and the environment. Specifically the bill would authorize the National Institute of Environmental Health Science to award grants for the development and operation of centers for the purpose of conducting research on environmental factors that may be related to breast cancer. This bill has strong bipartisan support and 268 members of the House have cosponsored the bill, including the majority of the members on this committee. A number of organizations have also endorsed H.R. 1157 and have called upon Congress to implement a broad research strategy as outlined in the legislation. Clearly, this bill is a priority for many people, and I am looking forward to hearing testimony from a few of them today.

In addition to H.R. 1157 we will also hear testimony on H.R. 758, "The Breast Cancer Patient Protection Act of 2007," introduced by my good friend and colleague from Connecticut, Congresswoman DeLauro. H.R. 758 would require that health plans provide coverage for minimum hospital stays for mastectomies, lumpectomies, and lymph node dissection for the treatment of breast cancer. I call it the drive-through bill. It would also require coverage for radiation treatment for women undergoing lumpectomies and coverage for secondary consultations when the patient requests one.

Presently 21 states have implemented minimum stay requirements to varying degrees. As a result, some people may question why this legislation is necessary. But this bill is not for the women who live in those states or have insurance policies that provide these protections. It is for the women who do not. For these women a federal remedy is their only hope. Having access to appropriate medical care should not be dependent on the state that you live in.

Once again, I want to thank my colleagues who have worked so hard on both of these bills. I assure you that not only Congressman DeLauro and Congresswoman Lowey, but many other members have been pushing, I guess is the best to say, over the last few months to bring up these bills and have a hearing. It is really because of their efforts and the efforts of the people that they represent that we are here today. And I also want to thank our witnesses for being here today. We look forward to hearing from your testimony.

And I now recognize the ranking member, Mr. Deal.

OPENING STATEMENT OF HON. NATHAN DEAL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. DEAL. Thank you, Mr. Chairman.

Diagnosis of breast cancer is certainly a devastating blow to any woman, and also to the sons, the daughters, and the husbands or a mother or a wife who is faced with this life-threatening disease. You have mentioned your family. I have three daughters as well, and four granddaughters, and certainly have a personal interest in this matter.

Fortunately, great strides have really been made in the treatment of breast cancer, and as a result the number of breast cancer survivors continues to increase. However, we must learn more about the causes and the treatments of this disease through continued research. Already the National Institutes of Health devotes considerable resources to breast cancer research in evaluating the environmental causes of this disease. As we pursue new treatments for all diseases it is important for us to always be considering the causes for the disease that we are trying to treat. By knowing the causes we can do more to prevent disease, rather than simply treating it.

These efforts of prevention will save lives, but to get to that point we must be learning more about the triggers of the disease. I applaud the ongoing efforts of the NIH to research breast cancer, so that we can continue to make life saving advancements. I signed on as a cosponsor of H.R. 1157 to show my support because I believe it is important for us to continue research into the causes of breast cancer. I also strongly supported efforts last Congress to fundamentally reform the NIH, which I believe was a vital step in improving research into all diseases. It is all too easy, I am afraid, for the political process to interfere with research funding questions which should be guided by science and medicine. My hope is that the NIH has been better able to coordinate their efforts between the various institutes since the passage of the NIH Reform Act.

Mr. Chairman, it would be my hope that we would have an opportunity in the remaining months of this Congress to hold a hearing on the NIH Reform Act to evaluate its success and find ways to further improve the research efforts at NIH.

I want to thank our distinguished witnesses for their attendance today, and I look forward to hearing not only about the work being done at NIH on breast cancer, but also hearing suggestions from our other witnesses about how those efforts at NIH could be made more effective.

And, Mr. Chairman, at the conclusion I have a letter from the Georgia Cancer Coalition outlining a project that they have undertaken as it relates to coordinating of information about breast cancer, and I would ask unanimous consent that it be made a part of this record.

Mr. PALLONE. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. DEAL. I yield back my time.

Mr. PALLONE. Thank you, Mr. Deal. Thank you.

The gentleman from California, Mr. Waxman, is recognized for an opening statement.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Mr. Chairman, for holding this hearing on two important bills dealing with breast cancer issues, which have broad bipartisan support. In fact, both bills have a majority of the House of Representatives as cosponsors of the legislation. I think it is important that we hold this hearing and move these bills forward.

Breast cancer kills so many people, strikes so many. It is a tragedy. And what is so troubling is that we are learning more and more about environmental causes of breast cancer. We don't know the cause of breast cancer. We are trying to figure out how to treat the disease. But wouldn't it be great if we could stop the disease and prevent it? And we can't figure out how to do that unless we can see if there is an environmental cause for breast cancer itself.

There has only been limited research on environmental factors, and in many cases the studies have raised, rather than settled these important questions. So it is critical that we do all we can to understand the links between the environment and cancer. Obviously, we need to do more research to do that. The Breast Cancer and Environmental Research Act would establish a peer review program at NIH to fund collaborative research across institutions, across disciplines, and with community organizations to study the environmental factors that cause breast cancer.

I hope that we could reach a consensus and move these bills right away. They should have been enacted into law in the last Congress. It was unfortunate that this particular bill did not go through.

I want to address one additional critical point. Some will say it is not the business of the Congress to tell the NIH what their research priorities should be. And I say nonsense. Of course we shouldn't micromanage the work at NIH, or we shouldn't make scientific judgments, or select specific projects, but it is our business to establish broad priorities. If we had not taken that role in the past we would not have seen the tremendous progress in AIDS research. We would not have changed the policies to ensure that women were involved in clinical trials. And we would not have been able to push for addressing racial disparities in health care. It is appropriate that we establish a priority for examination of environmental affects in breast cancer, and that is why this bill is so important. It has 268 of our colleagues as cosponsors. More than enough to pass the House.

I look forward to hearing from our witnesses today, and working with all of my colleagues to get this job done.

Mr. PALLONE. Thank you, Mr. Waxman.

Next for an opening statement the gentleman from Pennsylvania, Mr. Murphy.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. MURPHY. Thank you, Mr. Chairman.

I am particularly interested in this hearing today to gather some information not only because of the importance of continuing on with research and an extended understanding of breast cancer, but like so many people in this room knowing it has also touched my life with sisters who have suffered from breast cancer. And what I want to know is what else we can do to prevent it, and what else we can do to treat it and make sure that it is an acute illness and a preventable illness.

I also want to make sure that as we review the bills in front of us today that we are getting important information on what decisions doctors and patients need to make in hospitals. When I was the state senator I was the author of Pennsylvania's Patient Bill of Rights Law. And in so doing there were many times we thought it was important to review procedures that insurance companies had to make sure the decisions could be made by physicians and patients in cooperation in making important decisions about their care. And that decisions were not just made on a financial basis of saying how long and what patients should have as treatment.

I am hoping today to also gather information on this with regard to patient stays. Making sure we are not standing in the way of medical decisions of what is in the best interest of the patient's treatment, and quite frankly, sometimes the best interest of the patient's mental health in terms of their length of stay.

There is so much we can be doing, and I know so many folks in this country have dedicated themselves to raising money independently for things like the Susan Komen breast cancer research through NIH funding—NIMH funding. We have to continue to do that. All of us have to continue to be dedicated to eradicating this disease and finding the best ways of treatment and prevention of it.

And with that I yield back.

Mr. PALLONE. Thank you, Mr. Murphy.

Next for an opening statement our vice-chair, Mr. Green, the gentleman from Texas.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. GREEN. Thank you, Mr. Chairman, for holding the hearing on these two very important pieces of breast cancer legislation.

As a cosponsor of both bills I am pleased that we are moving them through the committee process. Breast cancer is the second most common cancer among women in the U.S. from 1973 to 1998. Breast cancer incident rates increased by more than 40 percent. Today a woman's lifetime risk of getting breast cancer is one in eight. The National Cancer Center Institute estimates that over 182,000 women, and more than 1,100 men will be diagnosed with breast cancer, and that over 40,000 women and 450 men will die as a result of breast cancer.

Research has shown that cancer can be linked to environmental causes. While some research is being conducted by the National

Cancer Center Institute and the DOD in these areas we still have not discovered why some people get breast cancer and others do not. The Breast Cancer and Environmental Research Act of 2007 will allow the National Institute of Environmental Health Science to make grants available for the development and operation of research centers specifically designed to study the link between environmental factors and breast cancer.

Some people would get breast cancer due to increased genetic risks. However, others who have no genetic predisposition for breast cancer will be diagnosed with it. This piece of legislation will allow for research to be conducted to possibly uncover the link between environmental factors and breast cancer. The Breast Cancer Patient Protection Act of 2007 will require group health insurance providers to provide coverage for no less than 48 hours of hospital care to mastectomy patients.

Texas already has a state mandate requiring minimum length of stays following the breast cancer surgery, but it is only one of 20 states to have this protection for cancer patients. Patients who have mastectomies are at risk of developing infections and need medical care from trained medical professionals following their surgery. Both these bills should have passed years ago, and I am pleased that we are having this legislative hearing today.

Mr. Chairman, I yield my time.

Mr. PALLONE. Thank you.

Next is the gentleman from Texas, Mr. Burgess, for an opening statement.

**OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. BURGESS. Thank you, Mr. Chairman.

And I will be brief because I am anxious to get on to our witnesses.

We all recognize that medical research, scientific research is lengthy and tedious and expensive. Many years of training for the young scientist who wants to spend a lifetime in research. They have to spend long years before even beginning a career in research, which adds to the expense. For certain non-governmental sources such as corporations and philanthropic organizations there is a great deal of money that they put forward, but the expense is too much for the private sector to bear alone. And we are fortunate to have the National Institutes of Health, which is truly a national treasure to really get the ball rolling on a lot of the very basic research that likely would not be borne by the private sector. And it is by partnering these elements the Federal Government does its best work and helps us motivate the innovation and keep the edge in technology and knowledge that truly makes America the envy of the world.

I am a believer that scientific research is important. I am not necessarily a believer that—I do part company a little bit with what Chairman Waxman says about us being in charge of making the decisions about the direction of the research. True enough, broad priorities should be set by bodies such as this, and committees such as this. But we also gave the NIH broad powers with their translational research in December of 2006. And we are bare-

ly past that reauthorization bill, and I do think we need to give Dr. Arhune and the scientists at the National Institutes of Health the freedom to explore where that translational research will take them.

Oftentimes I find myself in some difficulty because I don't know that I always know how to tell the American family how to budget their expenses. I don't know how to always tell the generals how to fight the battles. And I think we all need to be careful about being those micromanagers that Chairman Waxman said we should not be, and trying to direct at a micro level the NIH and other federal research entities, and telling them what to study and when to study.

This is well-intentioned legislation. At the end of the day I may well vote for it. I am grateful to have this hearing as a learning exercise. Again, I am concerned about prescribing a specific way of conducting federal research and the unintended consequences. We live in a time it used to be your unintended consequences might not happen for a generation. Now they happen in a matter of months. So we do need to be careful about the unintended consequences.

The NIH has established four standards of excellence for breast cancer and environmental research. That is a good thing. Nearly three-quarters of \$1 billion are devoted to the research of breast cancer and environmental factors. The NIH Reform Act was devised to give the NIH more authority to conduct a multitude of disciplinary research and establish priorities that were previously dominated by more political talk and not scientific action.

In my 25 year medical career I treated thousands of patients, and breast cancer was a daily specter over my practice. It has certainly visited me and my family in a personal way as well. I understand the importance of getting the upper hand on this disease. But I also think we need to acknowledge that the NIH is already doing good work, and we must be careful that what we do today doesn't further constrain their ability to do the correct kind of research.

And I will yield back the balance of my time.

Next for an opening statement the gentlewoman from California, Ms. Solis.

OPENING STATEMENT OF HON. HILDA L. SOLIS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. SOLIS. Thank you, Mr. Chairman, and thank you for holding this very important hearing to discuss two very important bills that will help millions of women and families affected by breast cancer.

I have been a proud supporter of both of these pieces of legislation for many years, and I am very pleased that finally the subcommittee is moving to address the breast cancer issue in a comprehensive way.

You know, it is estimated that about 180,000 women will be diagnosed this year with breast cancer. And for women of color, particularly minority women, Latinas, breast cancer is often diagnosed later with fewer treatment options resulting in increased risk of

death. Only 38 percent of Latinas over the age of 40 have regular mammograms. And even though Latinas have lower rates of breast cancer than white or African-American women breast cancer continues to be the leading cause of death for Latinas.

H.R. 1157, The Breast Cancer Environmental Research Act would provide important research on the links between our community's environment and its impact on breast cancer risks. I have long advocated for increased awareness for the inherent links between our environment and our health. In Los Angeles County, for example, poor air quality and pollution have incredibly damaging effects on everyone, especially our children who develop asthma. We owe it to the millions of American women who have fought this terrible disease to comprehensively study how our environment may have contributed to their breast cancer. This research we know could provide promising prevention strategies so that future generations of women are not impacted by breast cancer.

The second bill that we will be discussing today, The Breast Cancer Patient Protection Act, is long overdue. A piece of legislation will be provide basic standards that health insurers must adhere to for breast cancer patients. Twenty states, including mine in California, have already enacted minimum length of stay requirements for breast cancer surgeries, which is a key provision in H.R. 758. Both H.R. 758 and H.R. 1157 are important bills that grass root activists from across the country have worked tirelessly to champion for many, many years.

I look forward to hearing the testimony from our witnesses, and I yield back the balance of my time.

Mr. PALLONE. Thank you.

Next is the gentlewoman from Tennessee, Ms. Blackburn.

OPENING STATEMENT OF HON. MARCIA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Ms. BLACKBURN. Thank you, Mr. Chairman. I thank you for the hearing.

I want to welcome our witnesses, and I want to welcome the young women that I am seeing here in the hearing room today for this hearing.

I am a cosponsor of H.R. 1157, The Breast Cancer Environmental Research Act. I also cosponsored this in the 109th session of Congress, when I was in the state senate in Tennessee. This is an issue that I started working on then and have continued to follow.

One of the interesting things is that one in every three cancers diagnosed in women is breast cancer. And the way this affects us in Tennessee, in 2006, we had 4,400 new breast cancer cases and the lives of 1,000 Tennesseans were claimed that year. And the impact of the environmental conditions is something that has not been lost on us, and that we are continuing to follow, so I appreciate that legislation.

All in all, Tennessee is home to some stellar cancer research. We have the University of Tennessee Cancer Institute. We have the Vanderbilt-Ingram Cancer Institute, which is dedicated to breast cancer research.

We also have one that I know, our witness and my constituent who I welcome, Ms. Crow. Thank you for being here. I know she has been involved, as I have been very supportive, of the Minnie Pearl Breast Cancer Center at Centennial Medical Center in Nashville. And I thank you for that support, and I thank you for all you do to bring awareness to the issue.

The Tennessee Breast Cancer Coalition continues to work towards eradication of the disease through both education and advocacy on the state and national level. In fact, the coalition has raised over \$1.2 million since '95, and donates 100 percent of those funds to efforts within the state of Tennessee. We are serious about this issue.

We have had some talk this morning about the NIH, and their responsibility. It is our responsibility to continue to fund the NIH. I do think, however, the NIH rather than Congress should set those research priorities. We are going to talk more about that.

But, Mr. Chairman, I thank you for the opportunity to bring these issues forward, to bring attention to them. I welcome our guests.

I yield the balance of my time and will submit a longer statement for the record.

[The prepared statement of Ms. Blackburn follows:]

STATEMENT OF HON. MARSHA BLACKBURN

Today, the Subcommittee will discuss two important bills regarding breast cancer. I am a cosponsor of H.R. 1157, the Breast Cancer Environmental Research Act, and also cosponsored this legislation in the 109th Congress.

Since my days in the Tennessee State Senate, I have been interested in the link between breast cancer and environmental factors, and secured funding to research the relationship between the two issues in Tennessee.

One in every three cancers diagnosed in U.S. women are breast cancer diagnoses, making it the most common diagnosed cancer in women. Approximately 4,400 new breast cancer cases were diagnosed in Tennessee women in 2006, claiming the lives of 1,000 Tennesseans that same year.

Tennessee is home to stellar cancer research institutions, including the University of Tennessee Cancer Institute, the Vanderbilt-Ingram Cancer Center, and the Minnie Pearl/Sarah Cannon Cancer Center at Centennial Hospital in Nashville dedicated to breast cancer research. I would also like to recognize Sheryl Crow, a constituent testifying on the second panel today, who has been very involved with the Minnie Pearl/Sarah Cannon Cancer Center.

In addition, the Tennessee Breast Cancer Coalition (TBCC) continues to work towards eradication of the disease through education and advocacy on the state and national level. In fact, the TBCC has raised over \$1.2 million dollars since 1995, and donates 100% of raised funds to efforts within the state of Tennessee.

I also maintain a strong record of support for breast cancer research. I have co-signed multiple letters and cosponsored legislation in support of breast cancer, such as the National Breast and Cervical Cancer Early Detection Program Reauthorization Act which was signed into law last year.

Throughout my experience in the Tennessee State Senate and in Congress, I have met with all kinds of disease-specific groups advocating for additional research funding. Every disease is important and with the growth of entitlement programs consuming the federal budget, research dollars are scarce.

It is the responsibility of Congress to provide funding to the National Institutes of Health (NIH). As the agency developed in size and complexity, the Committee completed NIH Reauthorization last year to assist with the growing need for a more efficient inter-agency coordination and best practices. The NIH continues to formulate specific scientific directions and priorities, as well as operational oversight of its institutes and centers.

However, the NIH—rather than Congress—should set its research priorities. While I support continued research, Congress must be careful not to set NIH fund-

ing priorities and cherry-pick the most “worthy” diseases for research funds. Even with the best of intentions, it is irresponsible for Congress to micromanage NIH.

While I appreciate the focus of this hearing on important public health programs, I believe this committee could use this time to work on more critical and time-sensitive issues, such as reform of the Medicare physician payment formula.

I have met with doctors from all over Tennessee regarding their concerns about the impending 10 percent pay cut for physicians under Medicare, scheduled to go into effect July 1, 2008.

I have repeatedly supported congressional efforts to provide physicians with Medicare payment relief. It is unfortunate that this committee is not taking any action to prevent the looming payment cut from going into effect.

As health care providers in my district have stated time and time again, many Tennessee physicians have already stopped taking Medicare patients. With this cut, a critical number of doctors will cease to serve Medicare beneficiaries completely if a solution is not implemented to fix the physician payment reduction.

It is imperative that this committee and Congress act on this critical issue immediately. The alternative could be disastrous for this nation’s seniors.

I thank the Chairman and yield back the balance of my time.

Mr. PALLONE. Thank you, Ms. Blackburn.

Next for an opening statement the gentlewoman from Oregon, Ms. Hooley.

OPENING STATEMENT OF HON. DARLENE HOOLEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Ms. HOOLEY. Thank you, Mr. Chair.

As I prepared for this hearing I went back to my files to refresh my memory on the various bills and letters I signed onto in support of breast cancer research and funding. I found a draft letter written in 2000 in response to a constituent asking for my support for the Breast Cancer Environmental Research Act in the 106th Congress, which I am proud to say I did cosponsor.

In part, Mr. Chairman, the letter references a July 2000 article in the New England Journal of Medicine reporting on a new study showing that environmental factors are more important than gene factors in causing many types of cancer. Specifically the study reported that on average environmental factors caused about twice as many cancers as inborn genetic factors. The study also stated that researchers are unsure which environmental factors are cancer causing, which clearly shows a need for research in this area. The Breast Cancer and Environmental Research Act of 2007, of which I am proud to be a cosponsor is as relevant today as it was 8 plus years ago.

Mr. Chair, the constituent letter I referred to was written 8½ years ago. I understand that in the greater scheme of things here in Congress 8 years may be hardly any time at all. However, not to the people who have been diagnosed with cancer. Since that time 1.5 million people have been diagnosed with breast cancer, and the American public shouldn’t have to wait any longer for action on this issue.

I could make a similar statement about the need to act on the Breast Cancer Patient Protection Act of 2007. In Oregon we passed a minimum standard for mastectomy patients. I think it is only fair to give folks that are not fortunate enough to live in the great state of Oregon similar care in treatment.

Mr. Chair, I yield back the remainder of my time. I look forward to asking questions of the witnesses, and I think we need to get on with the business and not wait any longer for this. Thank you.
Mr. PALLONE. Thank you.

Next is the gentlewoman from North Carolina, Ms. Myrick.

OPENING STATEMENT OF HON. SUE WILKINS MYRICK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NORTH CAROLINA

Ms. MYRICK. Thank you, Mr. Chairman. Thank you for calling the hearing. I appreciate it, and for all of our witnesses who are going to testify. And, of course, I am delighted Dr. Lyerly is from North Carolina. We always like to have North Carolina people here.

But this is a really important hearing, and I appreciate the fact that we have got the opportunity today, and all of you are here to do this.

I have been an early cosponsor on the Breast Cancer and Environmental Research for several years, because of course I, like every other person basically, including men, not just women, believe it is critical to examine those potential environmental triggers that cause breast cancer incidents. And of course, as has already been mentioned, I too am very troubled by the growing number of young women who are diagnosed with aggressive, often deadly, forms of breast cancer. And I believe that dedicated medical research is the most effective way to figure out why this happens.

As a strong supporter of NIH reform in the NIH Reform Act, I understand the importance of encouraging the efficient, effective research at NIH. Congressional restraint in the disease-specific realms are important because none of us wants to unintentionally limit the effectiveness of any cross institutional research by being too prescriptive with legislation, and not letting science drive the research agenda.

And I was pleased to see the compromise language on the bill emerge from the Senate HELP Committee earlier this year, because I believe that this revised language improves the efficacy of the bill, and appropriately reflects the intent of its supporters to assist and improve scientific research on breast cancer's environmental links.

I am also supportive of the Breast Cancer Patient Protection Act to limit instances when women are forced to leave the hospital shortly after a mastectomy. It, of course, was supported by my dear friend, Joanne Davis, who tragically succumbed to the disease last year. We all still miss her a lot. The State of North Carolina has passed legislations other states have already mentioned to require a minimum hospital stay for mastectomies, which applies to health plans under the state's jurisdiction. This bill would extend the requirement to a ERISA plans and group and individual plans within the jurisdiction of the Public Health Service Act. And naturally this requirement does not apply if a medical decision includes sending a patient home will not hamper her recovery.

I again thank the Chairman for holding this hearing, and I look forward to hearing from our witnesses.

And as a breast cancer survivor myself, why it always has extra importance to me, because fortunately I am still here.

Thank you all for being here, and I yield back my time.

Mr. PALLONE. Thank you, and thank you in particular for all that you have done to bring attention to the issue. I know you have talked to me many times, and I appreciate that.

For an opening statement our next member is the gentlewoman from Wisconsin, Ms. Baldwin.

OPENING STATEMENT OF HON. TAMMY BALDWIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WISCONSIN

Ms. BALDWIN. Thank you, Mr. Chairman, and I very much appreciate your holding this hearing today, and our witnesses for joining us.

I am, like a number of my colleagues, proud to be a cosponsor of both H.R. 1157, which seeks to move us closer to identifying and understanding the causes of breast cancer, and H.R. 758, which seeks to ensure that breast cancer patients receive adequate care.

I was delighted last year to partner with my colleague, Representative Myrick, who we just heard speak, in authoring the reauthorization of the National Breast and Cervical Cancer Early Detection Program. And it was great to work with you, Mr. Chairman, and many other members of this subcommittee and the Full Committee in passing that important reauthorization.

I know that many of my colleagues on this subcommittee share my commitment to strengthening the federal role in fighting breast cancer. And I am glad that we are continuing that commitment by considering the two bills that we have before us today.

Mr. Chairman, unfortunately nearly all of us are touched by breast cancer in some form. Either as a patient, a daughter, a friend, a sister, a brother, a son, a father, or mother of somebody who has been diagnosed with breast cancer. The National Cancer Institute estimates that this year alone some nearly 200,000 women and men will be diagnosed with breast cancer, and they also estimate that over 40,000 women and nearly 500 men will die as a result of breast cancer.

I view these bills as important steps that cover both ends of the spectrum. In the case of H.R. 1157 we are strengthening the commitment that our Nation's health researchers are making to discover the cause of breast cancer and the environmental factors that play a role in the disease. And once we discover the cause, then we can work to improve prevention and treatment of breast cancer. In the case of H.R. 758 we are strengthening patient protections to ensure that breast cancer patients are receiving appropriate medical care. We are also ensuring that medical treatment decisions are being made by a patient and her doctor and not by the insurance companies.

While I am glad that a number of states have already enacted state level reforms to ensure minimum lengths of stay requirements for breast cancer surgery, I note that my home state of Wisconsin is not one of those states. So establishing a federal standard would certainly benefit the people that I represent in the state of Wisconsin.

Again, Mr. Chairman, I am a strong and enthusiastic supporter of both of the bills before us today, and I am looking forward to today's discussions. Thank you.

Mr. PALLONE. Thank you, Ms. Baldwin.

Next is the ranking member of our Full Committee, the gentleman from Texas, Mr. Barton.

**OPENING STATEMENT OF HON. JOE BARTON, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. BARTON. Thank you, Mr. Chairman. Thank you for the hearing.

I want to start out by thanking the Susan G. Komen Breast Foundation for their tireless dedication to breast cancer research. I have been associated with the leaders of that organization for a number of years and I am very proud of the work that they have done.

I want to say something about this specific bill. We have been talking a lot in this Congress about earmarks, mostly in the appropriation bills, but there are earmarks that can pop up in other places too. And the bill that is before us today is one of those bills. It is a disease-specific bill for earmark research at the National Institutes of Health. For more than a decade Congress and this committee on a bipartisan basis has been trying to make decision-based decisions on both policy—we have tried to fund each of the major institutes and centers that comprise NIH with a single appropriation line item. I had my staff look and we can't find one instance in the last 5 or 6 years where the appropriators of the House of Representatives funded a research project to benefit one specific disease.

Disease-specific earmarks are bad policy. They are bad for science. We shouldn't do it. Having said that, every year there are literally dozens of bills that are filed in this committee that designate disease-specific research activities. And I will say that all these disease-specific research activities are positive, that they are noble, they need to be done. So it is not the issue of whether we should be doing in this case breast cancer research or not. The issue is how do we instruct the National Institutes of Health to use the research dollars that we appropriate for the best possible good for all Americans.

If a patient advocacy group is looking for more attention for a specific disease it seeks out a member to sponsor a bill who does it with the noblest of intentions, signs up cosponsors, and who can be against breast cancer research, and pushes forward. I understand that that is good politics for the member that is introducing the bill, our members, and I know it is always helpful to show interest in a specific disease, and it is definitely good for the association that is pushing that particular bill. However, as I have said earlier, it is not good science and it is counterproductive in my opinion for Congress to politically micromanage the National Institutes of Health.

In the last Congress, on a bipartisan basis, we made a major effort to reform and improve the National Institutes of Health. It was one of the top priorities of my chairmanship. And the bill that I am most proud of in the 24 years that I have been in the Congress is

the National Institutes of Health Reform Bill which passed in the last Congress. We held dozens of hearings. We consulted with every major scientific society. We sat down with all the major research universities and medical colleges. We talked to all the institute directors at NIH. We talked to the director of NIH himself. We moved heaven and earth to put together a consensus package, and we passed it.

With the Breast Cancer and Environment Research Bill that we are discussing today, it is a bill that has been in the last several Congresses. It always has several hundred cosponsors, and the top cosponsors are very, very good people and good personal friends of mine. This bill would require the NIH to coordinate research activities between the Cancer Institute and the Environmental Health Institute. That makes sense. The problem is it is already being done. We don't need the bill before us today to make that happen.

In addition, in the NIH Reform Bill that is now the law of the land we have set up a common fund that any, any investigator that wants to work across the silos at the NIH can form a coalition with other investigators and other institutes and apply for research grants through this common fund. And the Common Fund has been funded by the appropriators. So again, the problem that this bill is addressing has already been addressed.

I could go on and on, Mr. Chairman, but my time is about to expire. Let me simply say this. It is good public policy for members of this committee and this Congress to be interested in research to find cures to all the various diseases, whether it be breast cancer, Alzheimer's, Parkinson's disease, you name it. But we should try to have a policy where we fund research, put priorities on certain research, and then let the NIH under this new reform package that we just passed find the best way to allocate the available resources. I hope that we don't go back to the way we used to do business, where whichever advocacy group has the most political clout in a specific Congress, they get their research funded at the top of the list. That is not the way, in my opinion, to do health-based scientific research.

With that, Mr. Chairman, I yield back.

Mr. PALLONE. Thank you, Mr. Barton.

Our next member for an opening statement, the gentlewoman from California, Ms. Eshoo.

OPENING STATEMENT OF HON. ANNA G. ESHOO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. ESHOO. First, Mr. Chairman, thank you for having this hearing on the bills. Thank you to our witnesses.

I see a real honor roll of great advocates sitting in the rows looking up at us. And I hope that you will respect what comes out of this as you are sitting there.

I want to thank our colleague Sue Myrick because she has been steely and gentle at the same time, and has inspired a lot of us. And I want to salute her for the work that she has done.

I paid special attention to what the ranking member of the Full Committee just said. I have worked with Joe Barton for years. We like each other. We have trusted each other. And it is—I think he

outlined where the Committee is and what we honored in all of these things. But, Joe, I want to say to you that life is not tidy. This is really more a competition for dollars, than it is for anything else. And so that is how I think that whole architecture has been set down about specific diseases and specific disease bills and whatever.

I for one think that this committee should just break through all of that and say as great as the United States is we can be greater and we are going to declare war on all of these diseases. We have the capability and the capacity to do this. We just haven't set forward the political will to fund these things, and so we have the DOD funding, breast cancer research—you know why we have that there? Because that is where the money is, and that Congressman Murtha took that call up years ago.

And so we are here today with two good bills. I don't think they deliver the world on this issue, but in terms of the research it is very important. Just in this last week four of my friends—actually two of my friends were diagnosed with stage II, and each one of their daughters was diagnosed with stage II. And that is in one week's time.

So there is work to be done here. This is as serious as it comes. Women, men, their families can't go to Macy's, they can't go to Neiman Marcus to get their problem solved on this. They come to us. They come to us. The least we can do is to put these bills on the books. They are important bills, but they are not the end-all. So let us do ourselves proud by doing the right thing, but understanding that, as Auntie Mame said, we have miles to go and places to see. And I hope all of my colleagues will consider breaking out of the pack, and saying let us declare war on a whole list of diseases and set the resources there. Set the resources to the task. There isn't anything that our researchers and our scientists in this country can't do if we are willing to fund it.

So thank you for starting out with this. I am proud to cosponsor them. I look forward to the people that are going to testify. And I am especially proud of the advocates and the breast cancer coalition advocates that never tire of knocking on our doors.

Thank you, Mr. Chairman.

[The prepared statement of Ms. Eshoo follows:]

STATEMENT OF HON. ANNA G. ESHOO

Thank you Mr. Chairman for holding this hearing on two very important breast cancer bills, the Breast Cancer and Environmental Research Act and the Breast Cancer Patient Protection Act which I'm proud to cosponsor.

Breast cancer affects hundreds of thousands each year and is the most common cause of cancer among women. There's still so much we don't know about breast cancer but there are strong clues that the environment is playing some role. How big a role is what we need to learn.

The Breast Cancer and Environmental Research Act is supported by the National Breast Cancer Coalition. It would establish a national strategy to study links between the environment and breast cancer and to bring us closer to learning what these exposures are, possibly unlocking new treatments and cures.

The Breast Cancer Patient Protection Act would guarantee mastectomy and lumpectomy patients a minimum hospital stay of 48 hours, and 24 hours for a woman undergoing a lymph node removal. It's important to note that this bill does not mandate a 48-hour hospital stay if a patient chooses to go home sooner, nor does it set 48 hours as a maximum amount of time a woman can stay in the hospital.

The bill only ensures that any decision in favor of a shorter or longer hospital stay will be made by the patient and her doctor, and not an insurance company.

I look forward to hearing from our witnesses today and I thank the Chairman for holding this hearing. We do not yet know what causes breast cancer or how to prevent it and that's why these bills can make important contributions to our understanding of this all-too-frequent disease.

Mr. PALLONE. Thank you, Ms. Eshoo.

I would like to request that the statement of our Full Committee Chairman, Mr. Dingell, be inserted into the record. Without objection, so ordered.

[The prepared statement of Mr. Dingell follows:]

STATEMENT OF HON. JOHN D. DINGELL

I am pleased that Chairman Pallone is holding this hearing to provide the Subcommittee on Health an opportunity to learn more about H.R. 1157, the "Breast Cancer Research and Protection Act of 2007", and H.R. 758, the "Breast Cancer Patient Protection Act". Breast cancer is the second most common type of cancer among women in the United States, and this Congress should closely examine how best to prevent and treat it.

One of the hopeful messages from cancer research is that most cases of cancer are linked to environmental causes and, in principle, can be prevented. Environmental factors such as exposure to excessive sunlight or to chemicals, cigarette smoking, diet and lifestyle can all contribute to an individual's chances of developing cancer. While it is known that certain genetic and environmental factors increase the risk of developing cancer, it is not known exactly which combination of factors is responsible for a person's specific cancer.

H.R. 1157 would provide for the development and operation of collaborative, multi-institutional centers for the purpose of conducting research on environmental factors that may be related to the etiology of breast cancer. Additionally, this legislation would establish a Breast Cancer and Environmental Research Panel at the National Institutes of Health. This Panel would be responsible for developing innovative approaches to study unexplored or underexplored interactions between the environment and the occurrence of breast cancer and outline the key knowledge gaps.

I look forward to taking a closer look at issues related to breast cancer and environmental research, and I am very interested in exploring how best to accomplish the goals of this legislation.

The other bill that is the subject of today's hearing is H.R. 758. This legislation is included as a part of the Patients Bill of Rights, which I have championed over the past decade. I was also a lead cosponsor when it was originally introduced as a freestanding bill.

H.R. 758 would ensure that women undergoing mastectomies would be guaranteed 48 hours of hospital care unless the provider and patient determine a shorter stay is appropriate. The legislation would also protect physicians who provide quality care for breast cancer patients from retaliation by health maintenance organizations (HMOs) and other insurance companies seeking to maximize profits at the expense of patient care.

Guaranteeing that treatment decisions are made by the provider in consultation with the patient, taking into account the patient's unique medical needs, is the cornerstone of good medical care and an important part of what makes H.R. 758 a good bill.

One of my own staff from Michigan, Connie Shorter, was victim of these unscrupulous insurance company practices when she was sent home after a mastectomy in considerable pain with no support to manage her condition. Connie ultimately succumbed to her cancer, but the heartless way her insurance company treated her was an outrage.

I am pleased the Subcommittee is shining light on these issues of great importance to women and their families and look forward to the testimony of today's witnesses.

Mr. PALLONE. And our next member for an opening statement is the gentleman from Arizona, Mr. Shadegg.

OPENING STATEMENT OF HON. JOHN B. SHADEGG, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ARIZONA

Mr. SHADEGG. Thank you, Mr. Chairman, and I want to thank you for holding this hearing. I want to compliment my friend Sue Myrick for her tireless advocacy of the cause of breast cancer and dealing with the issue.

I hadn't intended to make a lengthy opening statement but just to insert my opening remarks, but I think in light of the discussion we are having I would like to deliver my perspective.

My life has been touched directly by breast cancer. My oldest sister, who when I was young and before I was married was my best friend, is now a 20-plus year breast cancer survivor. And I thank God for that every day. She remains a very close friend.

In addition, I think in prior hearings many of you have heard me tell the story of my son, who in his young education needed tutoring assistance. He had a tutor that was with him for years and years. He grew phenomenally close to her, and tragically her life was taken by breast cancer.

There are valid merits to both of the arguments we have just heard. Both Mr. Barton's argument that the political allocation of research funds has drawbacks to it. That means that those with the greatest political power can get that legislation passed and perhaps that is not how we ought to allocate resources. At the same time, my colleague on the other side did a great job of articulating that sometimes it is appropriate to rise above that.

What I would like to say is something that people don't understand because it is a civics lesson, and that is often it is appropriate to introduce a bill and to hold a hearing on a bill whether that bill becomes law or not. The American people need to understand the importance of going after and allocating research dollars to go after breast cancer. And whether we enact these bills as they are written, or amend them and change them, or whether we remain with the current policy where NIH decides the allocation of these resources, this hearing is appropriate. Bringing these knowledgeable people forward, reminding the American people of the need for research dollars in this area, making people aware of the dire consequences of cancer on so many lives. The numbers show one in eight American women will be a victim of breast cancer in their lives. I think there is no amount of attention that you could pay to this issue that would be too great.

I simply want to say that I applaud, as again, my friend, Sue Myrick, for her tireless advocacy and all of the advocates of this legislation. We need to continue to focus on this fight. It is vitally important. I know that we need to find a cure, and if we ignore it, if we don't look at it, if we don't examine it, we won't get there.

I want to conclude with one last point. When I first got here to Congress, HMOs, I believed, were abusing people rather dramatically. They were failing to pay for services that people need. They were denying coverage, not based on medical reasons, but based on money. And so I became a champion of patient advocacy legislation. Sadly, we never passed that legislation. But I believe that just the legislative hearings, and the pressure Congress put by looking at that legislation, put pressure on the HMO industry to quit denying people care for reasons other than legitimately they didn't need the

care, rather than just to get rich off of their premiums. And I think this could be viewed in the same way. I believe it is important to hold these hearings and to focus on these issues, and to debate them and resolve whether or not we need to fund this particular legislation at this level or some other level, or follow the course that Joe was talking about.

But I compliment you, Mr. Chairman, and all involved.

Mr. PALLONE. Thank you.

Next for an opening statement the gentleman from New York, Mr. Towns.

OPENING STATEMENT OF HON. EDOLPHUS TOWNS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. TOWNS. Thank you very much, Mr. Chairman. I would like to thank you and, of course, Mr. Deal for holding this hearing.

This is a giant step in the right direction. I want to commend the gentlewoman from North Carolina for her work. And to say that I would agree with the fact that it might not be a total solution, but I think that it is moving in the right direction. And I support both H.R. 1157 and also H.R. 758. I am a sponsor of both of the bills. And the reason I am a sponsor of both is that the fact that my situation is that I come from a family of four. Mother, father, and a brother. All of them died from cancer. And to listen to some of the comments being made on the other side bothers me, because I think that we cannot sit back and not do everything that we can do to find a cure.

And let me just sort of pause and say that I want to extend my best wishes to a true health care advocate, the Honorable Senator Ted Kennedy, who has been fighting this battle for more than 40 years. I want to extend my best to him and to his family during this very difficult period.

I look forward to hearing from the witnesses, because I think that there is so much that we can learn from the witnesses. And, of course, through this process I hope we move forward with an open mind. That we really, really understand how important it is to put the resources wherever to be able to come up with a cure.

So I want to thank the witnesses for coming and sharing, and I want to thank the members for being here to listen. And I hope that through this process that we will be able to fund the research, do whatever is needed to be able to come up with a cure.

And I would like to associate myself with remarks made from the gentlewoman from California. Yes, we are piecemealing, but when you are frustrated and you know that something needs to be done, you are prepared to do whatever you can do at the time that you can do it. I agree with her. I think that we should fund all of that, and to be in a position to do—I think we can do it. But the point of the matter is that do we have the will? It is not a priority. And once we make it a priority then I think we can come up with the solution.

So I would say to you, Mr. Chairman, I think that you are doing the right thing by having a dialogue, and that hope out of this dialogue will come a solution.

Thank you so much for having this hearing.

[The prepared statement of Mr. Towns follows:]

STATEMENT OF HON. EDOLPHUS TOWNS

Thank you, Chairman Pallone and Ranking Member Deal for convening this hearing on H.R. 1157 and 758, recognizing the importance of breast cancer and environmental research, and breast cancer patient protection to enable longer hospital stays for women who undergo mastectomies. I am a proud cosponsor of both bills. Breast cancer is the most frequently diagnosed cancer among women, but it disproportionately affects African American women. Environmental research includes the ability to examine the health disparity aspects and better positions us for finding a cure. I am greatly motivated to find a cure because I lost my mother, father, and brother to cancer. Lastly, I extend my best wishes to a true health care advocate—the honorable Senator Ted Kennedy and his family during this period.

Thank you, Mr. Chairman, I yield back.

Mr. PALLONE. Thank you, Mr. Towns.

Next for an opening statement, the gentleman from Michigan, Mr. Rogers.

OPENING STATEMENT OF HON. MIKE ROGERS A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. ROGERS. Thank you, Mr. Chairman, for having the Committee.

As a 24-year cancer survivor myself I certainly understand the impact that the disease has on families across the country. I couldn't imagine that there aren't that many people in America whose lives who have not been touched by cancer in any way.

When it comes to breast cancer we have seen the lives of grandmothers, and mothers, daughters, wives, and friends all torn apart by the deadly disease, including my sister-in-law. But we also have witnessed tremendous stories of courage, and importantly, victory over cancer. I remember when I first ran in 1994 the folks were saying whatever you do don't tell people you survived cancer. We have come a very long way, because so many people with courage have stood up and said yes, we can beat this disease and yes, we can continue on with long and productive lives.

Finding a cure for cancer is a national priority. Last year alone the Federal Government spent over \$5.6 billion on cancer research. In fact, last year the National Cancer Institute spent \$500 million on breast cancer research alone. Along with support for this research I have been working on issues impacting cancer care and treatment. As a matter of fact, in 2005 a good friend of mine, Anna Eshoo from California, and I cofounded the Cancer Care Working Group here in Congress to educate members and staff about exciting new developments and challenges facing oncology.

It is my hope that through a strong federal commitment to cancer research we will soon find cures that will offer new hope to millions of people throughout the world. I hope this committee, and I hope this serves as an opportunity for us to address some concerns with H.R. 1157, just as the Senate HELP Committee has done in order to ensure that breast cancer research dollars are spent on actual research. Not overhead, not administration or duplicate efforts.

Again, thank you, Mr. Chairman, for holding this hearing today, and I look forward to working with you on this important issue as we move forward.

Mr. PALLONE. Thank you.

Next I recognize the gentleman from Utah, Mr. Matheson, for an opening statement.

OPENING STATEMENT OF HON. JIM MATHESON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF UTAH

Mr. MATHESON. Thank you, Mr. Chairman.

I am a cosponsor of H.R. 1157. As my colleagues have stated, this bill would invest in research still necessary to determine the potential links between breast cancer and the environment, so that we can cure it and eventually eradicate this terrible disease.

Our best weapon against cancer is research. Everyday the headlines reveal new information that cancer patients, their families, and their doctors can use in their battle against this disease. The national investment in cancer research has yielded, and will continue to yield, substantial returns in terms of lives saved and suffering lessened. Through that research these scientists are making advances in the causes, diagnoses, and treatments of cancer and are on the front lines in the quest for prevention and cure.

In my state of Utah nearly 1,000 people will be diagnosed with breast cancer this year, and it is anticipated over 200 will die from this disease. I am continually saddened by the fact that a woman in the United States has a one in seven chance of developing invasive breast cancer during her lifetime. This risk was one in 11 in 1975. Breast cancer remains the second leading cause of cancer death among women, second only to lung cancer.

I am committed to continue fighting for increased research into the potential links between the environment and breast cancer. And I have joined many of my colleagues on this committee in encouraging increased funding for NIH. Because we don't know what causes breast cancer I look forward to hearing from the panel of experts on this bill in ways that this committee should tackle the question of how our environment may affect breast cancer.

Mr. Chairman, I yield back my time.

Mr. PALLONE. Thank you.

And next is the gentlewoman from California, Ms. Capps. I thank her again. She has also been a tireless advocate for the environmental research bill.

OPENING STATEMENT OF HON. LOIS CAPPS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. CAPPS. Thank you, Mr. Chairman. And particularly I want to give some thanks this morning in my opening statement. Thank you first of all for holding this hearing. I fully believe that this hearing is long overdue and welcomed and needs to lead to passage of legislation. It is not just a showplace for discussion today.

In saying that, I give the utmost praise to our tireless advocates who are here yet again on the topic of breast cancer. As it is an epidemic in our country today with the numbers of one in eight women—that is astounding when you think of the number of women who have had cancer or will expect to be diagnosed with

cancer during their lifetime. And all of the people who will be affected by that.

I want to single out our celebrity, Sheryl Crow, because you are not coming today as a celebrity as much as a survivor, and you don't give just token status to this. I have watched you here on the Hill time and time again, advocating also around the country. I am putting a face, a human life, to this topic in ways that are very appreciated by women around the country as well, and the many other advocates.

I want to speak on behalf of the Caucus for Women's Issues in the House of Representatives. Seventy-four of us strongly support these two pieces of legislation, determined that these will pass and be adequately funded.

And then to the two authors of the Breast Cancer and Environmental Research Act. Nita Lowey, who will, I believe, join us shortly. But, Sue Myrick, my dear friend and survivor, and co-chair along with me and our friends, Deborah Pryce and Steve Israel of the Cancer Caucus. And this is a high priority for this Caucus as well.

We have also the opportunity now to have this hearing on the Breast Cancer Patient Protection Act. And I just want to say that I came to Congress as a spouse over 11 years ago. And one of the first things I heard about was the so-called drive-by mastectomy. That this famous person I hadn't met yet, Rosa DeLauro, was working tirelessly to eliminate that possibility that some of the insurers were making it so difficult for someone to go through a horrendous surgery and then be sent off, back home again so quickly.

And I think it is very, very important to acknowledge, and perhaps others have already, that along with Rosa DeLauro, the co-author of this legislation in this Congress, is our dear departed colleague, Jo Ann Davis. And it is with great determination that we need to pass this bill in her memory.

So I am going to yield back, and look forward very much to the testimony of our witnesses today. Thank you.

Mr. PALLONE. Thank you, Ms. Capps.

And next for an opening statement the gentlewoman from Illinois, Ms. Schakowsky.

OPENING STATEMENT OF HON. JAN SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

This is a great way for us really to close this legislative work period before returning home to our districts for a week.

As you have heard everybody has a personal story. I was proud when I was in the state legislature that we were able to pass legislation that stopped these drive-through mastectomies in Illinois. Give women a period of time to get the care that they need in the hospital. And several states have actually done that. And I have been with women, talked with women, who were shuffled out of the hospital before they felt ready to go. And unfortunately, too many women experienced those kinds of things, because their insurance companies don't do what is really needed and appropriate. And so I am so glad we are going to be making progress on H.R. 758 today.

And I also want to express my thanks to Congresswoman Rosa DeLauro for her tireless work on this. And I want to thank the cosponsors of the Breast Cancer and Environmental Research Act, H.R. 1157, Congresswomen Nita Lowey and Sue Myrick. And I am proud to be one of the cosponsors of that bill.

We know far too little about what causes breast cancer, but without a doubt we know that it affects far too many of our mothers and daughters and sisters and friends. And this bill will take a huge step toward learning more about the etiology of breast cancer by establishing a research panel, encouraging multi-disciplinary and multi-institutional research on the environmental factors that may be related to breast cancer and authorizing appropriations for these purposes.

I am particularly interested in finding ways to learn more about the relationship between chemical exposures from everyday products and the occurrence of breast cancer. I look forward to hearing our witness from the NIH, Dr. Winn, who I believe will discuss this area of research. I believe this is something that we can do in the United States of America with the kind of expertise that we have. That we can actually provide answers to some of these health care challenges. And I look forward as a member of Congress to be part of that effort to make it happen sooner, rather than later.

Thank you, Mr. Chairman. I yield back.

Mr. PALLONE. Thank you, Ms. Schakowsky.

I think that concludes our opening statements by the members, so we will now turn to our first panel, which actually has one witness.

Welcome, Dr. Winn. Let me introduce and give everyone your official credentials here. You are the associate director—this is Dr. Deborah Winn, who is associate director of Epidemiology and Genetics Research Program at the National Cancer Institute in Bethesda.

You know the ritual here. We have a 5-minute opening statement. It becomes part of the record. But we may, as Committee members, submit additional briefs or pertinent statements in writing and ask you to get back to us later in writing.

So I now recognize you. Welcome again, and thank you for being here.

STATEMENT OF DEBORAH WINN, PH.D., ASSOCIATE DIRECTOR, EPIDEMIOLOGY AND GENETICS RESEARCH PROGRAM, NATIONAL CANCER INSTITUTE

Dr. WINN. Thank you very much for the opportunity to speak with you today. I am Deborah Winn, the associate director for the Epidemiology and Genetic Research Program at the National Cancer Institute, NCI, within the National Institutes of Health, NIH, an agency of the Department of Health and Human Services.

Mr. PALLONE. I think Dr. Winn—do you want to bring that mic closer and make sure it is on?

Dr. WINN. Sure.

Mr. PALLONE. You might have to bring it closer.

Dr. WINN. OK. I specifically oversee research seeking—

Mr. PALLONE. I don't know. It seems to be something wrong. Is the light on?

Dr. WINN. Yes, the light is on.

Mr. PALLONE. Maybe just bring it closer.

Dr. WINN. OK. OK.

Mr. PALLONE. That is good.

Dr. WINN. How about that? Sorry. I specifically oversee research seeking to identify environmental and genetic factors involved in the etiology of breast cancer, which H.R. 1157 is intended to address.

We at NIH believe that the current Public Health Service Act provides sufficient authority to address this area of research, as well as others. As science advances through discovery it increasingly converges. We know that the answers to the most vexing scientific questions involving one disease often comes from areas of unrelated research. As scientists we know that it would be a mistake to focus on one disease without understanding the underlying biological mechanisms that affect multiple diseases. And this is one of the great lessons that we are learning from some of the recent advances in genomics and molecular biology.

In general, prescribing a specific way of conducting federal research could have the unintended consequences of narrowing the field of inquiry, and promoting an unwise use of precious resources. This morning I would like to share with you information about our progress in understanding the role of the environment and the development of breast cancer. The research activities that I describe were planned and carried out using our existing authority.

As you have noted it is estimated that approximately 180,000 women will be diagnosed with breast cancer in 2008. I certainly know about this, having been one of them diagnosed with breast cancer at age 42. Known risk factors include increasing age, family history, reproductive history, obesity, heavy alcohol intake, and hormone replacement therapies. We know less about possible environmental causes of breast cancer, but we recognize that breast cancer is a complex disease caused by multiple interacting factors including genes, hormones, and environmental exposures that interact across the lifespan and may share common etiologic pathways with other diseases.

NIH estimates that it will fund about \$705 million in breast cancer research in fiscal year 2008; almost \$100 million will be spent focusing specifically on the role of the environment in breast cancer. Despite this substantial investment, well-conducted studies of adult women have revealed little in the way of findings of possible environmental causes. One new approach is to study "windows of susceptibility." These are the prime events over the lifespan where exposures to environmental factors can directly or indirectly affect a person's risk of developing breast cancer. This approach stems from the knowledge that there are specific windows of time and physiologic changes in the mammary gland that may be important. And narrowing in on these time periods could be very important in our understanding.

To uncover the links between early environmental exposures and cancer risks, NCI partnered with the National Institute of Environmental Health Sciences, NIEHS, in 2003 to fund four Breast Cancer and the Environment Research Centers. We call these BCERCs. These BCERCs are specifically focusing on exposures during early

life and during puberty because they are important windows of susceptibility for breast cancer. The centers are headquartered at four sites across the U.S., but each center is a consortium and has many research partners. The BCERCs were designed to include breast cancer advocates as foundational parts of each center and as formal members of various steering committees and an advisory working group. Each center includes basic scientists, clinicians, population scientists, and advocates. They conduct research into the role of the environment in breast cancer by using both animal models and studies in human populations.

The animal models allow investigators to examine the entire reproductive span and breast cancer. The research also includes the study of young girls going through puberty to look at environmental, psychosocial, dietary, and other determinants of breast development.

My written testimony includes details about a number of other research efforts we have in the area of breast cancer and the environment. In conclusion, NIH funds research that takes a diverse approach to studying breast cancer and the environment. This approach includes identifying specific chemicals which change the structure and function of the mammary gland, or breast, during different windows of susceptibility, understanding gene environment interactions in the etiology of breast cancer and other associated physiological milestones that are associated with breast cancer risks.

In addition, our research is focused on identifying common pathways across a number of different types of cancer. While more research is needed and with continued collaborations of scientists, advocates, and Institutes, we are well equipped to continue to support and enhance this area of breast cancer and the environment research.

And I would like to thank you for the opportunity to testify today and welcome any questions.

[The prepared statement of Dr. Winn follows:]



**Testimony
Before the
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives**

**NIH Research on the Role of the
Environment in Breast Cancer
Development and Progression**

Statement of

Deborah Winn, Ph.D.

Associate Director

Epidemiology and Genetics Research Program

National Cancer Institute

National Institutes of Health

U.S. Department of Health and Human Services



**For Release on Delivery
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Wednesday, May 21, 2008

Thank you for the opportunity to speak to you today. I am Deborah Winn, the Associate Director for the Epidemiology and Genetics Research Program at the National Cancer Institute (NCI) within the National Institutes of Health (NIH), an agency of the Department of Health and Human Services. I specifically oversee research seeking to identify environmental and genetic factors involved in the etiology of breast cancer, which H.R. 1157, the "Breast Cancer and Environmental Research Act of 2007", also is intended to address. We at NIH believe that the Public Health Service Act, as amended by the NIH Reform Act of 2006, provides sufficient authority to address this area of research, as well as others. As science advances through discovery, it increasingly converges. We know that the answers to the most vexing scientific questions involving one disease often come from areas of unrelated research. As scientists, we know that it would be a mistake to focus on one disease without understanding the underlying biological mechanisms that affect multiple diseases. This is one of the great lessons learned from recent advances in genomics and molecular biology.

These lessons should apply to well-intended legislation, as well. In general, prescribing a specific way of conducting Federal research could have the unintended consequence of narrowing the field of inquiry and promoting an unwise use of precious resources. We must be careful to avoid such unintended consequences in the consideration of any bills, particularly those aimed at specific diseases.

As you deliberate, I want you to know about our progress in understanding the role of the environment in the development and progression of breast cancer in the hope it will illuminate your understanding of the issues under consideration at today's hearing.

It is estimated that 182,460 women will be diagnosed with breast cancer in 2008, and 40,480 women will die of cancer of the breast in 2008. Known risk factors include increasing age, family history, reproductive history, obesity, heavy alcohol intake, and hormonal replacement therapy. We know less about possible environmental causes of breast cancer, but we recognize that breast cancer is a complex disease caused by multiple interacting factors, including genes, hormones, and environmental exposures, that interact across the lifespan and may share common etiologic pathways with other cancers and diseases.

The NIH estimates that it will fund \$705 million in breast cancer research in FY 2008, representing a robust research portfolio covering etiology, prevention, early detection, diagnosis, treatment and rehabilitation. Within the portfolio, we expect \$60.7 million will be specifically spent on researching the role of the environment in breast cancer development at NCI, and \$35 million will be spent at the National Institute of Environmental Health Sciences (NIEHS), totaling almost \$100 million in support of this important area across NIH.

Despite this substantial investment, well-conducted studies of adult women have revealed little in the way of findings of possible environmental causes of breast cancer. Therefore

investigators are taking a fresh approach to this problem and have shifted their focus to studying “windows of susceptibility”. “Windows of susceptibility” are the prime events over the life span where exposures to environmental factors can directly or indirectly affect a person’s risk for developing breast cancer. This approach stems from the knowledge that there are specific windows of time that physiologic changes to the mammary gland occur. These include gestation, puberty, pregnancy and lactation. Exposures that occur during these periods of time early in life may influence the risk of developing breast cancer. Narrowing in on these specific time periods will improve our understanding of the interactions of genes, the environment, and cancer risk.

Breast Cancer and Environment Research Centers

To uncover the links between early environmental exposures and cancer risk, NCI partnered with NIEHS in 2003 to fund four Breast Cancer and Environment Research Centers (BCERCs). These BCERCs are specifically focusing on exposures during early life and during puberty because they are important windows of susceptibility for breast cancer. Studies have consistently shown age at onset of menstruation to be a breast cancer risk factor. It is important to study the factors that affect the age at breast development too, since girls who go through puberty earlier will have a longer period of exposure to estrogen and may be at increased risk for breast cancer later in life.

The Research Centers are headquartered at Fox Chase Cancer Center in Philadelphia, University of California San Francisco, Michigan State University in East Lansing, and the University of Cincinnati in Ohio, but each Center is a consortium and has many other

research partners. The BCERCs were designed to include breast cancer advocates as foundational parts of each Center and the program as a whole. Breast cancer advocates play a unique role at each of the BCERCs. They contribute to the dialogue on scientific themes, provide outreach to the general public and families of study subjects and they are developing materials to educate the public on what we should know about the role of the environment in breast cancer risk. Advocates play an active role in the governance of the BCERC as formal members of various steering committees and an advisory working group.

The BCERCs have been instrumental in expanding what is known about the role of the environment in breast cancer research by using both animal models and studies in human populations. Animal models allow investigators to examine the entire reproductive span of the animals to understand how environmental factors influence breast cancer development. For example, animal models are being used to see if treatment with soy and other estrogen-like plant compounds during early life may influence the structure and function of the mammary gland as it matures and may protect the gland by making it less susceptible to chemical carcinogens.

The BCERC also includes an epidemiologic study following young girls through pubertal development. Scientists are studying environmental, psychosocial, dietary and other determinants of breast development and other components of puberty. Investigators at one Center have found preliminary evidence that many girls have detectable levels of hormonally active chemicals, and the relation of these levels to breast development are

being studied more fully to see if they delay or speed breast development. This cohort is being followed to determine which environmental exposures may be associated (either positively or negatively) with earlier breast development so that preventive strategies can be developed to reduce exposures during this critical period of development in order to reduce breast cancer risk in the future.

Recent stories in the news around exposures to a plasticizer, Bisphenol A (BPA) highlight the type of work in the BCERC that bring together basic and public health scientists and advocates. BCERC is studying a cohort of young girls, and preliminary findings show that girls across the study sites have detectable levels of BPA in their urine, and those girls who are not obese tend to have higher rates of BPA. These data have yet to be finalized. In addition, data on the association of body mass index (BMI), BPA, and timing of breast development is being studied in the BCERC study.

The BCERC program is in a unique position to facilitate the exchange of emerging scientific information between basic scientists, clinicians, and population scientists to expeditiously test hypotheses that emerge from the coordinated studies of chemicals such as BPA. Not only can scientific discovery be expedited, but the involvement of advocates in the project also allows for dissemination of these research findings to the public.

Our understanding of breast cancer is changing, as is our understanding of the environment. These changes are necessitating a shift in our scientific strategies for

studying risk factors for breast cancer. In addition to the BCERCs, we are using other innovative approaches, such as genome-wide association studies (GWAS) to understand breast cancer susceptibility. GWAS are a new and promising area of research to understand susceptibility to many different diseases including cancer.

Genome-Wide Association Studies

Genome-wide association studies (GWAS) involve a systematic look across the entire human genome to identify genetic variants that are associated with increased risk for both common and uncommon cancers. By scanning the DNA of thousands of breast cancer cases compared to DNA from healthy women, NCI investigators have recently identified genetic variants in a specific gene that are associated with increased breast cancer risk and are estimated to be present in more than 60 percent of U.S. female adults. Another unexpected and exciting finding is the discovery that a region on chromosome 8 is associated with breast, colon, and prostate cancers. These findings, along with several others from multiple studies, suggests that looking at these genetic regions in conjunction with behavioral, reproductive, dietary and environmental factors together can shed some light on common causal pathways to cancer development in general. The results of genome-wide studies, with the follow-on studies targeted at the identified genes, promise to provide novel strategies for detection and prevention, well beyond what can be learned from studies of single genes.

National Toxicology Program

Over the past decade, the National Toxicology Program (NTP) has conducted experimental laboratory animal studies at NIEHS that show that chemicals identified to cause mammary gland cancer in rodents are frequently mutagenic or show estrogenic properties. In total, over 40 chemicals have been identified as mammary gland carcinogens. These include phenolic chemicals that may be both weakly estrogenic and further metabolized to mutagens. Other classes of chemicals that were identified to cause mammary gland cancer in rodents include halogenated hydrocarbons, aromatic amino/nitro compounds and chemicals that can be metabolized to epoxides. Many of these carcinogens and other chemicals have been shown by NTP studies to be endocrine disrupting chemicals and may also increase susceptibility to breast cancer through hormonal pathways.

Genes and Environment Initiative

The Genes and Environment Initiative (GEI) is a four-year, NIH-wide program led by the National Human Genome Research Institute (NHGRI) and NIEHS that is supporting efforts to identify major genetic susceptibility factors for diseases of public health significance and to develop technologies for reliable and reproducible measurement of potentially causative environmental exposures. The GEI has two major components.

The genetics component is conducting GWAS using DNA specimens collected from ongoing population studies of over a dozen major diseases in order to identify single gene variants that may be associated with risk. Complementary replication studies in other

populations and functional gene studies are also planned to validate the newly identified susceptibility genes.

The Exposure Biology Component is using a product driven approach to improving exposure assessment of commonly occurring exposures and lifestyle factors, such as chemicals, stress, addictive substances, diet, and physical activity. New biological and engineering technologies such as genomics, proteomics, global positioning systems (GPS) and spatial indicators, physiologic and chemical sensors, and image enhancements are being incorporated into new biomarkers or devices that will improve the characterization of these factors in human populations. The ultimate goal of the GEI is to look broadly at interplay between genes and environment to identify risks of disease.

The Exposure Biology program has several projects that directly address concerns about chemical exposures that may increase risk of breast cancer. These projects seek to develop new biomarkers of response to xenoestrogens by defining signatures of response in blood proteins and DNA methylation patterns in mammary gland tissues. These important projects will help better define the effects of exposure on breast cancer risk in women.

The Sister Study

The Sister Study, which NIEHS began in October 2004, is a unique long-term study of women aged 35 to 74 whose sisters had breast cancer. The study aims to uncover the links between genetics and the environment in the development of breast cancer using

epidemiological analysis and biochemical investigations of a cohort with about twice the risk of other women for developing breast cancer. The study is an unprecedented effort to understand the relative importance and interplay of genetic and environmental factors in the disease. The study is quickly approaching the goal of enrolling 50,000 diverse women, but to ensure the results benefit all women, researchers are focusing on increasing the number of participants from targeted demographic groups, such as African Americans, Latinas, Asians, Pacific Islanders, and Native Americans, as well as Caucasian women with high school degree or less, or who are between the ages of 65-74.

Recent funding from the Susan G. Komen for the Cure foundation will allow NIEHS scientists to conduct a family-based study. Called the Two Sister Study, its aim is to investigate the genetic and environmental factors that influence young-onset breast cancer—breast cancer developed before age 50. The study will include about 2,000 of the 50,000 women with breast cancer whose sisters enrolled in the Sister Study, along with their unaffected sister and genetic data from any parents who are still living.

The Sister Study team of partners includes many breast cancer organizations and advocacy groups. These groups include the American Cancer Society, NIH's National Center on Minority Health and Health Disparities, Sisters Network Inc., Susan G. Komen for the Cure, Breast Cancer Network of Strength (formerly known as Y-ME National Breast Cancer Organization), and Intercultural Cancer Council, and have been instrumental to the success in enrollment and follow-up of the study participants across the US.

The Polish Breast Cancer Study

Breast cancer is not just a domestic issue but a disease that exacts a heavy toll around the world. A global approach to research enables explorations of interactions between genes and specific environmental exposures found in diverse geographic settings. In a collaborative effort with researchers in Warsaw and Lodz, Poland, NCI investigators are conducting a population-based study to investigate a variety of potential risk factors, including tobacco, hormones, and occupational chemical exposures, and their interactions with genetic markers that may be important in breast carcinogenesis.

Conclusion

NIH funds research that takes a diverse approach to studying breast cancer and the environment. This approach includes identifying specific chemicals which change the structure and function of the mammary gland during different windows of susceptibility, understanding gene-environment interactions in the etiology of breast cancer and associated physiologic milestones that are associated with breast cancer risk. In addition this research is focused on identifying common pathways across different types of cancer. With the continued collaborations of scientists, advocates, and institutes, we are well-equipped to continue to support and enhance the area of breast cancer and environment research.

Mr. PALLONE. Thank you, Dr. Winn, and thank you for all that you and your colleagues do at NIH.

We are going to have questions now, and I will start with myself for questions.

In your testimony you talk about a lot of the research that is already ongoing at NIH or being funded by extramural research grants. The proponents of this legislation, as you know, believe that the research strategy outlined in the bill before us will help supplement research efforts currently underway. Do you think that the provisions of this bill will help build upon current research efforts and lead to a better understanding of the linkages between the environment and breast cancer, and basically why or why not?

Dr. WINN. Well, NIH already has the existing authorities to pursue this area of research through the Breast Cancer and the Environment Research Centers as well as many other opportunities. For example, through the Common Fund and through the Genes and Environment Initiative, we have ample opportunities to study breast cancer and the environment.

Mr. PALLONE. Well, how does the research strategy outlined in the bill compare or contrast from the efforts currently under way at NIH or being funded through NIH through extramural grants?

Dr. WINN. The bill would include a panel that would direct the funding of the research, as well as having a very specific disease focus. Our general approach at NIH that has worked very well for us is to use our existing peer review system that is really considered to be a gold standard across the world for its fairness and its focus on scientific merit. Also, our approach at NIH with respect to breast cancer and the environment takes a number of different routes through, for example, use of the Common Fund, use of various funding mechanisms, and use of workshops that include the advocacy community.

Mr. PALLONE. Now, there is a Senate equivalent of this bill.

Dr. WINN. Yes.

Mr. PALLONE. I try not to mention the other body too often here, but there is one.

Dr. WINN. Yes.

Mr. PALLONE. And I understand that NIH has—well, I understand that our colleagues in the Senate made some changes to the legislation when the HELP Committee marked up its version. Can you explain the concerns that NIH has with the House bill and tell me if the changes that the Senate made adequately addressed your concerns, or are there any other changes that NIH would like to see made?

Dr. WINN. Yes. Well, certainly from the scientific perspective the issue regarding the funding panel, as well as the single-disease focus, are concerns that we have because it circumvents the existing peer review system, and because a single-disease focus can actually constrain us in terms of the research that we can do and our ability to let the science direct the research agenda. Specifically, regarding the Senate bill, the Senate bill as amended is not opposed by NIH. However, the Administration does not have a position on the bill.

Mr. PALLONE. But you obviously had some input into the changes. Is there anything else? I mean I understand your basic concern—

Dr. WINN. Yes.

Mr. PALLONE [continuing]. With any of these bills, but you have obviously had some input on the Senate bill. Is there anything additional, other than the basic concern that you would like to see addressed here?

Dr. WINN. I think I will defer to my colleagues on that.

Mr. PALLONE. This is—

Dr. WINN. The changes in the Senate bill are very satisfactory to the National Institutes of Health.

Mr. PALLONE. OK. Let me ask you one more question, and then we will move on. You testified that advocates play an active role in the governance of the Breast Cancer and the Environment Research Centers, and its formal members—I guess they are formal members of various steering committees and then advisory working group. Can you, please, explain why you believe it is important for advocates to play an active role with respect to these issues?

Dr. WINN. Because they are the ones who are listening to the community. The advocates in our group have played a number of key roles in addition to participating in the overall scientific management and oversight. Some of these roles include our ability to help recruit and retain the young girls and their families who are part of the epidemiologic study. They also have an incredibly large role in developing materials that try and explain what it is that we do know about breast cancer and the environment that can be used both with the study participants and their families, as well as the broader communities. Each of the advocacy groups that is part of the Breast Cancer and the Environment Research Centers are local to that particular center and are very well aware of the issues that differ between the California, Ohio, Michigan, and New York City areas where the young girls are located.

Mr. PALLONE. OK. Thank you very much.

Mr. DEAL.

Mr. DEAL. As I understand it you currently work with outside advocacy groups in determining the direction of the research that NIH is conducting. Is that correct?

Dr. WINN. Yes, that is true.

Mr. DEAL. All right. Could you give us an idea how under the NIH Reform Act this collaboration of information across institute lines works in terms of, perhaps, advancing the cause of dealing with this specific area of breast cancer?

Dr. WINN. Well, I can give you one example, which is the Genes and Environment initiative, and that is the trans-NIH effort that comes out from the Common Fund. One major part of that is the environmental exposure area. We are really way behind in terms of our ability to monitor individual's environmental exposures and in the development of biomarkers that would indicate environmental exposure or early damage. And one of the particular projects that is being supported under that is looking at biomarkers for estrogen-like compounds in biological fluids that could be used as a future biomarker for example. So that is one area where

the Common Fund has directly impacted the breast cancer and the environment issues.

Mr. DEAL. As I read your testimony one of the concerns that you express is that if we try to statutorily be too specific in designating what you must do or should do that we run the risk of having unintended consequences. Is that a general summarization of one of your concerns?

Dr. WINN. Yes. So, for example, with this bill, were this bill to pass, we would have to fund it given the current fiscal environment. We would have to redirect funds from some other research area. This is what typically happens at NIH with a disease-specific requirement.

Mr. DEAL. I believe I have the figures right, that you currently spend about \$705 million on breast cancer research. Is that about right?

Dr. WINN. Yes.

Mr. DEAL. How does that compare with other cancer research activities?

Dr. WINN. Well, it is extremely high. For example, in the area of brain cancer research the estimate is \$148 million in fiscal year 2007. So that would compare with \$705 million for breast cancer research in 2007.

Mr. DEAL. All right. Thank you, Mr. Chairman. I yield back my time.

Mr. PALLONE. Thank you, Mr. Deal.

The gentlewoman from California, Ms. Eshoo.

Ms. ESHOO. Thank you, Mr. Chairman, and thank you for being here today with us.

The area that I would like to examine is—and I obviously don't know the answer to this. Is there research being done in other countries today to study the links between environmental factors and breast cancer?

Dr. WINN. Yes. In fact, the National Cancer Institute, through the intramural program, is funding what is called the Polish Breast Cancer Case Control Study. The study is focusing on—like many studies of breast cancer on many risk factors including occupational exposures. We sometimes like to look at occupational exposures because workers tend to have greater exposures, and it allows us to look at potential environmental factors better. So that is an instance where we are using a special opportunity to focus on environmental factors.

Ms. ESHOO. How big is that study in Poland?

Dr. WINN. My understanding is several thousand women with and without breast cancer. I can find out more information about the numbers.

Ms. ESHOO. And other countries?

Dr. WINN. With respect to environment and breast cancer research?

Ms. ESHOO. Yes.

Dr. WINN. We have a number of studies in China that are cohort studies that involve tens of thousands of people that have some environmental components. Usually they are focused on multiple factors.

Ms. ESHOO. And those are the two that come to mind? Are there many more? Is it widespread? Is it small? Would we be in the lead by doing this?

Dr. WINN. Would we be the lead in breast cancer and the environment research? I would have to get back to you on that. There are some countries that are particularly strong in environmental research.

Ms. ESHOO. Yes.

Dr. WINN. For example, Scandinavian countries where record linkage is much more common, which enables certain types of research more than others.

Ms. ESHOO. Well, I am particularly interested in the nexus between environmental factors and breast cancer because that is what one of the bills directs itself toward. Are women in other countries, do you know, getting breast cancer at the same rate as in the United States? The one in eight figure?

Dr. WINN. The probability of developing breast cancer can be very high in many parts of the world. It is likely to be higher in more developed countries than in less developed countries in general.

Ms. ESHOO. And can you speak to the enthusiasm that you have for these bills? Do you recommend any additions or subtractions or tweaking? You are an expert in the field and that is what a hearing is for. We want to hear, listen, build, make better.

Dr. WINN. Yes. We all appreciate the goal of the legislation, but NIH already does—

Ms. ESHOO. I mean on the specifics.

Dr. WINN [continuing]. Have authorities that would allow us to pursue these areas. We are, of course, from a scientific perspective concerned about the peer review aspect and the single disease focus. And the Senate bill is not opposed by NIH.

Ms. ESHOO. Why are you concerned about that?

Dr. WINN. We are concerned about the peer review system because the NIH peer review system is set as a gold standard with respect to its overall fairness and its overall focus on scientific merit. It is a very finely tuned instrument for that purpose. And the comparable safeguards with respect to the panel that is proposed would not ensure that same level of scientific overview expertise on the panel and the scientific merit focus.

Ms. ESHOO. Yes.

Dr. WINN. It also creates a parallel organization separate from the—

Ms. ESHOO. So the peer review process is what you believe should be in the—

Dr. WINN. The peer review process has worked very well for us.

Ms. ESHOO. Yes. And what was your other concern?

Dr. WINN. The other concern is the single disease focus—

Ms. ESHOO. Yes.

Dr. WINN [continuing]. In terms of boxing us in with respect to the types of research that could be undertaken.

Ms. ESHOO. Well, it seems to me though that this is one of the biggest question marks relative to breast cancer. I mean women in the Bay area where I come from have much higher rates. There have been—and when I think of all of the women and their fami-

lies that run and walk and we sponsor them, and the dollars from selling cupcakes to go into research, this seems to me to be an area that we need to really be pouring some efforts into. So I am more attracted to a bolder statement that, yes, we are going to take this on and not be so tied to—if we had succeeded with what you just stated I would say, hey, we have won. We have already discovered. We have made the breakthroughs. Amen. Let us move on to something else. But I don't think we have, so I don't understand why you would be essentially driving with an emergency brake on and be kind of hanky about research that is specific, and the nexus between the environment and breast cancer. That is my observation, so now you can't really respond because I am 29 seconds over time. Thank you.

Mr. PALLONE. OK. Thank you, Ms. Eshoo.

Dr. Winn, would you get back to us in writing, though, with some of the things that Ms. Eshoo mentioned about the——

Dr. WINN. I certainly will.

Mr. PALLONE [continuing]. Studies in Poland and the E.U. and——

Dr. WINN. Yes.

Mr. PALLONE [continuing]. How these compare in terms of funding?

Dr. WINN. Absolutely.

Mr. PALLONE. Thank you.

Next for questions is the ranking member, Mr. Barton.

Mr. BARTON. Thank you, Mr. Chairman.

Let me start out by putting a few things on the record I didn't in my opening statement. I have an aunt that died of breast cancer, and I have a sister that is a breast cancer survivor of 15 years. I also have a brother that died of liver cancer, a father that died of complications from a heart operation caused by diabetes, and my mother is in an early stage of Alzheimer's victim. My problem with this bill is not that we shouldn't do all we can do to combat breast cancer. My problem with the bill is that once again we look like we are going down the path of picking winners and losers and who gets the most research. You know, where does that leave liver cancer or breast cancer or bone cancer, leukemia, lung cancer, skin cancer, brain cancer, prostate cancer, pancreatic cancer? What about Alzheimer's? What about Parkinson's? What about autism? What about diabetes? So that is my problem.

Let me ask you, Doctor, right now in the National Cancer Institute we have four centers of excellence for breast cancer research. Is that correct?

Dr. WINN. Yes, we have four Breast Cancer and the Environment Research Centers.

Mr. BARTON. OK. Do we also—now, in the environmental—in the National Institute of Environmental Sciences, which is a separate institute from National Cancer Institute, does the National Institute of Environmental Sciences have centers of excellence for environmental research, and if so how many?

Dr. WINN. Well, first of all I would like to ask if Mr. Chairman would permit my asking my colleague, Gwen Collman, with the National Institute for Environmental Health Sciences, NIEHS, to join me at the table?

Mr. PALLONE. Sure. Let me introduce her. It is Dr. Gwen Collman from the National Institute of Environmental Health Sciences, Chief of Disease, Susceptibility and Population Branch.

Dr. COLLMAN. Thank you very much for the opportunity to answer the question directly. The NIEHS has 25 centers of excellence in environmental health sciences distributed across the country. Many of them are actively involved in research on breast cancer and environment, but of course the field of environmental health sciences is quite broad. They support research in basic science, toxicology, exposure assessment in human studies related to a host of environmental exposures as causes of a variety of different diseases.

Mr. BARTON. Now, the bill before us would require the creation of collaborative multi-institutional centers of breast cancer and environmental research in addition to what we already have. In the opinion of you—both of you expert witnesses—is that directive in the pending legislation necessary or helpful?

Dr. WINN. Well, we already have Breast Cancer and the Environment Research Centers that fall within what you described in that they are transdisciplinary, multi-center, and geographically distributed.

Mr. BARTON. OK. As I understand the pending bill it would require the creation of additional multi-institutional centers. And my question is, since we have 25 centers of excellence for environmental research and four centers of excellence for breast cancer research, are those currently collaborating and cooperating, and is it necessary to create these additional centers of excellence?

Dr. WINN. So my personal opinion on this is that there are lots of different mechanisms available to us at NIH to bring small projects together with larger projects and to create consortia around issues of importance. We have tackled some of these questions using a center mechanism, but we are concerned that we would not be able to tackle these pressing problems using other mechanisms with the language in the current bill. Also, we routinely bring center members together for joint meetings that are focused on synergizing the science. We have broad authority and ability to do that and do that all the time.

Mr. BARTON. Now, am I not correct that under the new common fund that has just been created, and has been funded by the appropriation process, if any of the scientific leaders, research directors, at the existing centers of excellence and your two institutes wanted to collaborate on a specific research project they could put together an application, submit it to the Common Fund, and it would be peer-reviewed by experts and if it was of merit it would probably be funded. Is that not correct?

Dr. COLLMAN. The investigators at our centers do collaborate and they have submitted applications that leverage the resources that we have given them in the original projects. An example is the study that Dr. Winn mentioned before in our genes environmental health initiative where two—three collaborators from different centers in our Breast Cancer Environment Research Centers submitted an application to the genes environment and health initiative and was funded through the Common Fund to develop new markers of exposure to disrupting chemicals. We can fund studies

collaboratively right now both from institute funds and other ways. So this is part of the authority that NIH already has.

Mr. BARTON. Mr. Chairman, my time is expired. I think I have made my point that people like myself are not opposed to doing everything we can for breast cancer research.

Mr. PALLONE. Thank you.

Mr. BARTON. Having just gone through the expert witnesses, though, this bill is not necessary from a scientific research—in my opinion.

Mr. PALLONE. Thank you.

You may as well stay up there, Dr. Collman.

Next is the gentlewoman from California, Ms. Capps.

Ms. CAPPS. Thank you, Mr. Chairman.

Dr. Winn, I understand that prior to markup in the Senate HELP Committee, the NIH indicated it would lift its opposition to this bill if certain changes were made, and that those changes were in fact made. Is that correct?

Dr. WINN. Yes, that is correct.

Ms. CAPPS. Now, this hearing today is on the legislation as originally introduced, and not the version that was passed by the Senate HELP. But I just want to be sure that the NIH's position would remain neutral if the House were to accept the Senate's changes. I want to get you on record as to your statement about that.

Dr. WINN. Yes, that is correct.

Ms. CAPPS. And oftentimes in a conference committee or, perhaps, even in the House this is a possibility that we would have is to accept the language in the Senate, particularly knowing that it would be something that you would not object to. And so you are now on record as saying that if that is something the House wishes to do that the NIH would not oppose it, or would remain neutral on that topic?

Dr. WINN. That is correct. NIH would not oppose it.

Ms. CAPPS. Thank you. Dr. Winn, you also testified that advocates play an active role in the governance of the Breast Cancer and Environmental Research Centers as formal members the various steering committees and as an advisory working group. Now, would you explain for us, please—and I know you have referenced this, but to get it specifically on the record why you believe it is important for advocates to play an active role? And I believe that is your phrase, active role, with respect to these issues?

Dr. WINN. I believe that it is important they play an active role, once again, because of their closeness to the ground and to the community. One example of how valuable they have been with respect to this particular project, the Breast Cancer and Environment Research Centers, is that they have been critical in developing, together with the scientists, the list of chemicals that we are actually going to look for. They have specifically listened to their communities to identify what chemicals might be of greatest concern. The list is being combined with lists that we are creating based on what may be found in animal models to create a master list that hypothetically and theoretically might be the most important chemicals to study. So that is one example. They are also very critical in the recruitment and retention of the young girls in communicating with the communities and in working with us on our annual sci-

entific conference that includes a wide range of advocates. We also are fortunate in having support from the Avon Foundation which is contributing to the BCERCs as well. And their support has been very important to us.

Mr. CAPPS. So even though they are not necessarily scientists, these are advocates and many of them are breast cancer survivors or loved ones of those who have not maybe survived. They are very mighty, powerful forces in my communities I know. But that you are able even to use their data collections in a fairly scientific way to help identify possibilities in the kinds of ways that research will go on. I want to ask one final question of you, because it has come up already today among many of the opening statements. We hear from critics of H.R. 1157 that the legislation is too disease-specific. But isn't it true that research on any cancer can often lead to progress in all cancers? And, in fact, isn't research in many other fields than cancer sometimes applicable to cancer cures or cancer treatments that may be beneficial?

Dr. WINN. Yes, it is true that one disease can inform another. But also what we are finding is that there is a lot of convergence of our understanding about diseases. We learn from one disease about another, and we are learning something about all of them that suggests common pathways. The best example I think I can give for that is the very recent findings in 2007 from genome-wide association studies that look at hundreds of thousands of places along the genome. And when you compare thousands of women with breast cancer and thousands of women without we find that a certain area that is implicated in breast cancer is the same area that has been found for prostate and colon cancer. So we are looking forward to finding out more about that and how environmental, life style, behavioral and dietary factors may influence all of these cancers by looking at them together.

Ms. CAPPS. So you would agree that—this is not a question, but a summary, Mr. Chairman. That even though this legislation is modeled to study the effects of environmental factors on the etiology of breast cancer, the structure that it puts in place has the potential to yield results relevant to all cancers and perhaps even other diseases, and could be used for that?

Dr. WINN. That could be an off-shoot.

Ms. CAPPS. Yes.

Dr. WINN. Certainly it is not directly intended to focus on that.

Ms. CAPPS. Understood. Thank you very much.

I yield back.

Mr. PALLONE. Thank you.

The gentlewoman from North Carolina, Ms. Myrick.

Ms. MYRICK. Well, in the interest of time I want to hear the other witnesses and I would just simply like to ask the Chairman's permission to put the letter from the Collman Foundation, that you have a copy of, into the record and then I will wait for the second panel.

Mr. PALLONE. Without objections, so ordered. And thank you.

[The information was unavailable at time of printing.]

Mr. PALLONE. And next is the gentlewoman from Illinois, Ms. Schakowsky.

Ms. SCHAKOWSKY. Dr. Winn, in your testimony you mentioned that investigators are looking at so-called windows of susceptibility, which are considered prime events over the lifespan where exposures to environmental factors can directly or indirectly affect a person's risk of developing breast cancer. This approach, as you have explained, recognizes that there are specific windows of time that physiological changes to the mammary gland occur, including gestation, puberty, pregnancy, and lactation. I am very interested in this, because knowing what we do about early puberty and the risk of breast cancer and first menstruation before age 12 apparently raises the cancer risk by 50 percent I think we most certainly need to be examining the causes of the falling age of puberty. And you touched on the recent stories we have all seen about the plasticizer BPA and its possible affects on female development. I wondered if you would expand on these comments and include, for example, where BPA is found in the environment and if ongoing studies find a negative association between BPA and female health, and what your recommendations might be for reducing the risks? For example, should we ban BPA?

Dr. WINN. Well, the NIEHS supported research on BPA in a number of different ways, not only in our Breast Cancer and the Environment Research Centers. But I think over the last decade or so information has come out that low levels of this chemical are commonly found in the environment in plastics, such as in plastic baby bottles, plastic water bottles, plastics that are used to store food. Many plastics manufacturers have been using BPA to make those products strong and hard. Softer plastics do not have as high of levels of BPA.

Ms. SCHAKOWSKY. So is that water bottles? I mean, you know, we all drink water and carry them around. That has BPA?

Dr. COLLMAN. Right. So some of them—the more rigid water bottles have higher levels of BPA than the ones that have—are more pliable.

Dr. WINN. Low doses have been implicated now to show toxicity in the mammary gland as well as the prostate gland, and so that is why several review committees that are associated with NIEHS have reviewed the evidence recently and have concern about that particular chemical in our products.

Dr. COLLMAN. So in the Breast Cancer and the Environment Research Centers program investigators have been looking at the mammary glands in the animal models and looking at exposure during pregnancy of the animals, looking at the mammary gland changes during puberty and are finding areas that we are concerned about. We have also done some pilot work measuring BPA in the blood—in the urine, excuse me, of the girls that are in our study, and we do find detectable levels of BPA in these girls. That there are some other data from CDC that also suggests that BPA levels in urine are quite ubiquitous in the human population. So we are just starting to try to pull all of this together to understand whether the exposures that we are finding in our bodies are necessarily related to factors—what makes somebody have a higher level of BPA versus a lower level, and then did that change the time window for when breast development first occurs? Does it affect the age at menstruation? Because we believe that if you extend

that window of estrogenicity in a young girl that go all the way through her adult years she may be at higher risk of breast cancer later. And, of course, that is the biggest concern that we have.

Ms. SCHAKOWSKY. Are we at the point yet of discouraging this ubiquitous water bottle among young girls?

Dr. WINN. Several companies that have been using BPA in their products have voluntarily taken them out, and so now there will be more choices for the consumer of products that will not have BPA.

Ms. SCHAKOWSKY. And how will we know?

Dr. WINN. They are being labeled as such in the stores.

Ms. SCHAKOWSKY. Thank you. Oh, I do have one more question. You also mentioned chemicals that have been shown by the National Toxicology Program to be endocrine-disrupting chemicals, and therefore associated with increasing susceptibility to breast cancer. You cite a list of 40 such chemicals that are mammary gland carcinogens and possibly estrogenic and mutagenic. Where are these chemicals found in our environment? Do they have common names? How prevalent are they?

Dr. WINN. There are quite a wide range of chemicals that have these effects on the various components of our hormone systems and interact with them in animal models. NIEHS is conducting research to understand the prevalence of those chemicals in human populations as well. There are consumer products, the chemical group called phtalates which have been found in products that have fragrances. and in shampoos and soap. There are carcinogens on that list including benzene, which is, of course, found in gasoline that have been shown to be a mammary gland carcinogen in the animal model systems that the National Toxicology Program.

Ms. SCHAKOWSKY. My time is expired. Thank you very much.

Mr. PALLONE. Thank you.

The gentleman from Arizona, Mr. Shadegg.

Mr. SHADEGG. Thank you, Mr. Chairman.

Fascinating testimony and I think that highlights how it is useful to do this kind of a hearing, and for us to learn. I mean those of us who can't concentrate all of our time on this issue.

Dr. Winn, I just want to walk through a clearer understanding of the progress of this legislation on the Senate side. As I understand it as that bill went to committee on the Senate side there were discussions between NIH and the proponent to the bill about the structure of the bill, and particularly about the fact that it was disease-specific and very prescriptive in what would occur under the legislation as introduced. Is that correct?

Dr. WINN. Yes, that is correct.

Mr. SHADEGG. And as a result of those discussions a number of amendments were agreed to, to make it less prescriptive?

Dr. WINN. Yes, that is correct.

Mr. SHADEGG. But it still remains disease-specific?

Dr. WINN. It still remains disease-specific.

Mr. SHADEGG. Do you know if the House sponsors of the bill were consulted in those negotiations? Sometimes the Senate includes us and sometimes they choose not to include us.

Dr. WINN. No, they were not.

Mr. SHADEGG. OK. Have those kinds of discussions gone on here on the House side?

Dr. WINN. No, they have not.

Mr. SHADEGG. OK. I might encourage you as this legislation progresses to have those discussions, because we all know that senators are very smart, but sometimes we think we are equals in the process and Ms. Myrick might want to have a discussion with you about the changes that were agreed to in the Senate amendment process. You might have different ideas about the amendments that might be agreed to.

Dr. WINN. We would be happy to.

Mr. SHADEGG. Great. Disease-specific legislation, I presume there are disease-specific bills introduced on thousands or at least dozens of different diseases every year here in Congress?

Dr. WINN. Yes, there are.

Mr. SHADEGG. And your concern about this bill being disease-specific would apply to all of those bills as well I take it?

Dr. WINN. Yes, it would because the passage of one bill would require that we reprogram funds from some other research area or disease condition to the one that is called upon by the bill.

Mr. SHADEGG. So as a general policy matter NIH would say it had concerns about any disease-specific bill?

Dr. WINN. Yes, that is correct.

Mr. SHADEGG. OK. And those are the kinds of concerns that were aired in your discussions—

Dr. WINN. Yes.

Mr. SHADEGG [continuing]. On the Senate side? And I take it NIH has had that position through the years? Republican Administration, Democratic Administration, Republican Congress, Democratic Congress?

Dr. WINN. Correct.

Mr. SHADEGG. Mr. Barton made a passionate plea for not enacting disease-specific legislation and for following the requirements of the NIH Reform Act. Many of us as an obligation to represent our constituents have a duty to listen to them and to be concerned about their concerns. One of the questions I have had about this—and this whole topic of disease-specific legislation relating to NIH has been around since I got elected in 1994. As you might recall, one of our former speakers wanted to double the NIH funding year after year after year. That was his goal, and he did that. How would someone concerned about this issue, breast cancer, or someone concerned about Alzheimer's or any other topic, express their concern to NIH and to its policy makers, and is there an avenue for open public input? And is that a factor that you would consider as opposed to just talking to scientific direction?

Dr. WINN. Yes. There are often calls in the NIH Guide for Grants and Contracts that request information from the public. It would say something on the order of the NIH is very interested in this area; what do you think? And we often get public input in that way. We also often as staff members get calls from the public and then try and respond to those issues. With respect to being able to follow the progress of all that input, something like the scientific management review board that was established in the NIH Reform Act in 2006 gives the public a way of finding out exactly where the

money went and what disease areas it has been focused on. It is sort of a post—way of monitoring what funds went into which particular area of scientific endeavor.

Mr. SHADEGG. Well, I thank you very much for your testimony. It has been very helpful, and I would encourage you to talk with Ms. Myrick and the other sponsors of this legislation, and at least have them better understand how the bill was modified by the Senate amendments. Maybe they are willing to go with those. Maybe they have different ideas that might add to that discussion.

Thank you very much, and I yield back.

Mr. PALLONE. Thank you.

The gentleman from Pennsylvania, Mr. Pitts. Passes.

And then the gentleman from Michigan, Mr. Rogers.

Mr. ROGERS. Thank you, Mr. Chairman, and I won't take long.

I am just trying to understand it, Dr. Winn, if I can. There is a—they put in place a panel that oversees the senator, but there is no NIH person on the panel as I read the bill. Wouldn't that make—

Dr. WINN. That is correct.

Mr. ROGERS. Doesn't that make it far more difficult to coordinate activities through the NIH if there is no NIH representative on the panel?

Dr. WINN. Well, it is my understanding that the panel would be making decisions about who would get funded, so that one could not get funded without the approval of the panel. That is the primary concern about the bill, and that the panel would establish the scientific directions that NIH would have to go into in this area.

Mr. ROGERS. Yes, I understand. But don't you try to take those into consideration at the NIH now based on resources available versus where you might be on a certain disease set?

Dr. WINN. Well, normally staff has a very important role to play. With the Breast Cancer and the Environment Research Centers staff was on the steering committee, and it has a lot of direct input into the nature of the research and how it is conducted. Does that address your question?

Mr. ROGERS. Yes. I guess it just didn't—the one part that doesn't make sense to me is that to try to separate it out, but still try to obligate NIH funding with no direct coordination. And I kind of scratch my head thinking is that the—I am a big believer in this research and other cancer research obviously. And it is never for me—we shouldn't be mad at the dollar that isn't spent as much as we should be mad at the dollar that is misspent. And we are appropriating a lot of taxpayer dollars, and I want every dollar we could possibly get on the bench. Some researcher spending valuable time doing that versus any other effort we might have. And I am a little concerned as I look at this that we may be creating more of a problem for you than we are a solution for you when it comes to trying to solve what I think is a critically important problem.

Dr. WINN. Yes. Normally what happens in NIH is that each Institute has an advisory committee that is composed of experts in their particular field of endeavor that provides oversight to projects that are proposed being considered for refunding and evaluation of them. The bill, 1157, calls for an exception to NIH's normal procedure.

Mr. ROGERS. And not only does the singular exception of disease—because sometimes we—it may pay to rush in like the cavalry and solve a problem. I am not a big believer in that. But this kind of takes it out of what is a—we all have been pretty hard on you in the last 2 years. Not you personally, but the NIH, about coordinating your efforts, taking waste out of the system, getting dollars to the bench. And as I look at this, and I am not decided where I am going on this yet, but it seems to me the more I understand it the more I think maybe it is creating another level of a problem for you versus trying to solve a problem for you. And I just want to make sure I am understanding that correctly.

Dr. WINN. Correct.

Mr. ROGERS. And tell me—can you just talk real briefly about some of the things you have been doing to do better coordination on all disease research projects? And what you have been doing to streamline your efforts so that less money is wasted, more money is put on the bench for research?

Dr. WINN. Well, I think at the highest levels of NIH, as well as at the Institute levels, transdisciplinary efforts are encouraged, and sharing and partnerships are encouraged. For example, the National Institute of Environmental Health Sciences, NIEHS, and NCI have any number of programs where we are sharing either the funding for a particular project or responsibility for development of initiatives. The way that the Common Fund is being spent through the NIH Roadmap Initiatives provides for extensive input from all of the Institutes into what areas of science are going to be focused on. And if an area is deemed to be a high priority, it provides for how that money is spent. This is happening at trans- and NIH levels.

Mr. ROGERS. How long have you been involved with NIH medical research? Obviously you have spent a lot of time and talent and energy becoming a doctor, but—

Dr. WINN. Between being at the Centers for Disease Control and Prevention and the National Institutes of Health, 28 years.

Mr. ROGERS. So you have really committed your life to trying to find solutions for diseases. You have tried to find cures for 28 years of your life. Is that correct?

Dr. WINN. Yes.

Mr. ROGERS. Is that fair?

Dr. WINN. Looking on the prevention side, yes.

Mr. ROGERS. And so there is no disease I could bring to you that you wouldn't be anxious and stay awake at night trying to solve. Is that—

Dr. WINN. That is correct.

Mr. ROGERS. And if I understand you correctly—and don't let me put words in your mouth. But you are a little concerned that this effort may make what you have spent 28 years trying to accomplish a little bit more difficult? Not because you don't care, but maybe it is just not the best way to do it. Maybe we can find another good way to do what I think the author's intent is. Is that fair? Is that a fair assessment?

Dr. WINN. Our particular focus is on balancing the broad range of conditions and diseases that influence the burden of disease in the U.S. population.

Mr. ROGERS. Well, I will join Mr. Shadegg's hope that maybe you can sit down with the House members and we can maybe find a solution here that works for everybody. And more importantly, doesn't work for us in this room, but works for the researchers and the scientists and the doctors who have committed their lives to trying to fix this problem, and give them some value added versus maybe taking a little time away from their bench time. And I appreciate you being here. Thank you for your presence today.

I yield back.

Mr. PALLONE. Thank you, Mr. Rogers.

I think we are done with our questions for Dr. Winn and Dr. Collman. Thank you very much, and we look forward to working with you on this legislation as we move to markup. And thank you.

And I will ask the second panel to come forward now. OK. I want to welcome our second panel. Let me introduce each of the individuals. From my left is Ms. Fran Visco, who is president of the National Breast Cancer Coalition. Next is Ms. Sheryl Crow, who is a famous singer and songwriter, and a breast cancer advocate from Nashville, Tennessee. And again, thank you for being such an advocate. I know you visited my office and many of the others in order to try to get this hearing today and move this bill, and we appreciate your advocacy. And then there is Dr. H. Kim Lyerly, who is the George Barth Geller Professor of Research and Cancer and director of the Duke Comprehensive Cancer Center at Duke University Medical Center in Durham, North Carolina. I think you probably heard what I said before that you each have a 5-minute opening statement. They become part of the record. And we may submit additional statements in writing or additional questions for you that you would respond back to later. But for now we will begin, and we will start with an opening statement from Ms. Visco.

**STATEMENT OF FRAN VISCO, PRESIDENT, NATIONAL BREAST
CANCER COALITION**

Ms. VISCO. I thank you, Chairman, for—

Mr. PALLONE. I think you have got to turn that on or move it closer.

Ms. VISCO. OK. Thank you, Chairman Pallone, and Ranking Member Deal, and members of the subcommittee for holding this hearing. I want to thank Nita Lowey, of course, the lead sponsor of the legislation for her leadership over the years, as well as our other lead sponsor and fellow survivor, Sue Myrick, and Congresswoman Lois Capps.

I am Fran Visco. I am a 20-year breast cancer survivor, and I am president of the National Breast Cancer Coalition. And the coalition is an umbrella of more than 600 member organizations across the country who come together to work on public policy and breast cancer.

I want to make clear at the outset before I get into my actual discussion that this legislation, which I will discuss in a few moments, is not about making centers happen. It is not about reprogramming funding at NIH. It is not about vacating the peer review process, which we are very strong believers in. And it is also the same bill that was introduced in the Senate that you have in

front of you that NIH and we negotiated on and came to decisions. It is not a different bill. It is now a different version in the Senate.

Now, I was diagnosed with breast cancer in September 1987. My son David was 14 months old, and I had no family history of the disease. I had two overriding questions. One, would I live to see David grow up? And two, why? What gave me breast cancer? I am happy to be here today. And the first question has obviously been answered in the positive. But the second—it is 20 years later. We didn't know then what caused my breast cancer. We don't know now.

I have had the honor of meeting thousands of breast cancer survivors over the past years of my involvement in this movement, and with the National Breast Cancer Coalition there are millions of us. More each year actually. More than 250,000 women who are diagnosed each year. We have daughters, granddaughters, sisters, friends, partners, and we don't know what to tell them to do to prevent breast cancer. We can sit by and wait and watch and hope the scientific community finds the answers. We can hope that these women do not also join our club, or we can fight as hard as we can to find the answers, find the cause and end this disease.

As you are all very well aware the National Breast Cancer Coalition chose the latter course. We have advocated for increased funding for breast cancer research. We have collaborated with researchers around the world on breast cancer. We have launched unique training programs to educate ourselves so that we can understand and engage in the science and help set the agenda.

In the beginning of the coalition we launched our 300 million more campaign, which resulted in working with you, the DOD program. We made new models of research happen, new collaborations. We worked on the first targeted therapy in breast cancer, which has had an impact well beyond breast cancer. The NIH report on what they are doing is exciting. It happened because advocates advocated for increased funding for research. We made that happen with you.

A lot of the research focuses on treatments, on new drugs. And that is very important, but these drugs bring with them life changing and often life threatening toxicities, incredible financial costs and results in most cases of modest impact on the disease. It is extremely important that we continue that research because each year 40,000 women die of breast cancer. A number of the founders of NBCC have died of their disease. We need to have better treatments and hopefully some day cures. But how much better if we can prevent this disease? Our daughters not live in fear of getting it, not face life threatening breast cancer, not suffer toxicities of treatment and the incredible financial and emotion drain on them and on this country?

We as advocates recognize how real the complexities are. I remember when I co-chaired a subgroup of the National Active Plan on Breast Cancer with Francis Collins, and he and I talked about how complex and very difficult this was. And I remember his words. We cannot let that be a reason not to do this. We know there is no magic bullet, no easy answers. Scientists over the years have told us, and we have seen, how they work in silos. How there is competition. Whose perspective is right? Whose idea of what it

is? How can I get funded? We can continue along those paths, or we can take this extraordinary opportunity to harness the incredible scientific abilities across the country working with engaged advocates and community groups and complete what has been happening. Building on the very real advances and the resources we have put into the investments we have made in breast cancer research.

You have heard some from NIH of what is going on in different pockets. There is other work being done in this arena, but there are many different approaches. What we need to do is bring all of this together to work in tandem. No one institution, no one institute, no one approach, no one individual has the answers. If they did we wouldn't be here. We need to work on many diseases. Yes, that is important. This is one of them. We need a balance. It is not enough to simply let scientists or administrators determine what they should focus on. We need to build on the science we have already invested in and the knowledge that we have in breast cancer. That is what this bill will do. I listen carefully and read carefully, and I am very happy that the NIH centers are helping and the model is one they like. They are not exactly what this bill contemplates. They are one small step toward that. The questions for those were chosen by NIH, but you have to remember that they are doing that because of the National Breast Cancer Coalition advocacy around this bill, and our working with Congress to get it in the report language and tell NIH to do that. So it is a great example of why this bill before you now is important. How it will work and how it must move forward.

So what is the bill going to do?

Mr. PALLONE. I am going ask you—you are a minute over.

Ms. VISCO. Right. I am going to—

Mr. PALLONE. And we also have votes, and I would like to at least get one more witness in. So if you could summarize.

Ms. VISCO. I just want to summarize by saying that the bill is not going to hurt the peer review process. The bill is going to let collaborative grants, peer review collaborative grants—the extended bill provides that the secretary will take into account the recommendations of the panel. The panel doesn't direct. The worldwide, nationwide, scientific community decides what the research questions are. Those questions will go through peer review. It is something that builds on reauthorization. It enhances the work that is being done. It is a strategic approach, which is what we need. It doesn't replicate, duplicate. It doesn't take money away. It is not intended to do that. We did our homework 16 years ago when we began advocating on behalf of breast cancer research, and we are here today to say it is time to take this next step. Seventy senators, 268 members of the House, two-thirds of the Committee are sponsors of this bill. And I look forward to this year when this bill becomes law.

Thank you very much.

[The prepared statement of Ms. Visco follows:]

STATEMENT OF FRAN VISCO, J.D.

Thank you Chairman Pallone, Ranking Member Deal and Members of the Subcommittee for holding this hearing on such crucial legislation, the Breast Cancer

and Environmental Research Act, H.R. 1157. I want to also thank Representative Nita Lowey, the sponsor of this legislation, for her leadership throughout the years on this critical bill, as well as our other lead sponsors, Representatives Sue Myrick and Lois Capps. I am Fran Visco, a 20-year breast cancer survivor, wife and mother, a lawyer, and President of the National Breast Cancer Coalition (NBCC).

NBCC is a grassroots organization dedicated to eradicating breast cancer. The Coalition includes hundreds of organizations and tens of thousands of individual members, many of whom you have heard from often over the past years to express their strong support for H.R.1157. In fact, as you know, we now have 70 Senate and 268 House cosponsors of this legislation.

NBCC's main goals are to increase federal funding for breast cancer research and collaborate with the scientific community; to increase access to high quality treatment and care for everyone as well as access to quality clinical trials; and to increase the influence of women living with breast cancer in all areas of decision-making that impacts breast cancer.

PURPOSE AND SUMMARY OF THE LEGISLATION

BACKGROUND

As you know, the causes of breast cancer have not yet been determined. We simply do not know what to tell women to do to prevent breast cancer. We have identified some factors associated with increased risk of breast cancer. Yet, about 70% of breast cancers are not associated with known risk factors. Less than 10% of breast cancers can be attributed to an inherited genetic predisposition. We know it is not solely a genetic question, nor is it solely a question of environment. Rather, it is a complex interaction between genes and environment that is at the core of this problem. Yet, the environmental influences remain largely unexplored and unexplained.

It is especially disturbing that we do not know the causes of this disease since the chances of a woman developing the disease have increased over time. Today, a woman in the United States has a one in eight chance of developing invasive breast cancer in her lifetime. In 1975, that chance was one in eleven. Recent reports of a decline and stabilization in incidence among some groups of women have been linked to the findings of the Women's Health Initiative and a decrease in use of hormone replacement therapy. It remains to be seen if this association between HRT and breast cancer is one of cause and effect or delayed diagnosis. In any event, it accounts for a small percentage of new cases.

The three million women living with breast cancer and all women at risk, which is all women, want to know what causes breast cancer. They want to know how to prevent this disease, so that they, their daughters, other family members and friends will not suffer from it.

There is no doubt this is a complex problem. Ten years ago NBCC held the first of two environmental summits, bringing together scientists, trained consumers, policymakers and other stakeholders to help us determine how best to address the issue of environmental links to breast cancer. The consensus was then, and is now, that little is known and little is done in this area of research. The participants had different perspectives on the problem, including what is encompassed in "environment" in this context. Some working on this issue believe that "the environment" should encompass external exposures (e.g., pesticides) only, and not "internal" (e.g., age of menarche, circulating hormone levels, etc.). Some want to exclude voluntary exposures (e.g., diet). NBCC defines environment broadly, for all its work in this arena and for this proposed legislation. All agreed that these issues are exceedingly complex and must be addressed on many different levels from many disciplines and perspectives, with a strategic approach that respects scientific freedom and public input. It was clear that this is not a question that can be addressed solely by government, or by advocates, or by scientists. This diverse input from all stakeholders was one element that led to the proposed legislation. There are many ways to look at this problem and no one institute, institution or individual has the answers. Of course, if they did we would not be here today.

After an initial significant increase 15 years ago, we have seen annual funding for breast cancer research in both the private and public sectors remain the same or perhaps increase slightly. We know that certainly in the private, and to a lesser extent in the public sectors, much of that research is invested in a search for the next new drug, or the next combination of existing drugs. Technology has increased, looking for biomarkers of disease, primarily so that a therapy can then be found to attack that biomarker. Yet drugs and other technology have made a modest overall impact in breast cancer. The majority of drugs that result from research result in

incremental improvement over existing therapies, often adding toxicity and great financial cost. While it is extremely important to find out how best to treat and hopefully to cure this disease, we must invest significant resources into figuring out how to prevent it. That would be the ultimate and optimum result of our research investments. And government funding is the primary source of support for this approach since there is little commercial incentive.

Why this bill?

NBCC developed this approach as it has many others. As described above, we brought together all stakeholders involved in this issue on several occasions to look at and discuss the issues surrounding the environmental links to breast cancer. NBCC has watched as Congress has funded studies looking at possible breast cancer “hot spots”. States have legislated pesticide and other registries. Given what we learned from our summits, from working with and looking at the Department of Defense peer-reviewed Breast Cancer Research Program, from our work with scientists around the world, we concluded that continuing to ask specific questions and funding isolated approaches is not enough. A piecemeal approach to this very complex area is not a good use of resources, nor is it in the best interest of the public. The decisions about which questions to research should not be made in a vacuum, rather they should be made as part of a national strategy that takes into account past research, research underway and prioritizes the gaps that still exist.

We see excellent research being done, such as the Sisters Study and other studies at the National Institute for Environmental Health Sciences, and the technological advances brought about in part through the Human Genome Project that underlie the Genes, Environment and Health Initiative at the National Institutes of Health (NIH). We are not suggesting nor would we want that this bill take the place of these or any other studies. This bill will enhance and complement those efforts. The approach contemplated by this legislation would allow the scientific community across the country to identify gaps in our knowledge, design ways to address those gaps and collaborate on the best research needed to respond. It will allow the research community throughout the country to set the agenda, to come together in multi-disciplinary, multi-institutional collaborations including the public, to decide questions to be asked, and to work together to launch a strategic, national approach incorporating all aspects of this problem.

What would the bill do?

With this country’s investment in biomedical research, we have learned a great deal about how science works best in addressing complex questions that require the attention of the full range of scientific expertise.

It is most important to recognize that this bill will allow the scientific community to decide how the funds should be spent and will require that they be spent through a peer review process and a programmatic review that is based on proven, successful research programs.

The legislation would authorize \$40 million a year for 5 years for the National Institutes of Health to develop a collaborative, peer-reviewed grant program to study environmental factors that may contribute to breast cancer. This number was based on analyses of existing research mechanisms and the input of many researchers across the country who are experts in this area.

The grant-making model in this bill is based on the successful and internationally acclaimed structure of the Department of Defense (DOD) peer-reviewed Breast Cancer Research Program, which has been replicated in other areas of research. The model was originally recommended by the Institute of Medicine at the National Academy of Sciences (IOM/NAS). The IOM has twice reviewed the DOD Breast Cancer Research Program and lauded its innovative and effective structure. There are several features of the DOD peer-reviewed Breast Cancer Research Program that are included in the legislation we are discussing today

- The Breast Cancer and Environmental Research Act would establish a Breast Cancer and Environmental Research Panel made up of experts in the field and trained consumers. (The Senate version includes an NIH representative also). The Panel would develop mechanisms based on the intent of the legislation, and a Request for Proposals will be published to the scientific community. The bill contemplates a strategic, broad approach to the issue that would be shaped by the scientific collaborations’ response to the Request for Proposals. Scientists working with community groups are free to decide the critical questions to ask and the scientific approaches to be taken. The request will be for proposals looking at broad approaches to a broad definition of environmental links to breast cancer.

- After scientific and technical peer review is conducted, the Panel would review the proposals to make certain they, as a whole, address in a non-duplicative, strategic way, the fundamental questions necessary to look at the issue. The Panel would then make recommendations for allocations of funds to the grantees. This

critical step will prevent unnecessary duplication of research and ensure consistency with an overarching strategy as contemplated by the bill.

- Trained consumer advocates are included on the Panel. We believe the perspective of informed, educated breast cancer advocates must be present everywhere that breast cancer research decisions are made. A true partnership between advocates and scientists is the most efficient and effective way to reach the mutual goal of eradicating breast cancer, because both parties bring distinct and valuable knowledge to the process. Trained advocates have been included on the Integration Panel and at all other levels of the DOD Breast Cancer Research Program since 1993. This unique feature has been hailed as a success by the scientists, the advocates and the Institute of Medicine.

This bill includes a broad definition of the environment—from contaminants to lifestyle factors such as diet and exercise, stress levels, socio-economic status and other endogenous factors. Multi-disciplinary and multi-institutional groups of researchers receiving the grants would look at the factors that may contribute to breast cancer development from different angles. A main feature of the research model proposed in this bill is flexibility. It is the grantees themselves, the researchers, who would identify the area to be studied—the science would not be dictated to them.

Collaboration is a key component of this legislation. The bill envisions that the best and brightest scientists and trained advocates from different institutions and different disciplines would come together to apply for a grant, studying a complex question of the relationship between breast cancer and the environment, and breaking down the traditional silos of research. In turn, all the grantees would then collaborate with each other as well as with community groups representing a breast cancer constituency. This would prevent duplication of research, encourage new ideas and dynamic thinking, and with the involvement of community groups and trained consumers, ensure that the research is innovative and meaningful.

HISTORY OF THE LEGISLATION

This bill was first introduced in 1999 by Representative Nita Lowey. I remember discussing the contents of the proposed legislation with then acting director of NIH, Dr. Ruth Kirschstein. As a result of those discussions, the content of the bill changed before it was actually introduced, as we wanted to address some of NIH's questions. We came to an agreement with NIH on the content and approach of the bill at that time. In 2000, Senators Lincoln Chafee and Harry Reid introduced the bill in the Senate. Since then the bill has had incredible bipartisan support and political momentum. Over two-thirds of the Energy and Commerce Committee Members are cosponsors.

The Senate Environment and Public Works Committee held a field hearing on this bill in the 107th Congress. In 2002, the Senate Labor-HHS Appropriations Subcommittee agreed that a strategic approach like the one taken in this legislation was necessary. They included language in their Committee Report urging the National Institute of Environmental Health Sciences (NIEHS) "to establish centers to conduct multi-disciplinary and multi-institutional research on environmental factors that may be related to breast cancer." The following year, the Labor HHS Conference Report included similar language.

In response, NIEHS established four research centers to focus on the environmental determinants of puberty and mammary gland development that may increase a woman's risk of breast cancer. These centers do not address an overall national strategy for researching the possible links between the environment and breast cancer, and they focus on a narrow question. They are important, but are not what is envisioned by this legislation.

The Senate HELP Committee approved S. 579 in February of this year. Prior to that mark-up, changes in the bill were negotiated to respond to concerns expressed by NIH. As a result of those changes, NIH no longer opposes the Senate version of the bill. We hope that this committee will approve the Senate version of the bill.

The Senate Version

The bill was clarified by removing references to centers. The intent of the legislation was never to establish brick-and-mortar centers, but rather, as I have said, the grantees would be a collaboration of scientists and consumers from various disciplines and institutions. The reference to centers in the language was confusing and distracted from the true intent of the legislation.

A peer review protection clause was added. The bill was never intended to override or otherwise interfere with the peer review process at NIH. The Panel takes the peer-reviewed research and makes recommendations for funding based on the

strategy that has been developed, to make sure that not only the most scientifically important research is funded, but also the research that will have the most impact.

Changes were made to the Panel at the request of NIH. First, an NIH representative was added to the panel, and language was added so that the selection of the Chairperson of the Panel is subject to the approval of the NIH Director. Finally, language regarding how the HHS Secretary adopts the recommendations of the Panel was changed at NIH's request.

The bill has evolved over the years, taking into account concerns raised by not only Members of Congress but also by the National Institutes of Health. I am hopeful that this committee will mark up this bill promptly following this hearing, and include the changes made to the Senate version.

Public Support

The National Breast Cancer Coalition has educated its grassroots membership across the country on the purpose and content of this bill. They in turn have worked very hard to get support from their Senators and Representatives for this bill. We are very proud of the fact that we now have 70 Senators and 268 Members of the House as cosponsors for this bill. We have had several negotiations with Committees and with the National Institutes of Health, to revise the bill and address concerns, while retaining the integrity and vision of the bill. The NIH has withdrawn its opposition to the Bill.

Now the public is looking to you. We have done all that you ask, with this level of bipartisan support for the bill, with no administrative opposition. Women's lives depend on your actions. It has been 8 years since this legislation was first introduced. Women can't wait any longer.

In summary, this bill offers a strategic approach to researching the potential links between the environment and breast cancer. It would establish a proven model for conducting this critical research. It would enhance and complement work that is ongoing at NIH. It leaves the scientific community and the public impacted by the disease free to decide, within the strategic approach of the legislation, what and how to research. Innovative thinking and meaningful research that gets us closer to finding the answers about the causes of breast cancer is critical to the eradication of this disease. The current research is not enough. We need to not only do more research, but we need to spend our precious federal dollars more efficiently and effectively. The approach this bill envisions does just that.

Mr. PALLONE. Thank you, Ms. Visco.

Let me explain where we are. We have six votes, which could take as much as 45 minutes, maybe more. But we have time for one more, because we still have 12 minutes left, so I am going to ask Ms. Crow to give her opening statement. And then, Doctor, you will have to wait until after if you don't mind. And then we will have questions after, so we are hoping that you can all stay around.

But I will recognize Ms. Crow now.

**STATEMENT OF SHERYL CROW, SINGER-SONGWRITER AND
BREAST CANCER ADVOCATE**

Ms. CROW. Thank you, Chairman Pallone, and Ranking Member Deal, and members of the Senate—or the House subcommittee for holding this hearing.

And I just want to say I am honored to sit in the presence of Sue Myrick, who is a rock star as far as I am concerned in the breast cancer advocacy community.

I appreciate the opportunity to testify before you today on the Breast Cancer and Environmental Research Act. As a breast cancer survivor and advocate I am very passionate about getting this bill enacted this year. In 2006 I was diagnosed with breast cancer. Needless to say, I was absolutely devastated. Before my diagnosis I had been helping raise awareness and funds for breast cancer for years. Concerts, events, whatever I could do because I knew it was an important issue. So when I was diagnosed this really hit home.

And I have the dubious honor because I am a singer of having a large female fan base, and I have become sort of a spokesperson for early detection. But as I look to my right and I see these young women over here as they embark on their adulthood and they are asking questions about whether the lipstick they are using, the shampoo they are using, whether they are drinking from a water bottle and not be a factor, and they are being the one in the seven. With breast cancer I don't have the answers to that, but I think it is a question that needs to be answered, and now is the time.

I know awareness is not enough. We need real strategic action, and so I am joining with Fran Visco and the National Breast Cancer Coalition, because I believe that what they are doing is good for all of us. About a year ago Fran asked me to learn about this bill and I did, and I am not here lightly. I know what this bill will do, and I am certain that it is the right approach. Why is this bill important to me? Because I know—because I want to know what causes this disease for me and for 2.3 million others who share this diagnosis with me, and especially for those of us who are at risk or putting themselves at risk without even knowing. Like the vast majority of women diagnosed with breast cancer I have no known risk value, including no family history. I have no idea why I got breast cancer, or what I can say to others on how to prevent it. But what I do know is we need more resources and to figure out what the environment has to do with breast cancer. And we need to do that through the government funding, because there is little financial incentive for anyone else to do this research.

I have spent a great deal of time out talking to people about the environment, obviously. I have traveled throughout the country to try to raise awareness about what we are doing to the environment and what we can do to help save it. And I know these issues are even more complex than that, especially when it comes to associations between environment and disease. And I know this bill and the National Breast Cancer Coalition includes a broad definition of environment to include not just exposures but lifestyles and the interaction between genes and the environment inside and outside of our bodies.

I can tell you that the public deeply cares about the environment. We are talking about it every day. It is no longer third page stuff in the newspaper. It is on the front page. Women are talking about it on a daily basis on every talk show and about how they can live healthier lives and prevent diseases. We are talking about how to live green in order to prevent disease. This is a question that everyone wants answered. And I will say that I understand the concerns of Congressman Burgess and Congressman Barton about this bill. But this bill establishes an opportunity for setting precedence where the environment is concerned for other diseases. I would hate to think that the benefits of today's vaccinations would not be possible because the research done on finding the polio vaccination was considered disease-specific.

Would it not be possible that any findings in this area for the environment affects disease be beneficiary to other diseases? For instance—in the instance of what Dennis Slamon did at the Revlon Cancer Center at UCLA where he did research on the HER2 posi-

tive and created the treatment that now is a targeted treatment that actually is benefiting brain cancer and other diseases.

And I want to say that I don't live in the political world and while this might be a political—seem like a political discussion until you are the one in seven women diagnosed with breast cancer. You will never know how not political this is. Now is the time. We have been talking about this for a long time, and thank God for Senator Edward Kennedy, who I love and adore and idolize, who took this to the Health Committee and has been pushing this through and has been a strong advocate. And I feel like we have had so much support on this that now is the opportunity to make this happen, to do the right thing, and to show the American people that we are concerned about what is happening, and that we are not going to let the brake stay on, as was alluded to earlier. We are going to keep driving this thing forward.

And I look forward to celebrating this with the good people here on Capitol Hill and being able to take good news back to the small towns in America as I go out and tour.

Thank you.

[The prepared statement of Ms. Crow follows:]

STATEMENT OF SHERYL CROW

Thank you Chairman Pallone, Ranking Member Deal and Members of this Subcommittee for holding this hearing. I appreciate the opportunity to testify before you today on the Breast Cancer and Environmental Research Act. This bill is responsible public policy calling for research to move us closer to understanding the causes of breast cancer and how to prevent it. As a breast cancer survivor and advocate I am very passionate about getting this bill enacted this year.

In 2006, I was diagnosed with breast cancer. I knew I wasn't going to sit back and let breast cancer control my life. Before my diagnosis, I had been helping raise awareness and funds for breast cancer for years. Concerts, events, whatever I could do because I always knew it was an important issue. Then it really hit home. And I knew awareness wasn't enough; real, strategic action was needed, so I joined with Fran Visco and the National Breast Cancer Coalition (NBCC) because I believe in what they are doing for all of us.

About a year ago, Fran asked me to learn about this bill and I did. I am not here lightly. I know what this bill will do and I am certain it is the right approach.

Why is this bill so important to me? Because I want to know what causes this disease—for me, for the 2.3 million others who share this diagnosis with me, and especially for all those who are at risk, or putting themselves at risk without even knowing it. Like the vast majority of women diagnosed with breast cancer, I have no known risk factor, including no family history. I have no idea why I got breast cancer, or what I can say to others who want to prevent it. Here's what I do know: we need to put more resources into figuring out what the environment has to do with breast cancer. We need to do that through government funding, because there is little financial incentive for anyone else to do this research.

I have spent a great deal of time working on environmental issues. I have traveled the country to raise awareness about what we are doing to our environment and what we can do to help save it. I know the issues are even more complex than that, especially when it comes to the associations between environment and disease. And I know this bill—and NBCC—includes a broad definition of environment, to include not just exposures, but lifestyle and the interaction between genes and the environment in and outside of our bodies. Looking at these issues in such a strategic, global way needs federal funding and oversight. But it also needs the input of researchers and advocates throughout the country and from every perspective.

I can tell you this: the public cares deeply about the environment and about breast cancer. And they look to you to help solve these problems. Don't let us down.

Breast cancer continues to be a puzzle. Rather than just continuing to invent new treatments, I believe we need to focus on prevention. And we are unlikely to prevent breast cancer if we do not know what causes it. The Breast Cancer and Environmental Research Act calls for a national, strategic approach to address the question of what in our environment—inside and outside our bodies—may be related to

breast cancer. It doesn't dictate the science. It doesn't tell scientists what to do. But it does give them the resources and the focus to address these issues. It will bring the best and brightest researchers together to work in collaboration with trained advocates and with community-based organizations. So, the scientists across the country, working with the community most at risk and impacted by this disease, working together to solve the problem seems like a great way to deal with such a difficult issue. It is a wise investment that our Federal Government must make. It is a small investment relative to the size of this problem that affects millions of Americans.

It is frustrating to me that this bill has been around for so long, with so much support, and it still has not been enacted. I know that this bill was developed after years of analysis by the National Breast Cancer Coalition, with the input of scientists, policymakers, consumers, and all the key stakeholders. It was developed after much thought and based on experience with different research models.

I can't imagine there are many bills with the level of bipartisan support this bill has. Advocates like me worked very hard to get 268 cosponsors here in the House, and 70 in the Senate. As a member of the public I must assume each and every one of those cosponsors supports the approach taken by this bill. And I have heard about the tremendous support from the scientific community. So, scientists support this, the public supports it, and the majority of both the House and Senate support it. A majority of this very committee supports it. My understanding is that after negotiations and discussions with the National Breast Cancer Coalition, the National Institutes of Health (NIH) does not oppose the Senate version of this bill. Those facts alone should support enactment.

Last April, I was up here on Capitol Hill with Fran and the National Breast Cancer Coalition, meeting with a number of you, and with Members of the Senate, to talk about this bill. Frankly, I thought after all the support, after all the promises I got last Spring, after 8 years of Congress supporting this bill, by now it would be law. Yet, here we are.

It's time.

I am so glad you are holding this hearing today. I understand it is a necessary step before your committee can actually approve the bill. And I hope that will happen very soon, perhaps today? I urge you to take action on this legislation—the time is long overdue. All across the country, women and their families are demanding that Congress act now to pass the Breast Cancer and Environmental Research Act.

We are looking to you for your leadership and your support.

Mr. PALLONE. Thank you, Ms. Crow.

Now, as I said we have six votes. That is about 45 minutes. We will come back and hear from Dr. Lyerly, and then we will take questions. Hopefully you can stay.

So the subcommittee is now in recess for about 45 minutes.

[Recess.]

Mr. PALLONE. This subcommittee will reconvene. I apologize. I think there was some confusion on the part of the members as to when we were going to begin again, so they will probably start coming in. But I want to keep going, because I know you have some time constraints too.

So we left off with Dr. Lyerly.

**STATEMENT OF H. KIM LYERLY, M.D., GEORGE BARTH GELLER
PROFESSOR OF RESEARCH IN CANCER; DIRECTOR, DUKE
COMPREHENSIVE CANCER CENTER, DUKE UNIVERSITY
MEDICAL CENTER**

Dr. LYERLY. Thank you, Chairman Pallone.

Mr. PALLONE. I think you got to turn that on and bring it closer, or both.

Dr. LYERLY. Thank you, Chairman Pallone, and thank you for holding this hearing on such an important legislation.

I am Dr. H. Kim Lyler, director of the Duke Comprehensive Cancer Center. I am a breast cancer researcher and a member and former chair of the Department of Defense Peer Review Breast

Cancer Research Program integration panel, and I am grateful for the opportunity to testify today.

I was going to focus a lot of my comments about specific issues regarding H.R. 1157 that have been described, and I can say that I find this to be an innovative approach to address this issue of breast cancer and the environment. I agree it should be done through the NIH due to the complexity of the collaborations contemplated, and I would echo the sentiment that has been expressed, that NIH is the crown jewel in the world of biomedical research. Clearly the engine that drives much innovation and the place in the world that the U.S. holds in advancing medicine and the biotechnology industries. The design of the proposed program is based on the model supported now by the Department of Defense Peer Review Breast Cancer Search Program, which actually complements and extends the NIH model. As a scientist and as a past chair of this integration panel I can tell you firsthand why this model has been so successful, and how it extends the thoughtful and groundbreaking reforms that the NIH has recently made.

No less than the Institute of Medicine recommended the existing structure that includes both sides of the peer review and programmatic review by integration panel is so-called two tiered approach. The integration panel of the Department of Defense includes scientists and breast cancer advocates. This panel recommends research investment strategies, reviews the scientific peer review results, deliberates and compares scoring across the multiple panels, and recommends applications to be funding as well as assisting in overall program evaluation.

The integration panel reviews proposals with the mission and the strategic investment strategy in mind looking at not only what proposals have scientific merit, but also at which proposals meet the stated goals. Scientific merit is always considered and weighted appropriately and this is consistent with the strengths of the scientific peer review process that we heard earlier this morning.

It is extremely important that the ongoing programs exploring the link between cancer and the environment use innovative approaches to include all potential contributors. These include contributors outside of the National Institutes of Health. Consider the role of the Centers for Disease Control, tumor registries maintained by the American College of Cancer, American College of Surgeons Cancer Program, and other environmental research centers supported by the National Science Foundation. Without a broad umbrella to incorporate these research centers they may be in fact excluded for research linking cancer and the environment.

The panel proposed and the Breast Cancer Environmental Research Act would act much like the integration panel at the DOD Breast Cancer Research Program. And this panel has a proven 12 to 13 year track record of successfully enabling peer review research and providing insight and empowering individual investigators to develop broad based, far reaching and inclusive research strategies. Mechanisms for funding would be developed and then released to the scientific community with a request for proposals. And the idea here is not to determine the specific scientific question to be asked. This would be allowed to be the purview of the scientists, but the idea would be to create funding mechanisms

which could be populated by the best and most innovative scientific ideas moving forward.

Again, this is an exciting and innovative strategy that allows the best scientific ideas to rise to the top, and allows the most potentially fruitful collaborative strategies to be engaged.

Let me finish by just commenting about how this approach has affected research at my own institution. As you may know Duke is one of the most outstanding schools of environmental research in the United States, as well as an outstanding medical center. Policies requiring cross-disciplinary approaches that have been promoted by the DOD mechanisms have led investigators at the cancer center to actively meet and engage in collaborations with the Nicholas School of the Environment. This is a first-time event even though both of the institutions have been in existence for a number of years. Environmental scientists, molecular epidemiologists, and basic scientists work together with breast cancer specialists to explore how environmental exposure can increase women's risk to breast cancer. And traditional forms of support would tend not to support these types of interactions. What one specific example is that one of the most prominent strategies to identify environmental exposures in environmental toxins is to look at fish models of accumulation of toxins within the lipid deposits of fish, and these fish in fact develop liver cancers. But the insight gained from these fish that are populating pools and rivers and streams downstream of environmental events informs us as to what potentially could lead to the type of developmental changes, the changes occurring within the development of the breast in young women.

Finally, there is an emerging opportunity for science to engage in a discovery process in which we look at the epigenome. And that means your genetic fingerprint is stable, but there are changes that are occurring outside of your genes that are influenced by the environment. For example, we now know that in animal models the diet of the mother can influence the genetic expressional genes in offspring, and these offspring will have inherited traits like obesity and cancer susceptibility that can be passed onto their offspring. You know, this epigenetic imprinting and get a—understudied area of environmental toxicology wouldn't actually be developed or sought by the traditional DNA sequencing methods, and you have to use specialized epigenetic types of inquiry to find these things.

Let me finish by again really applauding this committee and the work done in bringing this incredibly important issue to the forefront. Thanks very much for allowing me the opportunity to present.

[The prepared statement of Dr. Lyerly follows:]

STATEMENT OF H. KIM LYERLY, M.D.

Chairman Pallone, Ranking Member Deal and Members of the Committee, thank you for holding this hearing on such important legislation, the Breast Cancer and Environmental Research Act. I am Dr. H. Kim Lyerly, Director of the Duke Comprehensive Cancer Center. I am a breast cancer surgeon, researcher, and a member and former Chair of the Department of Defense peer-reviewed Breast Cancer Research Program Integration Panel. I am grateful for the opportunity to testify today.

We all know how serious the problem of breast cancer is. Unfortunately, it is difficult to find a person who has not been touched in some way by breast cancer—either themselves or through friends or family members. A woman's chances of de-

veloping breast cancer have increased over the years. It is estimated that more than 250,000 women and nearly 2,000 men will be diagnosed with breast cancer in 2008. Sadly, more than 40,000 women and 450 men will die of the disease this year. Despite some progress, we still do not know what causes most breast cancers, how to prevent them or how to cure breast cancer for any individual woman.

Finding the cause or causes of breast cancer could be the key to unlocking this and other diseases—finding ways to prevent the disease from occurring in the first place, and also helping to better treat the disease and eventually cure it. While it is clear that traditional genetic studies can help us understand the etiology of a small fraction of cancers, it was demonstrated in this decade that identical twins, those who are essential genetic duplicates of each other, have only a 10–15 percent chance of having breast cancer if their twin had breast cancer. Clearly, something other than your inherited genes, as we know them, is leading to breast cancer in the majority of women. It is important to focus significant resources on these issues and doing so will have ramifications beyond breast cancer.

BREAST CANCER AND THE ENVIRONMENT

Breast cancer is a complex and heterogeneous disease. Research into the causes of breast cancer is a difficult area to study, particularly when examining environmental links. To date, any efforts in this arena have been fragmented. Laboratory and epidemiologic research may give some clues to the possible carcinogenicity of chemicals and other environmental exposures. Some resources have been put into genetics programs at the National Institutes of Health (NIH) to look at genetic variation in groups of patients with specific illnesses. Some resources have been put into the National Institute of Environmental Health Sciences (NIEHS) to develop environmental technology to validate exposures. These are nascent areas of research that are necessary. While this research is ongoing, we are far from determining the clinical utility of these relationships.

Some resources have gone to analyze clusters of cancer cases to generate hypotheses about potential risk factors. Unfortunately, the identification of a cluster does not necessarily reveal the exposure, or whether an individual exposure is responsible for the elevated rate of disease. An added challenge is the measurement of exposures over a lifetime, as exposures are intertwined and may be confounded by socioeconomic, occupational and reproductive factors. Studies such as the Sisters' Study at NIEHS look into these areas. In addition, recent data has demonstrated the maternal exposure can influence risk. For example, dietary supplements in experimental animal models can cause "epigenetic" changes, or changes in the ability of genes to be expressed. These epigenetic changes can then be passed on from generation to generation and increase cancer susceptibility in offspring. Clearly, new knowledge and new concepts of what constitutes environmental exposure, are being brought to light at an ever increasing pace.

While biomarker, other genetic research, and cohort studies are important, these are only a few aspects of the needed research into this area. We need to fund scientific freedom to determine different approaches to this problem and a cohesive, strategic program. Supporting different approaches is a hallmark of great research. We cannot presuppose which discipline or which approach has the answers. We must support collaboration among all with the expertise to address a health problem, especially one that poses such a complex scientific dilemma.

THE DOD BREAST CANCER MODEL

The examples I discuss above are just a few examples of how trying to determine what in our environment causes breast cancer is so challenging. It requires an innovative and strategic approach, with many different scientific disciplines working together. I have carefully reviewed the approach that H.R. 1157 describes and I can say it is the right and the best approach in this context. And it should be done through NIH because of the complexity of the problem and the collaborations contemplated. This legislation moves beyond fragmented approaches to a broad, innovative approach that fosters scientific freedom and public input to work in collaboration on a compelling national public health problem. I have seen the framework suggested by this bill work so well. The design of the program in this legislation is based on the model at the Department of Defense peer-reviewed Breast Cancer Research Program. As a scientist and past Chair of the Integration Panel, I can tell you firsthand why this model has been so successful.

The Department of Defense (DOD) peer-reviewed Breast Cancer Research Program has established itself as a model medical research program, respected by the military and throughout the cancer and broader medical community for its innovative and accountable approach. The DOD Breast Cancer Research Program is meant

to challenge the research community to work together to design innovative research that will foster new directions in breast cancer research.

The Institute of Medicine recommended the existing structure that includes scientific peer review and programmatic review by an Integration Panel (IP). The IP of the Department of Defense peer-reviewed Breast Cancer Research Program is made up of scientists and breast cancer advocates, including experts in basic, transitional, clinical, psychosocial, and public health research. The Integration Panel recommends a research investment strategy; reviews the results of the peer review panels' deliberations and comparison of scorings across panels; recommends the applications to be funded; and assists in overall program evaluation.

The IP's overarching role is to ensure the Program remains focused on its mission: eradicating breast cancer. The Panel is there to guarantee scientific freedom and minimize duplication. Once the scientific and technical peer review has been completed, the Integration Panel reviews the proposals with the mission and the strategic investment strategy in mind—looking at not only what proposals are scientifically meritorious, but also at which are the most meaningful. This step is critical. It is extremely important to note that, unlike most traditional funding programs, the DOD Program—and the structure proposed by the pending Breast Cancer and Environmental Research Act—does not tell the scientific community what to do, or what specific study to perform. The scientists are free to use their best judgment to decide what questions they will ask and what areas their proposals will address. And they do so with input from the consumer advocate community.

Another aspect of the proposed legislation has been validated by the DOD Program. It is extremely important that the program require grantees to be multi-disciplinary, multi-institutional, and to collaborate with community-based organizations. As I said earlier, environmental research is complex and difficult. It requires the best minds working together. We cannot stay within the silos of science if we want to unravel the secrets of how our environment is related to breast cancer.

The DOD Breast Cancer Research Program has been a model in this area. It has spearheaded concepts such as team science that proposed combining expertise to address significant issues, by promoting funding mechanisms that require disparate disciplines and/or investigators to communicate, cooperate and jointly address problems. These collaborative grants encourage not just individual scientists but also institutions to work together. I have seen the results of promoting team science and interactions through the multi-disciplinary and multi-institutional model, and I fully support inclusion of this model in the Breast Cancer and Environmental Research Act. Team-oriented science can work, it is especially critical for complex environmental research, and it requires novel funding mechanisms to ensure that teams are both recognized for their successes and accountable for their shortcomings.

SPECIFIC APPLICATION TO THE PROPOSED LEGISLATION

The Panel in the Breast Cancer and Environmental Research Act would act much like the Integration Panel at the DOD Breast Cancer Research Program. The Panel would determine the mechanisms necessary to address the overarching goal of the legislation. Those mechanisms would be released to the scientific community with a request for proposals in response. The plan ensures that we do not restrict but rather foster scientific freedom, creativity, and innovation. The idea is not to predetermine for the scientific community what specific research areas are to be addressed. The idea is to create a framework for scientists and consumers to fund scientifically meritorious research related to the environment and causes of breast cancer—research that is meaningful and will get us closer to finding the answers we need, in a strategic, collaborative way.

THE IMPORTANCE OF CONSUMER INVOLVEMENT

Breast cancer is not just a problem of science, but it is a problem of people. The inclusion of trained consumers at every level is critical to the success of the DOD Breast Cancer Research Program. The Program is a collaboration of the critical stakeholders—scientists, clinicians, the military, and trained consumers with a connection to breast cancer.

The consumers play a key role in ensuring that the research that is funded is responsive to needs of both the scientific and patient communities. Their perspective is necessary to ensure that the grants funded are meaningful and will have impact. Consumer advocates bring a vitally important perspective to scientific research. And they keep the scientists on task. Together, they can look at the current state of knowledge, and then design appropriate and necessary mechanisms to allow scientists, in collaboration with advocates, to develop proposals to research the most important questions.

I have quotes from several of my colleagues in the scientific community who have worked on the Integration Panel or in other capacities in the DOD Breast Cancer Research Program. Many of the scientists who have participated in the Program have said that the Program—and working with the advocates—has changed the way they do research. This has a profound impact on the way scientists approach their work.

For example, Dr. George Sledge of Indiana University said, “Of the many advances in breast cancer research over the past decade, among the most important is the role of advocates in furthering and focusing the research agenda.”

Dr. Regina Resta of New York said, “I served as a scientist on a DOD breast cancer study section [peer review panel]. The idea of the ‘consumer reviewer’ frankly, struck me as somewhat forced and potentially unhelpful in the review process. I was WRONG. These women added immeasurably to the process.”

Finally, Dr. Michael Diefenbach of Mount Sinai School of Medicine wrote, “I have served as a reviewer for the Department of Defense’s Breast and Prostate Cancer Review programs and I am a member of the behavioral study section for the National Cancer Institute. I find survivors or advocate reviewers as they are sometimes called bring a sense of realism to the review process that is very important to the selection and ultimately funding process of important research. Both sides bring important aspects to the review process and the selected projects are ultimately those that can fulfill scientific rigor and translatability from the research arena to clinical practice. I urge that future review panels include advocate reviewers in the review process.”

In addition to these scientists, and many others who have praised the DOD Breast Cancer Research Program, the IOM has reviewed the Program twice and has praised the design of the Program. In its 1997 review of the Program, the IOM stated:

The program fills a unique niche among public and private funding sources for cancer research. Among the most outstanding features of the program are the flexible approaches for setting priorities annually [and] the involvement of breast cancer advocates (consumers) in the peer review process.

The report goes on to state, “The Integration Panel, along with the USAMRMC, is responsible for a breast cancer program viewed as successful by this committee.” In 2004 a report by the IOM reiterated these remarks.

Finally, I would just like to talk a bit about how this approach has affected my research in my own institution. As you may know, Duke University has one of the most outstanding schools of environmental research in the United States, as well as an outstanding medical center. Policies of required cross-disciplinary research promoted by the DOD, led a number of investigators in the Cancer Center to actively meet and engage in collaborations with the Nicholas School of the Environment, an event that had not taken place previously. Environmental scientists, molecular epidemiologists, and basic scientists work together with breast cancer specialists to explore how environmental exposures can increase a woman’s risk of breast cancer, and possibly inhibit current strategies to prevent cancer. In addition, we have seen rapid increases in breast cancer in parts of the world undergoing rapid economic growth, which must be explored. Traditional forms of support could not, and did not support interactions reflecting these collaborations in the past. It is imperative that mechanisms that will enable these types of interactions be supported

In conclusion, the approach used by the DOD peer-reviewed Breast Cancer Research Program has changed the world of breast cancer research. We now need to apply the same model to investigate the causes of breast cancer. And it is our hope that this research model might inspire new approaches in other areas of scientific inquiry. As I said earlier, if we know what causes the disease, we can learn how to prevent it, how to better treat it and even to cure it. It is time that we take a fresh look at the environment and breast cancer. This proven approach will bring innovation and new thinking to the problem, will best use our resources and will complement ongoing work at NIH and elsewhere.

Mr. PALLONE. Thank you, Doctor, and thank you to all of you. We will now have some questions. I know that you may not all be able to stay for the whole time, but we will start out.

And I wanted to ask Ms. Crow a question. First of all, thank you for coming to meet with me and the other members, because I know you are a strong advocate on this legislation. You testified

that the bill before us gives scientists the resources and the focus to address issues pertaining to breast cancer and the environment. And you stated that the bill would bring researchers together to work in collaboration with trained advocates and with community based organizations. Can you tell me what impact you think the legislation will have on determining the linkages between the environment and breast cancer, and how that will help us develop a cure or preventive measures?

Ms. CROW. Well, obviously I think Fran could probably answer that more efficiently. But I would say that this bill has been set up very thoughtfully with the exchange of information between researchers and with the grants being peer-reviewed and information being just submitted through that. That hopefully a lot of questions will be answered. I would have to defer to you on that. I can tell you from my perspective because I am not a scientist and have not been involved in actually writing the bill, but what I understand of it is that it is very efficient and will by no means tie up anybody's arms as far as what they can and can't do, but that it creates opportunity for research to go forward. And if I can, I would love to defer that to Fran.

Mr. PALLONE. Sure. I mean either one of you really. What I am trying to get at obviously is how the provisions of this bill would help us understand these linkages better than the current research efforts. So Ms. Visco or Ms. Crow, either one of you.

Ms. VISCO. Well, Chairman, this bill is meant to look at these issues in a strategic way. The NIH has devoted resources to this issue. We have worked with, over the past 10 years, we have met with and collaborated with research who have devoted decades of their lives to looking at this particular issue. And what happens is we look at these issues in silos, and to some extent in a vacuum. There is very good important work going on, but what isn't happening is a really broad overarching strategic approach to looking at the links between the environment and breast cancer.

What this bill will do is it will compliment and enhance the ongoing work at NIH and it will allow researchers across the country, again many of whom who have devoted their lives to these issues, to work in collaboration and to submit their ideas and their questions to the NIH. And looking across all of those ideas the NIH has the ability to make certain that there is going to be a strategic approach. So it is complementing and enhancing and increasing scientific freedom and a strategic approach to this question.

Mr. PALLONE. Now, you said, Ms. Visco, that the annual funding for breast cancer research, both private and public, has remained relatively stagnant for the past 15 years. Do you know why that is true, and do you think that this—I mean one of the purposes of this legislation was to increase the public investment.

Ms. VISCO. Yes. Well, we recognize that first of all this is an authorization bill. This is not an appropriations bill. It is not our intent that NIH take the limited funding that they have to fund this bill. It is our intent to bring the power of advocacy and working in collaboration with you to increase the appropriations to make certain that this bill has an appropriation so NIH can do the work.

So here we have a situation where you have scientists around the country who are eager to see this happen. You have advocates

and the political will to make it happen. We have incredible sponsorship all behind, looking at this issue and taking an innovative, new, exciting approach that will compliment everything that is ongoing. They——

Mr. PALLONE. Did you want to talk—I mean my time is running out. Did you want to talk about the Senate bill? What do you want? We don't like to follow the Senate just so you know, but——

Ms. VISCO. Well, actually what we are doing is following the NIH. Because the bill that was marked up in the committee in the Senate and was a result of negotiations with NIH taking into account their concerns with the bill and coming to an agreement on what they would agree to, and then withdraw opposition to the bill, so the bill makes clear that the peer review——

Mr. PALLONE. Would you be satisfied if we amended this to conform with the Senate?

Ms. VISCO. Yes, yes, we would very much like to see that.

Mr. PALLONE. And you think that would still accomplish your goals?

Ms. VISCO. Yes, we think that would retain the integrity of the approach and of the legislation. Yes.

Mr. PALLONE. OK, thank you. Mr. Rogers.

Mr. ROGERS. Mr. Chairman.

One of the things that concerns me most about when we weigh in on these issues is—as I said I am a 24-year cancer survivor—is that we keep partisan politics out of them. Because if it seeps in in any way we end up fighting about things that are ridiculous when we have people who have committed their lives to solving this problem for real people who are going through some pretty horrible events in their life. And, you know, I had heard some expressed concern, at least through Senate negotiations, that there has been some strong rhetoric on this. Ms. Visco, you don't believe that this is a partisan issue do you?

Ms. VISCO. Well, this is without question not a partisan issue, and the bill itself has incredible bipartisan support.

Mr. ROGERS. And my understanding is you support the Senate bill as amended.

Ms. VISCO. Yes, we do.

Mr. ROGERS. OK. You know, that is reassuring to me, because I think that we will probably, if we can get close to that Senate bill, we are going to have very—excuse me—broad bipartisan support for this bill, and you would support that.

Ms. VISCO. Yes.

Mr. ROGERS. Wow. That is—I mean that is good to know, Mr. Chairman. And I hope that we put that in our calculus here as we move forward, because I think the concerns are actually legitimate concerns. As I said I really don't want to take away a doctor's time doing research to fill out a form to talk about a grant that isn't quite coordinated to find out if it is duplicative is not a good use of time, I don't think. So I am glad to hear you say that and that——

Ms. VISCO. Can I just——

Mr. ROGERS. Sure.

Ms. VISCO [continuing]. Address one of those issues? And, in fact, one of the purposes of the structure, which mirrors the DOD struc-

ture, is to make certain there isn't unnecessary duplication. So the scientific peer review is—maintains its integrity. We don't have unnecessary duplication, and at the same time we have a strategic approach to the problem, and that is what the Senate bill underscores.

Mr. ROGERS. Right. And I—you are talking about the Senate bill. And this bill, that panel—when I went back and tried to read that language I just felt, boy, I think there is a better way that we can do this that gets the result that we all want to have, I think, at the end of the day. So I appreciate you working with them and your note that this is not a—or this is a bipartisan effort, and that you do support the Senate version of it, which is a little different from this. So I don't think any members here, including some of my good friends who had some objection to it, were doing it in any other way other than somebody saying, hey, there might be a better way to do this. Thank you for that.

And Ms. Crow, I want to thank you for something. When I was a young army lieutenant—and I had suffered cancer prior to getting in the military—I had gone through all my military stuff and I got a very shocking call one day. And this was back in the 80's when it was still not really—it was uncouth to talk about having cancer at any time in your life. They called me into the office and said, we went through the medical review and found out that you had cancer. Before I had completed all the training by the way. So I had completed the training. And said, we don't think you are eligible to be an officer in the United States Army. And after a very long process of going—getting through the notion of that is the most ridiculous thing I have ever heard—and the reason that happened is because there weren't a lot of people having—willing to have the courage and commitment to stand up and say, hey, wait a minute, I am a cancer survivor. I am leading a productive life.

Ms. CROW. Yes.

Mr. ROGERS. And there are a lot of great things and a lot of great days ahead. And one of the things I want to compliment the doctor for, and others, is we have made such strides in survivability in cancer. That is—we haven't found a cure necessarily yet, but we have found a lot of ways to keep people alive. Earlier prevention, catching it early, the treatment regimens, the next generation of treatment regimens that are going to be less harmful in their side effects is all right here. It is all coming down the pike. And I think this a very exciting time to be in research, and it is an exciting time to be involved in cancer research for you doctor. And so, you know, there are a lot of things you could do with your time, to spend your time doing that, and letting people know that, listen, you can survive it and you can move on and you can still do great things.

I look forward to your next album, by the way.

Ms. CROW. Thank you.

Mr. ROGERS. Yes, you are welcome.

One of the things that the Senate did—and maybe I can get a comment from all of you—is they moved back the grant process. Rather than create that center they wanted to do grants. And I thought that was a pretty good idea, so that we don't do—and I think it would be easier to get to the research. Did you agree with

that portion of the Senate bill? Instead of having that dedicated center with a panel funding it that they would go to a grant structure to do the research, the very research that you are talking about accomplishing?

Ms. VISCO. That was actually the intent of the legislation from the beginning. It was simply using an inartful word—center—to describe it. But we very much—that is the approach that we are interested in. We are not interested in the bricks-and-mortar or rigid structure. We are interested in a grant program that will respect scientific freedom.

Dr. LYERLY. Thank you. And I would concur with that. It is really, you know—probably the more contemporary term would be a social networking type of support that allows the type of communication, the non-duplicative events, the ability to engage. And, again, I think this idea that, you know, in the past centers have excluded others and supported only those within it, and the exact opposite intent. And I think the language does improve that to develop a policy in which information is pushed out, the ideas are brought in, and respectfully and thoroughly considered, and so forth. And I think the DOD track record in establishing that is it provides an assurance that that type of template, that type of thinking, will move forward.

Mr. PALLONE. The gentleman's time is expired.

Mr. ROGERS. Just a comment for Ms. Crow. You had—in your testimony you said this was the bill, but you would be, as an advocate, willing to get to where we are all going I would assume—

Ms. CROW. Absolutely. And I think one of the strongest arguments for that is seeing this young group of women over here, and not having—they were here earlier. And they are working tirelessly on behalf of this bill as well to not be able to dictate, at this point, while they are coming into their maturity earlier than in the past, and what kind of correlation that has to the uprising statistic in young women who are being diagnosed with a much more advanced kind of cancer that is more difficult to treat. And as, obviously, a person who is in the media I get all kinds of e-mails about don't use this kind of lipstick, don't use that kind of shampoo. A lot of it is misinformation. A lot of it is information that has not been investigated. These young women are living with that every day, with having the kind of information that I am getting as well, knowing that is this going to be a factor in my getting an early diagnosis with breast cancer, or any other disease. And to me this bill, instead of having a cannonball shoot at a fly, it creates a much more, I think, directed opportunity to look at breast cancer with the hope and the knowingness perhaps that will correlate not just breast cancer but cancer across the board, and to these diseases outside of cancer as well.

Mr. PALLONE. Thank you, gentleman.

Mr. ROGERS. For the record, Mr. Chairman, my staff warned me—I am the big Sheryl Crow fan—that I was not allowed to faun over the—

Ms. CROW. Please, faun away. If it means getting the bill passed, faun, faun, faun.

Mr. PALLONE. Thank you, Mr. Rogers.

The gentlewoman from California, Ms. Capps.

Ms. CAPPs. Thank you, Mr. Chairman.

You know, a lot of people hear that this bill is about research on breast cancer and the environment. They may only be thinking of things like pollution in air or tainted water, things like that. And I know, Ms. Crow, you elaborated a little in your opening statement that the use of the word environment can be very broad-based, and you mentioned the lifestyle and stress as environmental issues that may clearly affect a woman's health or a person's health. I am going to start with Ms Visco, and ask—because I know you have some strong opinions about this as well, or beliefs, and ask you to start this conversation. And I hope Ms. Crow will chime in. But I also—just to lay out my 5 minute time I do want to ask Dr. Lyerly the same question that I asked Dr. Winn in the previous panel just to get some information on the record, so please, Ms. Visco.

Ms. VISCO. Well, I will say quickly that we do, as an organization, and this legislation would define environment very broadly. It is not just about chemical exposure. It is about lifestyle. It is about endogenous environmental influences, what is happening in our body, outside out body, so it really is a broad strategic, a broad look at the issues and the links between the environment and breast cancer. Sheryl, did you want to—

Ms. CROW. Well, and I would go one step farther and say that as anybody who has been diagnosed knows that you sort of become a student of cancer, and you learn a lot more than probably what you want to know. And one of the things that is really interesting with regard to the environment is in the correlation in different places such as China that never had cancer before 1950, and what is the correlation now to lifestyle, to environmental exposures that is causing a rise in—does that apply to us in America? I think we work together as a complete scientific community, but America is so much at the forefront of research and we know it and we do it so well. And this to me is a great opportunity in the fact that everyone right now is concerned about the environment, and as we watch it move into our personal space and affect our personal lives we know that there is a correlation. We don't know what it is, and it creates and incites a lot of fear in us. And when we are talking about what kind of plastics we are drinking out of—I have a 1-year-old who is still drinking out of a baby bottle. I want to know if later on that is going to cause some sort of cancer, some sort of disease, that could have been prevented. So I agree with Fran that the environment is difficult to define or to narrow, but this is a great starting place for us to tackle.

Mr. CAPPs. Thank you. And I will ask my question of you, Dr. Lyerly, in a minute. But, Ms. Crow, while you were speaking a group of young women that you were referencing in an earlier comment came back in. And I know that we are all impressed with the girl power, soon to be women power, that is—

Ms. CROW. Yes.

Ms. CAPPs [continuing]. Going to really take leadership in the areas that we are talking about today, and you are going to have plenty of material to work with. Let us put it that way, because as much as we want to pass this legislation there is certainly more to come, and the advocacy groups can hardly wait. And as I said,

as I shook a few hands earlier some of them are going to be sitting back here one day too, so that is a very good strategy that you are embarking upon.

Dr. Lyerly, I asked this question before, but I want to have your take on it as well. We have heard from critics of H.R. 1157 that the legislation is too disease-specific. Isn't it true that research on any cancer can often lead to progress for all cancers? In fact, doesn't research for one condition often lead to a cure for another?

Dr. LYERLY. Thank you for that question. I think there is clear evidence that inside into how cancers are diagnosed and treated can lead to very clear advances and treatment for other diseases. One example that stands out for breast cancer specifically is the idea of targeting the Epidermal Growth Factor Receptor type II or ERBE II and developing strategic therapies against this pathway was widely thought as not going to be effective, was demonstrated to be highly effective in breast cancer, and this has led to anti-EGFR or Epidermal Growth Factor Receptor therapies that are proven to be effective in lung cancer. They are proven to be effective in colorectal cancer. They are proven to be effective and very promising in pancreatic cancer, and a very interesting, but yet unproven approach for the treatment of malignant brain tumors. Something that is very near and dear to many of our hearts at this point, because again EGFR mutations are found in brain cancers, and we can imagine that insight developed in the development of therapies and insight into why breast cancer is developed could now be applied.

I do think breast cancer has led the way in forming collaborations, forming networks for tissue acquisition, for research approaches. So I do think there is a—like everything in life one foot has to go first. Breast cancer has led the way in many examples in advancing the entire field of cancer, as well as helping us understand fundamental biological principals like metabolism of cancer cells, and how that metabolism can affect weight gain or weight loss or myocardial function, and so forth and so on. So broad implications for even this narrowly defined starting point.

Ms. CAPPS. Thank you. And interesting that you would say what you just said next to two of the real leaders in this advocacy movement that have highlighted that breast cancer has shown the way in many areas. And it is a lot because of the advocates, and many of them are survivors. I just have to give credit where credit is due.

Thank you so much.

Mr. PALLONE. Mr. Deal.

Mr. DEAL. Thank you. I want to thank all of you for being here today.

I hear a great deal of commonality of concern, even though different points of view have been expressed. And I think that the issue of whether we know best, or whether the scientists and the experts at NIH know best, we probably lose in that on every basis, and I think that is the concern we have heard expressed.

And, Ms. Visco, I understood you to say in your earlier testimony that you are supportive of the Senate version of the bill. And, of course, it does address some of the concerns that were expressed by the NIH representatives in terms of the issues that they

thought were somewhat troubling. Is that your understanding as well?

Ms. VISCO. Yes, we do support the Senate bill, and it did come about as a result of negotiations with NIH to address their concerns.

Mr. DEAL. OK. Dr. Lyerly, I understand that you are the director of the Cancer Treatment Center there at Duke, and I assume you treat all sorts of cancers, not just breast cancer. Is that correct?

Dr. LYERLY. We do.

Mr. DEAL. Yes. And one of the things that causes us concern about trying to put everything back in the old silo approach is that, as you probably know better than I do, the non-melanoma cancers and the bronchial cancers and lung cancer. Those are taking substantial number of women's lives as well. In some cases maybe even exceeding the breast cancer deaths. So the fact that we may not all agree that everything needs to be focused in one area I think we are all saying that we need research, because it does overlap, does it not, as to what you find out in one area, as you have already elaborated?

Dr. LYERLY. It really does. And I think the emphasis here is imagining a complementary and potentially open extension of the really elegant model for NIH funding, and allowing scientists and the science to drive the opportunities for it. So I think—what I think that I found most comforting in long discussions about this opportunity is to hear and open and not to look at plastics or to look at specific toxins or a specific industry, but to allow the science to really drive the opportunity. But what I think is really important is that it creates a overarching strategy to move forward, and it allows engagement of investigators that perhaps may not have been traditional environmental scientists to be involved. And this is really where great opportunities abound. Having people with deep insight into computational models, nano-technology, environmental scientists at the Environmental Protection Agency. These are investigators that traditionally would not be engaged in any NIH-funded research, and this opportunity allows and opens up and creates the sort of power of persuasion to get them onto the table to have those discussions. So I concur with the sentiment that we don't want to be exclusive, but as we are beginning to start innovative models that address the fundamental problems in cancer we have to have some focus, otherwise we will be a mile wide and an inch deep.

Mr. DEAL. But I think you understand the concerns some have expressed here that we don't want to undo the good we think we did in the NIH reform model that did some of those very same things of breaking down the silos and allowing cross institute sharing of information. Things that really needed to be done for a very long time. I think that is the concern that you have heard expressed by a lot of people.

I will conclude, Mr. Chairman, with a personal reference, and my daughter probably will not like this. But our family has just gone through a real traumatic experience of my 2½-year-old granddaughter suffering strokes. And that has been one of the most traumatic situations, and fortunately they live close to Eggleston's Hospital there in Atlanta and she has been treated there and is out

of the hospital now. But I understand the importance of research because currently we don't know the cause, we don't know how to treat it, and that is one of the most frustrating experiences anybody could have is that uncertainty. So all of us hold great hope for scientific research and to a lot of different areas, and this of course being one of the ones that all of us are empathetic with. And I think you will find that we will have the support necessary to move this legislation forward. Personally, I hope it is the model that the Senate has adopted. I think it does eliminate a lot of the controversy that we would otherwise encounter.

Mr. Chairman, thank you for your time and I thank all the panel members for their presence today. Thank you.

Mr. PALLONE. And you have to leave? That is OK.

Ms. CROW. I do have to leave.

Mr. PALLONE. Oh, please.

Ms. CROW. I sure do appreciate your allowing me to give my testimony—

Mr. PALLONE. Sure.

Ms. CROW [continuing]. Today.

Mr. PALLONE. Thank you very much. We appreciate your advocacy.

Ms. CROW. And I will—thank you.

Mr. PALLONE. Take care.

The gentleman from New York, Mr. Engel.

Mr. ENGEL. Thank you. Thank you, Mr. Chairman.

Having lost my mother last year to pancreatic cancer it certainly opens your eyes in terms of all kinds of cancers. And certainly I think that the Congress ought to be doing everything we possibly can, not only for research, but the ability to have people diagnosed, see doctors as well.

I want to—I understand we have a lot of young women here from Georgetown Visitation High School, and on behalf of myself and our colleague, Ed Towns, I would like to welcome them because I know they worked hard on this bill through student advocacy. So thank you very, very much, ladies, for coming and for being great advocates.

This, of course, should be bipartisan and is bipartisan, but I think that I would be remiss if I didn't say that the levels of funding, the Administration's levels of funding, for NIH for breast cancer has been inadequate. And we had a doubling of monies directed to cancer research, and then in 2003 that doubling was sort of left by the wayside and kind of flattened out. And NIH has lost more than 13 percent of its purchasing power as a result. So I think that we need to keep pushing for more funding. Money doesn't cure everything, but it sure helps, and I think we ought to keep doing that.

And I was glad that people mentioned environmental issues, because—Ms. Capps did. And I think it is very important, because it is not a coincidence that cancer is just multiplying in leaps and bounds from what it was only a few short years ago, so we know that the environment is certainly a major factor in this as well.

I would like to ask Dr. Lyerly a couple of questions. Doctor, based on your work with DOD, Department of Defense's Peer Reviewed Breast Cancer Research Program, can you enlighten us as

to why you believe that that approach is the right approach for looking at the environmental causes of breast cancer? And also in conjunction with that if you could explain why getting consumers involved as the DOD research program does is beneficial for the research process.

Dr. LYERLY. Yes, thank you. Well, in my experience on the DOD integration panel I was able to see that the process was slightly different than the NIH process. And the NIH process in general allows for investigators to come up with their own ideas. But usually if there is an idea that it wants to be promoted by the NIH they will send out a request for applications and they will say we want to study broadly pancreatic cancer or nano-technology or imaging, and that creates opportunities for people to apply for funds to look at cancer imaging. The DOD approach is different in that it really begins to allow a completely clean slate and allow the scientists to say what are the fundamental issues, the most pressing issues, in breast cancer research today, and we will not begin to apply for funds to address those issues.

We also think, as we have heard earlier, that many of the opportunities involve collaborative research where we don't try to have everyone replicate themselves, but in fact, partner, develop relationships, and leverage scientific input. So we wanted to promote mechanisms that facilitated that and provided incentives for investigators to work together within their own institution, but even with other institutions. Something typically not promoted by the usual structures in which deans or other center directors are rewarded for accumulating as much as they can in their own center. And so the DOD approach was, how do we address this question and who are the players in the world that need to be on the team to address that question? And we are going to promote those interactions by providing funding mechanisms, and those teams would self-assemble and say we want to understand why women don't respond to hormonal therapies, or we want to understand why mammograms don't detect all breast cancers, or we want to understand why triple negative breast cancers are so lethal. And that is the question. It is not we have three investigators working on breast cancer and we want to form a center because we have three people. It is what are these fundamental questions?

And I think that mechanism and the intent of that mechanism requires advocacy involvement, because I don't think the scientists—and I include myself in that population—in a vacuum can really know what are the most pressing issues in breast cancer research without really understanding what are the most pressing issues in breast cancer.

Mr. ENGEL. Thank you.

And, Mr. Chairman, before I yield back I just want to add my voice to all our colleagues who have mentioned Senator Kennedy and wish him Godspeed and the very best in his battle against cancer. Thank you.

Mr. PALLONE. Thank you, Mr. Engel.

And I think we are done with our questions for this panel. Thank you both really for really providing some worthwhile testimony to us. And I think we are well on our way to moving this legislation based on this hearing today. So thank you again.

Ms. VISCO. Thank you.

Mr. PALLONE. And I will ask the third panel to come forward. Now, this panel is going to focus on the second bill, H.R. 758, "The Breast Cancer Patient Protection Act." And thank you for being here. Let me introduce the two of you.

First, on my left is Dr. Kristen Zarfos who is assistant clinical professor at the University of Connecticut School of Medicine, and director of the St. Francis Comprehensive Breast Health Center at St. Francis Hospital in Hartford, Connecticut. And then we have Ms. Alva Williams from Jacksonville, North Carolina. Thank you for being here.

You probably heard me say before that we are going to hear 5-minute statements from each of you, and that we may have additional questions that we would ask you to get back to us in writing.

And I will start by recognizing Dr. Zarfos.

STATEMENT OF KRISTEN ZARFOS, M.D., FACS, ASSISTANT CLINICAL PROFESSOR, UNIVERSITY OF CONNECTICUT SCHOOL OF MEDICINE; DIRECTOR, ST. FRANCIS COMPREHENSIVE BREAST HEALTH CENTER, SAINT FRANCIS HOSPITAL

Dr. ZARFOS. Thank you. Good afternoon all of you and thank you for those of you who are here. I appreciate you this afternoon being here. We thank you Congressman Pallone for bringing this bill to hearing, and we thank you certainly for the honor of being here today.

As Congressman Pallone has said, my name is Kristen Zarfos. I am a general surgeon with a specialty in breast care in Hartford, Connecticut.

A little background information. A mastectomy is one of two surgical procedures used to remove breast cancer. It is a 2-hour operation, usually under general anesthesia, where all the breast is dissected off the chest wall removing most of the overlying skin, sampling some of the lymph nodes under the adjacent arm. And as you might know, because I hear many of you on the Committee have personally experienced a family member with breast cancer, or at least you might expect it is painful, accompanied by nausea many times, compounded by the need for rubber tubes to drain blood from under the remaining skin. It is deforming and it comes under the shroud of a woman facing a potentially life-threatening disease, possible chemotherapy, radiation, therapy. And uppermost in her mind the fear of impact on her children and husband.

Until 1996 the average hospital stay for a mastectomy was 2 to 4 days for basic physical health care needs. And in 1996 exclusively patients paying for private health care insurance were suddenly being told that they would have to leave the hospital a few hours after their mastectomy, regardless of any underlying complex medical problems they might have. This unilateral decision on the part of several health care insurance companies was made without any perspective clinical research showing that it was safe.

Women, as consumers, earlier in the year before they knew they would be diagnosed with breast cancer had purchased health care insurance policies based on their reputation and the track record of what services the company provided. These consumers paid for

and assumed they would receive what basic care they had contracted for during the time of that contract. Yet, in mid-1996 without informing the patients, the insurance customer, several insurance companies changed the provision of their contracts. Thus, women with newly diagnosed cancer who had previously known other women who had stayed in the hospital 2 to 4 days after a mastectomy now are shocked to be sent home within a few hours despite contracted services that they were still paying premiums for. They were facing a breach of contract for services at a time when they were sorely needed.

Imagine first being told you had breast cancer and that conjures in your mind. And you are told then you are going to lose your breast, and then you are told you cannot stay more than just a few hours after surgery. To be certain, fighting a consumer issue would be far from the foremost in your mind. Government data showed that women with Medicare, Medicaid, or no insurance at all were given the length of hospitalization that they needed. Yet, women paying health care premiums were denied that.

Following the precedent Congress set in the mid-1990s of legislation to prevent mothers and newborns from being discharged prematurely, a few hours after delivery, drive-through delivery legislation, U.S. Congresswoman Rosa DeLauro introduced The Breast Cancer Patient Protection Act in 1997 and annually thereafter. This legislation does not mandate hospitalization, but instead restores a right for a woman to choose whether she be hospitalized 24 to 48 hours if she needs basic care. Without protective legislation women and their spouses will continue to pay double digit increasing health care premiums, yet be denied care when they need it.

Now, women who have had adverse consequences from being sent home a few hours after a mastectomy question what had their insurance premiums that they paid for done for them. It had not covered their physical needs. And indeed, 22 million people who signed the Lifetime TV online petition asked the very same question and share the outrage. In addition, many of the 40,000 women who call the Breast Cancer Network of Strength each year have echoed the concern. In 1997, 21 states responded to the issue by passing legislation in various forms. Yet, American women in 29 states and many still in the 21 states with legislation where there is ineffective law face what has been coined as a drive-through mastectomy. Sixty-five percent of 125,000 women having mastectomies across America today face leaving home in a few hours.

Now, remember none of us want to be in the hospital at all. And I have had patients determined, the morning of their surgery, that they want to go home that night, and yet most of those women choose to stay for 24 hours. Indeed, women who are ready to go home the same day, who are well enough to go home the same day and choose to go home the same day, have the right to do so. And so shouldn't women who post-operatively have physical needs requiring hospitalization have the right to receive the care that they paid for? It is not a woman's issue. It is a family issue. In the last decade nearly a million families had to face this, and their caregivers most of the time are not health care professionals. But most

important is hearing the voices of women who face this, which you will hear from Alva.

Now, included in the supplement given to you are testimonies from women taken from the Lifetime TV petition, and I would ask you please to look at those, because they are more important than what I have to say. But there is a common denominator. Pain, intractable vomiting, and infection, which was rarely seen when we did inpatient mastectomies, emergency room visits, and readmissions. And I can say in my 20 years of practice, covering over 30 surgeons during the course of my career, I have never had to see a patient in the ER shortly after their surgery, or readmit them.

I must also tell you that despite being immersed in this issue daily for over a decade I am still shocked at what happens outside of Connecticut. And just 6 weeks ago I was called from a woman in New Hampshire. A woman in her 50s partially paralyzed and on blood thinners for clots who would told she would have to go home a few hours after surgery. Now, not to bore you with details, but if you are paralyzed your mobility is limited to handle the drains, and being on blood thinners it makes it very tricky for handling hemorrhage from the standpoint of a surgeon. Yes, she had to fight to get one night in the hospital. And what this says to me is that unilaterally denying hospitalization says that each woman in this country needs to be treated individually and not as a faceless procedure.

Mr. PALLONE. I am going to have to ask you to summarize.

Dr. ZARFOS. I shall.

Mr. PALLONE. Because it is over a minute.

Dr. ZARFOS. I believe, as do most Americans, that our legislators have served the consumer rights and health protections rights of American people when we bring issues to you as in the drive through delivery issue. We turn to you to do that as you have done before. To help American families faced with breast cancer in a way that brings no additional cost to the American taxpayer and adds no burden to the health care premiums, because after all, patients have already paid for basic care.

I also want to—before introducing Alva I would like to also acknowledge the several young women, who I have met before joining us today representing the 150 members of the Think Pink Society. It is a student-run organization at Georgetown Visitation Preparatory School who have been working diligently to raise awareness and garner support for The Breast Cancer Patient Protection Act. We are pleased to have you join us for this important issue today.

I would like to recognize the statement that the co-president of Think Pink, Kaley Costino, has submitted for record. And I echo what our Congressman said. I will be delighted when they are running this country, and they are the future doctors of this country.

Thank you.

[The prepared statement of Dr. Zarfos follows:]

STATEMENT OF KRISTEN A. ZARFOS, M.D, FACS

Good morning Congressmen Pallone and Deal, along with the entire Subcommittee on Health of the Energy and Commerce Committee. It is an honor to

come before you to share information on one aspect of breast cancer care of women and their families in America today.

My name is Dr. Kristen Zarfos, fellow in the American College of Surgeons. I am a general surgeon with a focus in breast cancer care. I am an assistant professor of surgery at the University of Connecticut School of Medicine, as well as Director of the St. Francis Comprehensive Breast Health Center in Hartford, Connecticut.

Until 1985, almost all women who were diagnosed with breast cancer underwent a surgical procedure called a mastectomy. It is likely that someone in your family has had this procedure. It is a 2-hour operation, usually under general anesthesia where all of the breast is dissected off the chest wall, removing most of the overlying skin and approximately half of the lymph nodes under the adjacent arm. As you might know, or at least expect, it is painful, accompanied by nausea many times, compounded by the need for rubber tubes to drain blood from under the remaining skin. It is deforming and comes under the shroud of a woman facing a potentially life threatening disease, possible chemotherapy, radiation therapy, and uppermost in her mind—the fear of the impact on her children and husband.

The good news is that federally funded prospective clinical research showed in 1985 that not all women with breast cancer need have a mastectomy, but could have a lumpectomy with radiation therapy. The even better news is that each year since the early 1990s, because of early detection, fewer American women have mastectomies each year. Yet each year, more women are diagnosed with breast cancer—now over 200,000 each year. And still, because of certain individual characteristics (which I would be glad to share with you in more detail if you wish) approximately 125,000 American women require mastectomies to give them the best possible chance that the cancer will not recur.

Until 1996, the average hospital stay for a mastectomy based on data collected by a hospital association, was 2–4 days. This hospitalization was for the basic health care needs of pain control, nausea control for the needed pain medication, management of the necessary tubes draining blood from the chest wall, overcoming the effects of anesthesia, and nurses teaching the patient, after she is awake, and her caregivers how to dress the wounds and handle the drains. Rarely were infections seen in the mastectomy incisions. Even more rare was a patient seen returning to the emergency room with a problem or being readmitted. In fact, in the 20 years of my practice, I have never had a patient of my own or the surgeons who I covered return for these needs.

In 1996, exclusively patients paying for private health care insurance were suddenly being told that they would have to leave the hospital a few hours after their mastectomy—regardless of any underlying complex medical problems they might have, such as diabetes requiring close monitoring and adjustment of insulin shots because of the stress of surgery, severe heart disease, or being on blood thinning medication. Under no consideration was if the patient had a prior history of adverse reactions to anesthesia, post-operative pain that oral medications would not control, how far they needed to travel home still groggy, in pain and nauseated, or if they even had an adult to care for them at home. This unilateral decision on the part of several health care insurance companies was made without any prospective clinical research showing it was safe.

As the Commerce Committee, you should be aware that as consumers, earlier in the year, before knowing they would have to face breast cancer, women had purchased health care insurance policies based on the reputation and the track record of what services the company provided. These consumers paid for and assumed they would receive what basic care they had contracted for during the time period of that contract.

In mid 1996, without informing the patient, i.e., the insurance customer, the several insurance companies changed the provision of their contracts. Thus, women with newly diagnosed breast cancer, who had previously known other women who were admitted for 2–4 days after a mastectomy, now were shocked to be denied even 24 hours in the hospital, despite the contracted services they were still paying for. They were facing a breach of contract for services that they now so badly needed.

Imagine first being told that you have breast cancer, and all that conjures in your mind. Next you are told you would lose your breast, and the impact that has on you. Then you are told that you could not stay in the hospital but for a few hours after losing your breast. To be certain, fighting a consumer issue would not be the foremost thought on your mind. The questions that women ask when faced with breast cancer are, “Am I going to die?” (over 40,000 women die each year in the US from breast cancer); “Am I going to leave my children?”; “How painful and deforming will the surgery be?”; Will I be able to return to taking care of my family or working?”

This denial of care was faced primarily by women paying for private insurance. Government data showed that women with Medicare or Medicaid or no insurance at all, were given the length of hospitalization after a mastectomy they needed.

Following the precedent Congress set in the mid 1990s of legislation to prevent mothers and newborns from being discharged prematurely a few hours after delivery (known as the Drive-Through Delivery legislation), your colleague, U.S. Congresswoman Rosa DeLauro introduced the Breast Cancer Patient Protection Act in 1997 and annually thereafter. This legislation does not mandate hospitalization, but instead restores the right for a woman and her doctor to choose whether she be hospitalized 24–48 hours if she needs hospitalization she has paid for through premiums for basic health care. Without protective legislation, women and their spouses will continue to pay double digit increasing health insurance premiums, yet be denied basic—not embellished, superfluous or elective—health care at a time of the crisis of being told the diagnosis of breast cancer. There is consensus that pain control, alleviation of the physical act of vomiting against a painful chest wall, control of rubber tubes draining blood from a fresh surgical area fit the definition of basic health care. Women who have had adverse consequences from being sent home a few hours after their mastectomies ask what have they paid insurance premiums for if their basic physical needs were not covered.

Please do not rely on what I am telling you, but refer to the many testimonies gathered on the Lifetime TV online petition of 20 million people, in which many women tell their own stories of being sent home within a few hours of their surgery. What they tell makes even me, a seasoned surgeon of two decades of practice, cringe at the consequences they endured. (A condensed list of testimonies is provided.) The Breast Cancer Network of Strength (formerly the Y-Me National Breast Cancer Organization) fields over 40,000 a year from breast cancer patients. On many occasions the hotline has received calls from patients told that their insurance will not cover a hospital stay after their mastectomy—stories about women forced to leave the hospital shortly after surgery without proper recovery time have surfaced—many forced to leave while still under anesthesia.

In 1997, 20 states responded to this issue by passing legislation in various forms—some truly protective, others just token—as you will hear. Yet, American women in 30 states and many in the 20 states where there are ineffective laws face what has been coined as “drive-through mastectomies.” Sixty-five percent of the 125,000 women having mastectomies across America today leave the hospital within a few hours of their surgery, regardless of their physical health needs. Remember that nobody wants to be in a hospital at all. Even the most determined patients I have had who preoperatively request going home the same day, after having surgery have requested staying at least 24 hours. Many women have the resources and they choose to go home the same day of their mastectomy. They have the right to do so. And, so shouldn’t women who postoperatively have the physical needs requiring hospitalization should have the same right to receive the care they need and have paid for.

But, let me pause here to clarify that this is not solely a woman’s issue. This is a family issue. 125,000 American families face this each year. Approximately 975,000—nearly 1 million families have faced this over the last decade since this practice started. This is a family issue, which I am sure many of you may have experienced. As husbands or sons hearing this information today, you may be thinking what it would be like for you to take care of your wife or mother in pain and frightened. The entire family—husbands, young children, elderly parents—have become caregivers, most often with no previous medical experience.

These are the background facts. Following is the most important perspective from women with breast cancer who had outpatient mastectomies. These American voices from across the country will tell you what happened to them with the treatment—or lack thereof—of their breast cancer.

Today in this audience is Alva from North Carolina. Alva came to Congress to share her story at a press conference to announce the introduction of the Breast Cancer Protection Act in 2006. Alva has asked me to share her and her husband’s story in her words to help you understand the real impact of being sent home a few hours after a woman loses her breast.

Alva was 65 at the time of her diagnosis of breast cancer. Her health care insurance was covered by her husband’s insurance along with their contribution. Her insurance company mandated that she have a surgeon who performed her surgery in an outpatient facility 1 hour away by back roads from her home. Alva was sent home directly from the recovery room a few hours after her surgery, still groggy from the general anesthesia. She was given pain and nausea medication to take by mouth, neither of which worked. She vomited, causing more pain in her chest wall, and of course preventing the pain medication from being absorbed. Her husband,

a washer-dryer technician, with no prior medical experience, was her caregiver. She developed a Staphylococcal infection, causing her mastectomy incision to pull apart, and drain. The open wound required weeks and weeks of antibiotics, dressings and packings, which delayed her much needed chemotherapy for 6 weeks.

Alva was so moved by her diagnosis that she has embraced helping other women diagnosed with breast cancer in many ways. Through her advocacy, she has met two other women who underwent outpatient mastectomies in her state, despite the fact that North Carolina has a state law to prevent this. One woman is a widow in her 40s with 3 children she is raising by herself. She went home to be taken care of by her eldest son who is 10 years old, being the only person to help her with bandages and the draining tubes. As a city employee, her employer was not self-insured, so that even ERISA was not an excuse for her being sent home a few hours after her surgery. A third woman who Alva met has insurance with a very well respected company. She, too, was denied hospitalization the day of her surgery.

In Alva's words, "No person should be treated like an animal; even my Cocker Spaniel with breast cancer was kept overnight when she had surgery."

Let me share yet more personal stories from women across the country—all of which have the common themes of pain, intractable vomiting, infection (something rarely seen before outpatient mastectomies), emergency room visits shortly after surgery, re-hospitalizations, and even a fatal postoperative heart attack at home. These are included in the supplement to my testimony taken from the on-line petition. I will stratify those from the states which already have laws, with additional compelling reports.

But first, I must again tell you that despite my being immersed in this issue day in and day out for two decades, I am still shocked at what is going on outside Connecticut. I was called by a woman in New Hampshire just 6 weeks ago. She is a woman in her 50's, partially paralyzed and on blood thinning medication for blood clots, who was told she would have to go home a few hours after her surgery. Her paralysis limits her mobility; managing the blood thinners can be tricky to prevent her from hemorrhaging. The thought she would be unilaterally denied hospitalization says that each woman in this country needs to be treated individually, not as a faceless procedure.

These are facts from the people who matter—American women and their families across the country and in ever increasing numbers. What they say is the reality. This is a major obstacle to the treatment of 125,000 women with breast cancer each year.

The purpose of the Breast Cancer Patient Protection Act is simple and straightforward:

1. To restore consumer services of basic health care that women have paid for, but is being withheld.
2. To restore a right to the basic health care of a choice of the services of a 24–48 hour hospitalization. This is not a mandate for hospitalization, but rather quite the contrary, a restoration of the individual patient's rights based on her physical needs for care she has paid for.
3. To provide uniform protection to all American women and their families across the country rather than the current disparity in the care of women with breast cancer in the United States.

Shouldn't all American women and their families have the right to having basic health care they have paid for the day they face mastectomy?

I believe, as do most Americans, that our legislators have served the consumer rights and health protection rights of the American people when we have brought issues to you attention, as with the Drive-Through Delivery legislation. We turn to you to do as you have before to help American families faced with breast cancer in a way that brings no additional cost to the American taxpayer, and adds no burden to health care premiums, as the services of basic health care the patient has already paid for.

We turn to you to help us. Pass the Breast Cancer Patient Protection Act.
Thank you.

Mr. PALLONE. Thank you.

Let me ask unanimous consent to enter into the record several statements including the one you mentioned from the Think Pink Society of the Georgetown Visitation Prep School, Lifetime Television Network statement, a statement from the Breast Cancer Network of Strength, a statement from the sponsor of the bill, Con-

gresswoman Rosa DeLauro, and a number of letters of support from various organizations. Without objection those will be entered into the record.

[The information appears at the conclusion of the hearing.]

Mr. PALLONE. And now let me ask Ms. Williams to give us your opening statement. I forgot to mention that you are actually a patient and you are here representing other patients. Thank you for being here.

STATEMENT OF ALVA WILLIAMS

Ms. WILLIAMS. Thank you so much for having me. It is a real pleasure to be here.

I have quite the story to tell and I will try to tell it within 5 minutes. I am the mother of five children, four sons, and one daughter, and have a wonderful husband. So I am fortunate on that side.

But when I went in and had to have a mastectomy I found out I had to go straight home from the recovery room. Well, to add insult to injury my insurance was not accepted by a surgeon in the town we live in, so we had to go to a town about 40 miles away. And a two lane road at that, and they were working on it to make it four lanes. So it took a little over an hour each way.

But anyway, we left early that morning. I went in for outpatient surgery. I was home before the sun went down. I barely remember the trip home. We were like a caravan. My sister—excuse me—my sister and my 82-year-old brother-in-law who was a Naval corpsman in World War II, Korea, and Vietnam came from Georgia to take care of me. And my sister drove me in her car and my husband and brother-in-law were behind them, and my children in the third car. And the reason we did that is we didn't know the shape I would be in after the surgery. Perhaps I would have to lie on the back seat of the car.

And anyway, we got back home. Everyone is worn out. I am terrified. I have tubes—excuse me—hanging from my chest to my knees. And my sister comes at me and she says here is two pills, please take these pills. I said what are the pills for? She said I really don't know, but the doctor said take them. I said I am not taking them until you tell me what I am taking. So she came back and she said one is for pain and one is for nausea. And I said I will take the one for nausea, because I really was sick. And she insisted on the second pill so I took it to satisfy my sister. Well, then I really got sick.

You see if I had been in a hospital I would have been getting this medication through my veins, not through pills that I ended up throwing back up. And it was a horrible night. Everyone went to bed. They were worn out, but me, I just couldn't lay down. I was so afraid. And for the first time in my life I talked to God out loud. And I promised God—excuse me—if he would just make me well I would do everything in power to help one other woman to never, ever have to go through what I am going through.

And the tubes—I was so afraid of the tubes, getting them caught on something that I decided to put on my husband's pajama bottoms, because they were big and roomy and I could fit the tubes down into my pajamas. And my husband is retired now, but at that time he was still working, and he is a washer/dryer technician.

This man had to drain my tubes, measure, and record. And we find out when we got back to the surgeon several days later Larry had drained the tubes just fine, but he had not measured correctly. He was to measure the drainage from each tube separately, and he had just combined the two. But we lived through it.

But I ended up with a staph infection. I don't know if you have the photographs of my chest. They are available if you would like to see them. And that caused me to be 6 weeks late getting my chemotherapy. But I never lost faith in God that he would bring me through it, and I have never forgotten what I promised God that night. If he would help me to get well I would everything in my power to help one other woman. And I was so lonely that night and I needed someone to talk to, and it was 2 or 3 o'clock in the morning. I got on my computer and I found Lifetime for Women, and up pops a survey. I took Lifetime's survey on breast cancer, and at the bottom it wanted my story, which I wrote my story. That is the way I vented that night. That was who I talked to was my computer.

I forgot all about it. It helped me. Six months later my phone is ringing and it was Lauren from Lifetime in New York. Since September of '06 I made my trip to Washington D.C., my first trip, and spoke at a congressional press conference. And I am so honored to be here to speak to you today to ask you to please help us. My damage is done. Nothing can repair my damage, but I want to help other women, your wives, your daughters, your cousins, your nieces, whoever in your life to never, ever have to go through what I have been through.

And I thank you very much.

[The prepared statement of Ms. Williams follows:]

STATEMENT OF ALVA WILLIAMS

A BREAST CANCER SURVIVOR FROM NORTH CAROLINA SPEAKS OUT AGAINST "DRIVE-THROUGH" MASTECTOMIES

About 2 years ago, I had a "drive-through" mastectomy. I left my house for my surgery at sunrise and was back home before sundown. I was not given the option of staying in the hospital. When I went to schedule my surgery, I was told by my surgeon's office that my health insurance would not cover a hospital stay. So my mastectomy was scheduled as an outpatient procedure at the New Bern Surgical Center in New Bern, North Carolina.

My older sister, Nell, who is 73 years old, and her husband, Charlie, an 80-year-old retired Chief Hospital Corpsman who served in WWII, Korea, and Vietnam, live in Georgia and came to take care of me. On the morning of my surgery, Nell drove me to the surgery center, approximately 37 miles from my house. We didn't know how I would feel after the surgery and if I would need to lay down in the backseat, so Charlie and my husband, Larry, as well as three of my children followed us. We joked that we were a caravan.

My surgery seemed to go well. When I got home, I stayed on the sofa in our den. I didn't want to be away from my family. I had never been so scared in my life and I didn't want anyone to know how terrified I was. I was used to always taking care of them, not the other way around. I was in shock—my God, my entire breast had just been removed! I felt like a butchered animal. And though my family really wanted to be there for me, they really couldn't understand all of the feelings that I was going through. I just wished that I had been in the hospital, so I could have shared my fears with a doctor or a nurse.

Even though I was lucky enough to have my family there to take care of me and they tried their best, I really needed expert medical care, especially during the first couple of days following my surgery.

The worst part was emptying the drainage tubes. These tubes hung from my chest to my knees. Terrified that I'd catch them on something, I ended up wearing

my husband's pajama pants and tucking them into there. We had to empty the drains and then measure and record the bloody fluid. Though Charlie was a retired Navy medic, he couldn't handle doing this. That left my husband Larry, a washer and dryer repairman without a medical bone in his body, to try. God bless him. As he struggled to get the gloves over his big hands, he proceeded to empty the drains. However, we later found out that poor Larry had been combining the amount of fluid, rather than measuring each drain individually.

I ended up getting a staph infection and had to seek medical help from Dr. Turlington, my primary care physician in Jacksonville. He cleaned the site, taught my husband how to change the dressings and put me on heavy antibiotics. In about 2 weeks, the infection started to heal. My oncologist told me he could not begin the chemotherapy treatments until the infected site was completely healed. In the end, I was 6 weeks late starting my chemotherapy.

I just thank the good Lord everyday for Dr. Turlington; this man saved my life! He is not only my family doctor, but also a very close friend who lives just up the street. Not everyone in my situation is fortunate enough to have a doctor close by.

I never thought this could happen to me. It's not right for an insurance company to dictate how a physician must treat a patient. I pay for health insurance to protect myself, in case the worst happens. And when it did happen to me, I found out just how little coverage I really had. And I didn't know the right questions to ask. I just found out from Lifetime that my state, North Carolina, has a law on the books to prevent "drive-through" mastectomies, but unfortunately, it did not protect me.

I hope that my story makes a difference. I really want to help other women and make sure that they get the expert medical care and attention they need and deserve. I signed Lifetime's petition to end "drive-through" mastectomies. I know now that I am not alone. My signature is just one of more than 20 million Lifetime has collected. That means that I am not the only one who cares and has had this happen to them. I urge Congress to pass the Breast Cancer Patient Protection Act of 2007. Unfortunately, one in eight women will be diagnosed with breast cancer in her life. Please make sure that others don't have to experience a "drive-through" mastectomy.

Mr. PALLONE. Thank you, Ms. Williams. I appreciate the way you explained your situation and how many others would be impacted in the same way.

We are going to have questions now, and I will recognize myself.

You know, I went through this I don't know how many years ago now with the drive-through deliveries for babies. And, of course, everyone—well, I shouldn't say everyone, but you know, the naysayers say that we shouldn't be mandating these things. You know, it should be up to the insurance companies. And I don't agree with obviously, and I went through the situation where my son was released after he was born, very quickly. He ended up going home, having jaundice, and had to go back to the hospital again. So I mean it is different circumstances, but a lot of the same rationale as to why we would pass this kind of bill.

But let me ask Dr. Zarfos a couple questions. Would you agree that physicians should make the decision as to when to discharge a woman after surgery based on their medical needs, and not what is in the best interest of the insurance company? And is there any reason to believe a woman would want to stay in a hospital if it isn't in her best interest?

Dr. ZARFOS. No. I think, yes, the patient-doctor relationship is really a very special relationship. It is one on one. It is face to face. It really can't be legislated by a faceless physician a distance away who has never looked into a patient's eyes or understood their circumstances.

The second part of your question, of course, nobody wants to be in the hospital. And, indeed, for women who have resources and support and feel well, aren't having pain or nausea, they should

have every right to go home with the supportive care they need. A visiting nurse or whatever.

But two patients come to mind to me in the last 2 weeks. And one is a personal trainer who is in the most robust shape I have ever seen anyone, who if you thought anybody would have wanted to go home the same day. And she had pain, significant pain. And this is someone who is not a wimp by any stretch of the imagination. And a patient I just operated on Monday who had had a thyroid operation 2 years. Who had a lousy roommate and was awake all night and really hated the idea of being in the hospital, and needed to be in for 2 days for nausea and pain. So your question is right. We have to individualize care whether we have no insurance, private insurance, Medicare, or Medicaid. The sanctity of the patient-doctor relationship cannot be ignored or we are going to be nothing but machines.

Mr. PALLONE. I don't know anybody who wants to stay in the hospital by the way.

Now, in Connecticut you have this on the books, but obviously a lot of states haven't enacted the laws in this area, so that is why we are talking about a national bill. But opponents of the bill say that the legislation is unnecessary. It would raise costs. What was the experience in Connecticut after the protection was enacted? Did the costs spiral out of control as a result of the state legislation? And to your knowledge did Connecticut's law cause small businesses or any other employers to drop health insurance?

Dr. ZARFOS. Well—

Mr. PALLONE. Because that is another criticism we got.

Dr. ZARFOS. In Connecticut we can give patients individualized care, and sometimes we aren't aware of what is going on around the country except for people like Alva and the Lifetime TV petition.

No. Now, let us think about this. The average length of stay in Connecticut in 1996, based on Connecticut Hospital Association statistics, not my personal experience, was 2 to 4 days. So if insurance companies are paying for 4 days, which would cost the premiums to be at a certain level, this legislation is asking for 1 to 2 days as necessary. So there, in fact, is the cost savings for the insurance company.

Number two, we have looked at data about—there are concerns about nosocomial infections that occur while in the hospital. That is why a person shouldn't stay in. There is no perspective data looking at breast cancer surveys that says that women are more likely to have an infection if they stay 1 night or 2 nights versus not at all. And indeed, women are really pretty bound and the wounds are very covered, and the drains are covered when in the hospital.

Mr. PALLONE. Well, is it also true that if the doctor suggests you leave and you want to leave you still would be able to after—

Dr. ZARFOS. Absolutely.

Mr. PALLONE [continuing]. This bill?

Dr. ZARFOS. But the issue of infection I think we really need to address where everyone says you stay in the hospital you will get an infection. I have to reiterate that in my experience in 20 years I never had anybody with an infection that had to be readmitted.

Yes, if you look at the Lifetime TV petition testimony it is a recurrent theme across the country. Now, I did a little research on numbers, and in my hospital if you stayed overnight, if one stayed overnight, for basic care it would be about \$860. The literature, on the other hand, says that for a readmission for an infection after a mastectomy, with or without reconstruction, the cost is \$4,600. Let us say a patient has an infection and gets IV antibiotics using one drug called Vancomycin for 3 weeks. It would be \$6,000. So to answer your question in a circuitous way, indeed, it is less expensive for the insurance company to pay if a patient wants to stay 1 night, than the consequences of infection readmission. So, no, to the best of my knowledge no businesses have gone out of—no small businesses have gone out of business because of that, gone into bankruptcy, nor have premiums gone up because of this particular issue.

Mr. PALLONE. OK. And there is also the issue of dropping health insurance. We have no evidence that any businesses dropped health insurance because of it either in your state.

Dr. ZARFOS. Well, across the country we have seen double digit increases—

Mr. PALLONE. Right.

Dr. ZARFOS [continuing]. Every year since 2000, including the 30 states that don't have the legislation.

Mr. PALLONE. Yes, so that would be very difficult to make any conclusions.

Dr. ZARFOS. I think so. I think to blame those few states that have patients, and if we could say that those states didn't have increasing premiums and the others did, but indeed, it is across the country. The premiums continue to rise.

Mr. PALLONE. OK, thank you.

Mr. DEAL. Thank you.

I agree with both of you that we need some reforms in our health delivery system and in our health care system in general. And I think it applies to the health care insurance companies, the physicians, the hospitals, the government. And in that end let me ask you just a—Dr. Zarfos, I guess I will ask you these questions.

Do you think a patient who is facing breast cancer should have access to more quality and price information on the different health care providers that are available and the options that are available to them?

Dr. ZARFOS. I think if you look at quality as defining it as the individualization of care, access to antibiotics not necessary. If you want to look at physicians, on how much they spend, let us not judge us only by that. Let us look at the—

Mr. DEAL. Well, do you think patients are entitled to more information? That is what I am asking.

Dr. ZARFOS. Well, but also how much time the doctor spends with a patient as well as not the amount of money they spend on the doctor.

Mr. DEAL. All right. Let me ask you some specifics about that. If a lady has breast cancer and she is trying to choose between hospital A and hospital B. And hospital A has a higher infection rate than hospital B, is that the kind of information that this patient

should have access to before she decides where to go for a mastectomy?

Dr. ZARFOS. Well, I think breast cancer is such a personal issue that one has to take that into consideration. But you know what I tell patients to do? Always get a second opinion. Go try on a doctor like a shoe, because one—a hospital might have an infection rate, but a particular surgeon may not. So I think there are a lot of criteria that every woman and her spouse should take into consideration before choosing their surgeon.

Mr. DEAL. So you would even dissect it down to the individual information about the individual surgeons ought to be available?

Dr. ZARFOS. Well, indeed, when I do conformed consent for any patient I tell them what my infection rate is or complication rate. The American College of Surgeons sort of mandates it if you are a fellow in the American College of Surgery that when you do informed consent you should be telling patients that.

Mr. DEAL. Should the patient have that information maybe on the Internet before they go make that decision?

Dr. ZARFOS. You know, I am sure that it is true in the political realm too that all sorts of misinformation can be on the Internet. I am not sure the perfect way of how to get—

Mr. DEAL. Well, if it is a sanction—

Dr. ZARFOS [continuing]. Those profiles on—

Mr. DEAL. If it is a sanctioned Web site for the particular purpose of disseminating information so consumers will be well-informed you wouldn't have a problem with that would you?

Dr. ZARFOS. I think that as long as we do it in a sensitive, professional way with dignity.

Mr. DEAL. So if hospital A has a 25 percent lower success rate in the breast cancer arena than hospital B, that might be something that the patient might also want to know.

Dr. ZARFOS. But you always have to look at those numbers based on the type of hospital. For example, I am in the inner city hospital and the biggest other hospital in town is inner city. So we have more patients without insurance, co-morbidities, so indeed, our patients present with a later stage, certain micro-populations. If you were to look at that population of my hospital and also Hartford Hospital, the two big hospitals, we would look like our patients have a higher recurrence rate, but they present. So I guess what I want to say to you is when that information is presented as long as it is stratified and qualified as Medicare is doing now with the gravity of illness of a patient and the stage. So you get—you are comparing—I hate to say apples to apples when we are talking about surgery, but you are getting all the information without it being skewed, because of taking care of more ill patients..

Mr. DEAL. And if those two hospitals had a \$5,000 difference in what they charged you for the very same procedure do you think a prospective patient ought to have that information before they make a choice as to where to go?

Dr. ZARFOS. But let us hope they don't choose it just on cost, but where they get the best kind, comprehensive, individualized care.

Mr. DEAL. But if they have got all that other information I just asked you about coupled with price they would be a better informed patient as to where they should go wouldn't they?

Dr. ZARFOS. I spend about an hour with each of my patients before we even entertain whether I am going to be their surgeon, so informing—

Mr. DEAL. But we know you are the—

Dr. ZARFOS [continuing]. Patients is number one.

Mr. DEAL. We know you are the exception to the rule.

Dr. ZARFOS. No, I am not.

Mr. DEAL. Don't you think patients ought to have this kind of information?

Dr. ZARFOS. I think patients should have what information is going to help guide them to make the decision as long as the information is valid.

Mr. DEAL. OK. And since you support this H.R. 758, which we are talking about in your testimony today, don't you think that if we are going to mandate certain things we ought to give patients with breast cancer this kind of specific information, so that they can be better informed and make better choices?

Dr. ZARFOS. Well, but Congressman Deal, this is not a mandate. This is restoring a choice to patients. This is not a mandate to the—

Mr. DEAL. No. Well, it is a mandate. I mean for those 30 states that don't have any legislation. And your state and Ms. Williams' state and my state already have legislation on this issue. But for those 30 states it is a mandate, and if we are going to draft a mandate bill, then why don't we mandate the kind of information about quality, infection rates, costs, the kind of things that I would think patients would want to know?

Dr. ZARFOS. I think as long as you mandate then the insurance companies give people what they pay for. Let us make it an equal playing field for insurance industry and the medical profession.

Mr. DEAL. This would be for everybody. You have no problem with that do you?

Dr. ZARFOS. Well, I would like to see equal transparency in the insurance industry. I feel bad for these women who in January signed up for one company, really good company, and in August when she had breast cancer that transparency became foggy.

Mr. DEAL. But you can't—as a physician you can't say you want to mandate things on the insurance industry, and then as a physician shy away from giving patients the kind of information that they need to know about the—

Dr. ZARFOS. I agree with you.

Mr. DEAL [continuing]. Treatment part of it.

Dr. ZARFOS. I think transparency—

Mr. DEAL. OK.

Dr. ZARFOS [continuing]. For all components of the health care field is very important.

Mr. DEAL. I think we agree. Thank you.

Mr. PALLONE. Thank you.

Ms. Capps.

Ms. CAPPES. Thank you again, both of you, for—our witnesses for your testimony.

I want to ask—give each of you a chance to respond to a question. I have a couple of questions for Dr. Zarfes, if you would, and that implies a brief response, please.

Your state of Connecticut and my state of California are two states that do have patient protection laws in place already. Would you discuss the affect of these laws on patient outcome? You did in your testimony, but I want to see if we can draw contrast with states that have these patient protections and some states that don't.

Dr. ZARFOS. Most of the states have different working of their laws, so some of them are affected and some are not. And so when you—I hate to be redundant, but when you look at the testimony—

Ms. CAPPS. Yes.

Dr. ZARFOS [continuing]. Of those patients you will see patients having horrific experiences in states that have legislation. Even in my state of Connecticut. So certainly how the physicians interact with the patients is important, though we have to at least give that opportunity for the physician and the patient to work together on it. So there are some states with great laws and some with no so great, and then of course the states without.

Ms. CAPPS. So if there is federal legislation it shouldn't preempt the states with stronger laws, but it should be then a floor for states that have bad or weak laws now—

Dr. ZARFOS. It should—

Ms. CAPPS [continuing]. Or no law?

Dr. ZARFOS. It should—the disparity across the country.

Ms. CAPPS. I hear you. So you are kind of implying then that despite 20 states or more having protection laws that many of them are not adequate enough in each state. Thank you.

And that this bill that we are discussing could help to eliminate the disparities among the states, which is one of our goals as the Federal Government. Thank you very much.

Ms. Williams, as a patient your very eloquent testimony to your experience, and I want to thank you for providing a really insightful sort of personal glimpse into what must have been a very terrifying experience for you. And I just have to say that the promise you made to God when you prayed out loud certainly seems that you have lived—you have met your pledge, probably multiple times now, at least certainly today, in what you are doing because your statement is now part of the permanent record of the U.S. Congress.

I want to—and it may seem like we are repeating some, but I want to get it really clear about some of what is driving this legislation. You noted that when you had your mastectomy you didn't have the option of staying. In fact, you got up literally from the recovery room?

Ms. WILLIAMS. Yes, ma'am.

Ms. CAPPS. You never did go into a patient room. And the recovery room is quite a different place from the normal patient room.

Ms. WILLIAMS. I never went into a patient—

Ms. CAPPS. So you got right up off the—and oftentimes one is feeling quite groggy at that point.

Ms. WILLIAMS. Very groggy.

Ms. CAPPS. And not even very clear-headed about it. So you maybe were given some instructions that hopefully some other people were writing down or could remember. Your sister was—

Ms. WILLIAMS. Yes.

Ms. CAPPS [continuing]. Your interpreter? OK.

Ms. WILLIAMS. If I may tell you this—

Ms. CAPPS. Sure.

Ms. WILLIAMS. For some reason—it is a rural area where we are from and—

Ms. CAPPS. Yes.

Ms. WILLIAMS [continuing]. For some reason all I can remember from the hospital home was a herd of goats in a field. I don't know why, but it was goats, and the next thing I knew we were home.

Ms. CAPPS. Well, you probably were having even some of the affects of the anesthesia still wearing off.

Ms. WILLIAMS. Yes, but I made sure they were real goats.

Ms. CAPPS. Oh, I am not saying they weren't real goats. I am not—

Ms. WILLIAMS. I really saw the goats.

Ms. CAPPS. You may have missed some other things though along that way home. May I ask you, when you signed up to be a patient in the hospital was it your goal of leaving the hospital early? Was this something your doctor recommended or did you have to leave because of your insurance plan?

Ms. WILLIAMS. I wasn't in a hospital. It was done in an outpatient—

Ms. CAPPS. Oh, so you didn't even—

Ms. WILLIAMS [continuing]. Surgical center.

Ms. CAPPS [continuing]. Go to a full fledged hospital?

Ms. WILLIAMS. Ma'am, I was in a surgical center. And I fell through the cracks in the state of North Carolina. How I don't know, but—

Ms. CAPPS. Is this done as procedure, as far as you know, in North Carolina to have—

Ms. WILLIAMS. I have found four other—well, I am the fourth one in my county. There is about 150,000 in our county, and through me being out and speaking to different groups—

Ms. CAPPS. Yes.

Ms. WILLIAMS [continuing]. And being known I had found four others that the same thing has happened to.

Ms. CAPPS. That they have had their surgeries in the—

Ms. WILLIAMS. They have had the drive-through mastectomies and—

Ms. CAPPS. In places where there were no—the doctors and nurses all went home at 5 or 6 o'clock or—

Ms. WILLIAMS. That is right. And this one lady—

Ms. CAPPS [continuing]. Whatever time the surgery center closed.

Ms. WILLIAMS. May I tell you about one lady?

Ms. CAPPS. Sure.

Ms. WILLIAMS. She is in her early 40s and she has two little boys. Her husband had passed away from cancer when was diagnosed with breast cancer. And we walked 2 or 3 weeks ago in the Relay for Life. We walked as buddies.

Ms. CAPPS. So this story you are telling is 2 or 3 weeks ago that you heard about it?

Ms. WILLIAMS. Her—no, no. I knew about her story, but—

Ms. CAPPS. OK.

Ms. WILLIAMS [continuing]. Two or three weeks ago when we walked for Relay for Life we walked together. And she said I want to show you my caregiver who emptied my drains, and it was her 12-year-old son who was approximately 10 years old when he had to do that.

Mr. CAPPS. So as recently as 2 years ago——

Ms. WILLIAMS. Yes, ma'am.

Ms. CAPPS [continuing]. This procedure of a surgery center or a free-standing center is or was, or maybe it still is, is offering services for mastectomies in your——

Ms. WILLIAMS. Yes, ma'am.

Ms. CAPPS. I am out of time. I thank you very much.

And I appreciate again, Mr. Chairman, we are having this hearing today. Thank you.

Ms. WILLIAMS. Thank you.

Mr. PALLONE. Thank you. I know that we haven't spent as much time on this bill, but I certainly think that the two of you have made a very strong case. And we have been able to get to the bottom of this even in the limited time that we have. So thank you again, and again we are going to be trying to move on this legislation. And we appreciate your being here. Thank you very much.

Dr. ZARFOS. Thanks for hearing us.

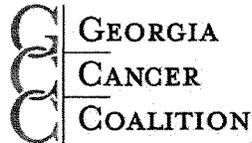
Ms. WILLIAMS. Thank you.

Mr. PALLONE. Sure. Let me just remind our members that you can submit additional questions for the record. They should be submitted to the clerk within the next 10 days, and the clerk will then notify the witnesses if we have additional questions.

And without objection this meeting of the subcommittee is adjourned.

[Whereupon, at 3:25 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]



*Mobilizing Georgia.
Immobilizing Cancer.*

*50 Hurt Plaza, Suite 700
Atlanta, GA 30303*

May 20, 2008

Honorable Nathan Deal
2123 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Deal:

Pursuant to the Subcommittee on Health hearing scheduled on Wednesday, May 21, 2008, I would like to share a very exciting initiative focused on improving the quality of care for cancer patients in Georgia.

The Georgia Cancer Coalition is a not-for-profit organization that was founded in 2001 to reduce the number of cancer deaths in Georgia and to move Georgia to the top ranks of cancer care in the nation through prevention, early detection, treatment and research. The Coalition brings together government agencies, universities, hospitals, non-profit organizations, bio-tech firms to achieve our mission.

Seeing the need for a set of key quality indicators by which to measure progress, the Coalition engaged the Institute of Medicine to develop an indicator set. A panel of experts completed a year-long study funded by the Robert W. Woodruff Foundation that culminated in the 2005 report, *Assessing the Quality of Cancer Care: An Approach to Measurement Georgia*.

The Cancer Coalition launched The Georgia Cancer Quality Information Exchange (The Exchange) Demonstration Project in 2006 to work toward collecting data for reporting the 52 IOM-recommended indicators on a central "dashboard." As envisioned, the dashboard will indicate stronger and weaker areas and the direction of trends, and will allow "drilling down" for more detail by geography, demographic, and other factors.

The Exchange has the potential to become the first statewide, evidence-based cancer quality measurement program in the country. Its purpose is to facilitate the design, access and retrieval of clinical information and public health data for key quality indicators across the continuum of cancer control. Reported results will stimulate process change and inform state policy, with the end of improving patient-centered care, adherence to practice standards, and cancer outcomes.

For the demonstration phase, the Coalition is partnering with facilities around the state to validate the use of the 52 IOM metrics in clinical settings. The first demonstration partner

was St. Joseph's/Candler (SJ/C) in Savannah, whose new Lewis Cancer & Research Pavilion showed a strong commitment to technology—the foundation for data collection systems needed for quality measurement. Focusing on breast cancer indicators, a broad-based working team at SJ/C developed a “toolkit” to support subsequent efforts. The toolkit includes data definitions, sources and collection methods, and processes for analysis and reporting.

A second demonstration project addressing lung cancer and breast cancer indicators is underway with three collaborating partners in Rome: the Harbin Clinic, Floyd Medical Center and Redmond Regional Health System. SJ/C has begun a lung cancer demonstration effort along with a renewed breast cancer project. In September, 2007, Piedmont Hospital became a demonstration partner for The Exchange with a multi-specialty team, including surgeons, oncologists, primary care doctors, oncology nurses, administrators, information technology professionals and data analytics staff, reviewing what data is collected and how to best use that data to improve patient outcomes, especially as it relates to colorectal cancer. The John B. Amos Cancer Center in Columbus most recently began their efforts as a demonstration pilot focused on capturing the IOM metrics focused on colorectal cancer.

In the fall of 2007, the Exchange Technology Advisory Board was convened to oversee the Information Technology (IT) vision and to select a vendor to implement the IT infrastructure for a “proof of concept” to operationalize the dashboard. At this point, we are completing the due diligence for the top two vendors.

The Exchange has been the foundation of other key initiatives in Georgia. Over two years ago, the Georgia Cancer Coalition partnered with the Georgia Department of Human Resources to revise the Georgia Comprehensive Cancer Control Plan, basing the new, revised plan on the 52 metrics identified in the Institute of Medicine's report. We successfully engaged over 125 individuals, representing many statewide cancer control organizations and associations, who embraced the process and actively participated in the revision of the plan. The finalized Georgia State Cancer Plan was presented at the Georgia Cancer Summit in January 2008.

We are very proud that St. Joseph's/Candler (SJ/C) in Savannah, GA received a grant as one of the NCI Community Cancer Center Program (NCCCP) pilots last year. The proposal submitted by St. Joseph's/Candler had a very unique approach to include a statewide Georgia “Clinical Alliance” comprised of four carefully selected organizations involved in the Georgia Cancer Quality Information Exchange. Included were: 1) St. Joseph's/Candler in Savannah. 2) The Harbin Clinic in Rome. 3) The John B. Amos Community Cancer Center in Columbus Georgia. 4) The Georgia Cancer Coalition.

While much remains to be done, The Exchange already has generated enthusiastic support and a number of successes. New feedback loops have shown the need for process improvements that facilities have implemented seamlessly; and new collaborations have sparked tangible and intangible benefits. The best example of a process improvement centers on metric 5.1 Timely Breast Cancer Biopsy. The IOM recommends that from

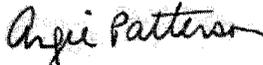
the time of an abnormal breast cancer mammogram to the time of a biopsy should be within 14 days. When a demonstration partner began to measure this time and found that it might be as long as 30 days, they modified their care process to insure a biopsy within the 14 day metric. Currently, 16 of the 52 metrics are specific to breast cancer.

The Exchange not only has strong potential to make a difference in Georgia, but may become a model for other states' cancer control efforts as well as for use in fighting other types of disease.

We welcome your advice on ways to showcase this quality of care initiative: The Exchange. I am currently attending the Comprehensive Cancer Control Policy and Practice Summit in Chicago and will be able to share our vision with other state cancer coalitions. We welcome any recommendations that you have for federal funding opportunities for the Georgia Cancer Quality Information Exchange. The Georgia Cancer Coalition is funded by the state and we are committed to leverage the state dollars invested in the Exchange with federal dollars.

Thank you for all that you do to improve the quality of care for cancer patients.

Sincerely,

A handwritten signature in black ink that reads "Angie Patterson". The signature is written in a cursive, flowing style.

Angie Patterson
Vice President and COO



BREASTCANCER.ORG

May 20, 2008

The Honorable Rosa DeLauro
U.S. House of Representatives
2262 Rayburn House Office Building
Washington, DC 20515

Dear Representative DeLauro:

I am compelled to write this letter on behalf of my constituency: the thousands of women who trust me with their lives as their personal doctor, and the eight million women who trust Breastcancer.org for the best medical information about breast cancer. As an oncologist—and as President and Founder of Breastcancer.org—I have a unique perspective on the needs of these brave women.

When a woman has a mastectomy, her life is on the line. And so are her relationships with all of those she supports...and those who care for her. The impact is enormous and the stakes are extremely high.

Therefore, the decision about the length of needed in-hospital recovery time following breast surgery must be made within the sacred relationship between a woman and her doctor. Not reduced to a business decision that overrides a doctor's best judgment and the patient's best interest.

Breast cancer is a serious condition that requires serious—and sensitive—attention to the physical and emotional needs of each patient.

As someone who has treated thousands of women, I know that the care of these women at this most vulnerable and high-risk time *must* be individualized. There is no "one size fits all" solution. To suggest otherwise demeans the challenge these women face in their fight against breast cancer.

When insurers set themselves up as the "hospital police", short-cutting the in-hospital recovery process solely for economic reasons—and in disregard for best medical practice—legislation must be enacted to protect American lives.

This same problem has already been addressed with baby deliveries. Women who have mastectomies certainly deserve the same respect.

I thank you for your initiative in championing this life-saving Bill, and urge Congress to take proactive steps to eliminate this misguided practice.

Sincerely,

Marisa C. Weiss, M.D.

7 East Lancaster Avenue
3rd Floor
Ardmore, PA 19003
610.642.6550 T
610.642.6559 F


Oncology Nursing Society

125 Enterprise Drive • Pittsburgh, PA 15275-1214
 Toll Free: 866-257-4ONS • Phone: 412-859-6100 • Fax: 412-859-8165
 customer.service@ons.org • www.ons.org

March 3, 2008

The Honorable Rosa DeLauro
 U.S. House of Representatives
 2262 Rayburn House Office Building
 Washington, DC 20515

Dear Representative DeLauro:

On behalf of the Oncology Nursing Society (ONS) - the largest professional oncology group in the United States, composed of more than 35,000 nurses and other health professionals dedicated to ensuring access to quality care for people with cancer - we are writing to thank you for your leadership in reintroducing the "Breast Cancer Patient Protection Act" (HR 758). ONS believes that your legislation will work to improve the quality of care for women undergoing treatment for breast cancer.

As oncology nurses, every day we see the pain and suffering caused by cancer, and we know all too well the physical, emotional, and financial challenges that people with cancer face throughout their diagnosis and treatment. Unfortunately, too many times, people with cancer also face the challenge of a health care plan and a health care system that add additional pressures and frustrations on top of an already strained situation. Specifically, ONS supports your legislation, because it helps ensure that decisions pertaining to treatment for breast cancer are made by patients in consultation with their cancer care providers, not by health plans or insurers.

Please know that we stand ready to work with you and your colleagues to advance policies - such as HR 758 - that will reduce and prevent suffering from cancer. Should you have any questions, or if we can be of any assistance to you and your staff, please feel free to contact us, or our Washington Representatives, Ilisa Halpern Paul (202/230-5145, Ilisa.paul@dbr.com) and Jeremy Scott (202/230-5197, jeremy.scott@dbr.com).

Sincerely,

Georgia M. Decker, MS, RN, CS-ANP, AOCN®
 President

Paula Rieger, RN, MS, AOCN®
 Chief Executive Officer



May 16, 2008

The Honorable Rosa L. DeLauro
U.S. House of Representatives
2262 Rayburn House Office Building
Washington, D.C. 20515

Dear Representative DeLauro:

On behalf of the volunteers and supporters of the American Cancer Society Cancer Action NetworkSM (ACS CAN), the partner advocacy organization of the American Cancer Society, we would like to express our appreciation for your continued leadership in addressing the needs of women undergoing treatment for breast cancer. H.R. 758, Breast Cancer Patient Protection Act of 2007, will ensure that women undergoing mastectomies and lymph node dissections for the treatment of breast cancer will receive coverage for an adequate hospital stay based upon an informed choice determined between the woman and her doctor.

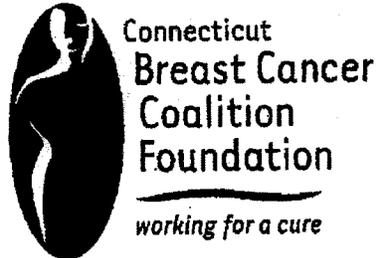
This year 182,460 new cases of breast cancer will be diagnosed. In support of these women who must deal with tremendous medical and emotional challenges to overcome this disease, we believe it is critical that physicians and patients have the ability to freely discuss and decide together what treatment options are medically necessary and appropriate, including an adequate hospital stay. To that end, ACS CAN opposes any effort on the part of a health plan or health insurance organization that seeks to limit patient access to available treatments deemed medically necessary by a physician.

ACS CAN joins you in your dedication to reducing cancer mortality rates and improving treatment by confronting barriers to quality cancer care. We recognize that significant health disparities still exist with regard to access to breast cancer screening and early detection, as well as to quality breast cancer treatment. Accordingly, we would ask that you support full funding of the National Breast and Cervical Cancer Early Detection Program which now serves fewer than one in five eligible women who lack insurance coverage for mammogram screenings.

Again, we commend you for your many efforts in the fight against cancer, and for your continued concern about optimizing the quality of life for women living with breast cancer. Thank you so much for your support.

Sincerely,

Daniel E. Smith
President



May 19, 2008

Dear Congresswoman De Lauro,

We are writing in support of your bill that would end "drive through mastectomies" in the United States. We have a similar, though not as encompassing, bill in Connecticut and we have found that it has greatly benefited women in the state who have breast cancer. We have spoken with many women who stayed in the hospital after mastectomy and were taught by nurses how to take care of themselves once they got home. They were thrilled to have had the time and instruction. Women who had the surgery before the bill was passed here were not so lucky. One recounts being forced out of the hospital after a few hours – she had a difficult time at home, as she didn't really know what to do with the bandages and the like.

That's why we whole-heartedly support this legislation – as no woman deserves to have a "drive through mastectomy". We all deserve equal access to quality health care.

Thank you,

Susan Davis for the
Connecticut Breast Cancer Coalition Foundation

Connecticut Breast Cancer Coalition Foundation
P.O. Box 509 South Windsor, CT 06074
(860) 984-6215
cbccf.org



May 21, 2008

House of Representatives
Energy and Commerce Committee
Subcommittee on Health
Testimony of Lifetime Television
H.R. 758, the Breast Cancer Patient Protection Act

Dear Members of the Subcommittee on Health:

In 1996, 12 years ago, Lifetime first heard about the practice of "drive-through" mastectomies, when women are forced out of the hospital hours after major breast cancer surgery, even if they and their doctors do not think they are ready to go home.

That was the year that Representative Rosa DeLauro (D-CT) first introduced the bipartisan Breast Cancer Patient Protection Act, to allow a woman and her doctor to decide whether she should recuperate for at least 48 hours in the hospital or whether she has enough support to get quality care at home. It never did and still does not mandate a hospital stay, if both the woman and her doctor feel it unnecessary.

It may be unusual for a television network to be involved in any legislative effort, but as the #1 channel for women, Lifetime has a long history of advocating for its viewers.

As soon as the network began talking to viewers about the issue of "drive-through" mastectomies, we heard from thousands of women and their families that they were indeed facing the problem and wanted Congress to take action to address it.

Lifetime went on the air with spots and launched an online petition to urge Congress to pass the bipartisan Breast Cancer Patient Protection Act. In the first year, the petition had 17,000 signatures. Today, the petition on myLifetime.com has been signed nearly 22 million times. Based on unscientific research, this may be the largest petition in support of a bill.

Routinely, Lifetime and members of Congress from both sides of the aisle, including Representative DeLauro and Senators Snowe (R-ME) and Landrieu (D-LA), have come together to present these signatures and stories to all lawmakers.

Nearly five years ago, Lifetime stood on Capitol Hill with a single mother from Maryland named Shelly Slick, who had signed the petition after she had been forced out of the hospital too soon and got an infection that delayed her chemo treatment. No one can know if the delay made a difference, but sadly, Shelly died, leaving a young son behind.

Two years ago, Alva Williams, who signed the petition from her home in North Carolina, came to the Capitol steps and recounted how, after her breast surgery, she was forced to drive three hours to get home following her outpatient surgery and then have her 80-year-old brother change her drainage tubes once she was home. She too developed an infection that delayed treatment, but fortunately is doing well today.

This January, another woman named Lynn Bradley from Maryland also shared how she was told that her double mastectomy should just be an "in and out" procedure.

Grammy-nominated singer/songwriter Jewel and "Desperate Housewives" star Marcia Cross have also come to Washington and joined the chorus to bring even more attention to the cause.

In addition to signing the petition, many women and men have shared their stories about "drive-through" mastectomies.

Ann wrote, "I had a bilateral mastectomy in April 2003 and was sent home on pain meds and with drain tubes still in place. A few days later I had a severe infection in the left side drain incision and was back in the hospital."

Bethany shared, "I had a mastectomy in July 2004. I stayed one night and had to leave the next morning. My drains became a problem; one stopped working and became infected."

Betty said, "I'm one of those who suffered from the 'kick 'em out, even with tubes' rules. I developed a staph infection that became deadly -- I believe it would not have gotten so bad if I'd stayed another night."

Today, the Breast Cancer Patient Protection Act is championed by more than half of the Congress, with 219 cosponsors from both sides of the aisle. The Senate bill, introduced by Senator Olympia Snowe (R-ME), has 19 cosponsors. Prestigious organizations including the American Cancer Society, breastcancer.org, Breast Cancer Network of Strength (formerly Y-Me National Breast Cancer Organization), Families USA, the Oncology Nursing Society, Sisters Network Inc. and Susan G. Komen Foundation also support the legislation.

This is a political election year, but this is not about politics. It is about people. One in eight women will eventually develop breast cancer and, according to the National Cancer Institute, more than 182,000 will be diagnosed with the disease this year. These women, facing very scary, painful and emotional surgery, deserve to have options. They should be able to go home right away if they're ready or spend a short time in the hospital if they and their doctors think that is best.

Lifetime's viewers, lawmakers from both parties and prominent nonprofit organizations believe this bill is an important first step to increasing research into the causes and treatments of breast cancer and to improving access to quality health care for all Americans.

For Shelly, Alva, Lynn and the millions of women and families who have shared their horrific stories of "drive-through" mastectomies on myLifetime.com, it is 12 years too late. But for the nearly 200,000 women who will face breast cancer this year, it is about time.

On behalf of the millions of women and men who have signed the petition on myLifetime.com, we thank Representative Pallone and the entire Subcommittee on Health within for the House Energy and Commerce Committee for your initiative in giving the Breast Cancer Patient Protection Act a hearing. We hope that you will move quickly in order to allow this life-saving bill to come to a vote on the House floor.

Thank you.

Sincerely,



Meredith Wagner
Executive Vice President
Lifetime Networks



May 15, 2008

Congresswoman Rosa DeLauro
2262 Rayburn House Office Building
Washington, DC

Dear Congresswoman DeLauro:

We are writing in support of the Breast Cancer Patient Protection Act (H.R. 758).

The mission of Breast Cancer Network of Strength, formerly Y-ME National Breast Cancer Organization, is to ensure that no one faces breast cancer alone. To fulfill that mission, our 24/7 hotline answers over 40,000 calls each year from those diagnosed and/or touched by breast cancer. Our trained breast cancer survivors offer callers support and information.

We are appalled when calls are received from women who have been told that their insurance will not cover a hospital stay after a mastectomy. These women are trying to deal with the fearful diagnosis of breast cancer and then often face going home the same day of this major surgery, alone. While we recognize that some women are comfortable doing this, it should be a decision made solely between the patient and her physician -- not the health insurance company.

Breast Cancer Network of Strength supports the Breast Cancer Patient Protection Act (H.R. 758) because women should not have to negotiate recovery time in the hospital after a mastectomy. Let's put the health care decision making in the hands of those who know best -- patients and their doctors.

Sincerely,

Kay Wissmann
Director of Government Relations



May 16, 2008

The Honorable Rosa DeLauro
2262 Rayburn House Building
Washington, DC 20515

Dear Representative DeLauro:

On behalf of Families USA, the voice of health care consumers, I am writing to commend you on the introduction of the Breast Cancer Protection Act of 2007 (H.R. 758). The legislation, which would require health plans to provide coverage for a minimum hospital stay for mastectomies, lumpectomies and lymph node dissection for the treatment of breast cancer as well as coverage for secondary consultations, will help ease the burden for those struggling with breast cancer.

One of the challenges of the private market is that insurance benefits vary by state. This practice has led to a patchwork of coverage; for example, only a handful of states have benefit protections that include a minimum mastectomy stay. Women struggling with a life threatening disease should not have to worry about whether the insurance company in their state will provide them with the same level of coverage as neighboring states or whether they will hit their lifetime cap as a result of expensive cancer treatments.

The number of uninsured Americans is rapidly increasing, in part because of a lack of protections for health care consumers. Health insurance companies are permitted to deny coverage for individuals with pre-existing conditions, including women who have been treated for breast cancer, even if they currently are cancer free. Those living without health insurance are more likely to forgo or delay necessary medical care and are more likely to die prematurely, in part because they forgo required cancer screenings.

Thank you for introducing this much needed legislation. We look forward to working with you to pass the Breast Cancer Protection Act of 2007

Sincerely,

A handwritten signature in black ink that reads "Ron Pollack". The signature is written in a cursive, slightly slanted style.

Ronald F. Pollack
Executive Director

1201 New York Avenue, NW, Suite 1100 ■ Washington, DC 20005 ■ 202-628-3030 ■ Fax 202-347-2417

E-Mail: info@familiesusa.org ■ Web site: www.familiesusa.org



May 19, 2008

The Honorable Rosa DeLauro
2262 Rayburn House Office Building
Washington, DC 20510

Dear Representative DeLauro:

The Susan G. Komen for the Cure Advocacy Alliance writes to offer its support for the "Breast Cancer Patient Protection Act of 2007" (H.R. 758), legislation you introduced that would amend the Employee Retirement Income Security Act of 1974 to require coverage for a minimum hospital stay for mastectomies, lumpectomies, and lymph node dissections for the treatment of breast cancer and coverage for secondary consultations.

The Komen Advocacy Alliance works tirelessly to ensure access to high quality care for all patients. We believe that decisions concerning the length of a patient's hospital stay subsequent to mastectomy, lumpectomy or lymph node dissection for the treatment of breast cancer should be made jointly by physicians and patients, rather than by insurance companies. Further, we believe that patients should be able to obtain secondary consultations to confirm or refute the diagnosis of breast cancer. We are committed to helping patients access high-quality care and encourage patients to talk to their doctors about all treatment decisions, including the length of any hospital stay.

The Komen Advocacy Alliance is a sister organization to Susan G. Komen for the Cure®, and is a next step in Komen's evolution: expanding our reach in the health policy arena. Susan G. Komen for the Cure is the world's largest grassroots network of breast cancer survivors and activists fighting to save lives, empower people, ensure quality care for all and energize science to find the cures. Thanks to events like the Susan G. Komen Race for the Cure® — scheduled this year for June 7, 2008 on the National Mall — Komen for the Cure has invested \$1 billion to fulfill its promise, becoming the largest source of nonprofit funds dedicated to the fight against breast cancer in the world. To continue this progress, Komen for the Cure has pledged to invest another \$2 billion in the next ten years.

Thank you for introducing this legislation and for your strong history of support for women's health initiatives.

Sincerely,

Shelley Fuld Nasso
Director of Public Policy