RAISING HEALTH AWARENESS THROUGH EXAMINING BENIGN BRAIN TUMOR CANCER, ALPHA ONE, AND BREAST IMPLANT ISSUES

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

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CONTENTS

RAISING HEALTH AWARENESS THROUGH EXAMINING BENIGN BRAIN TUMOR CANCER, ALPHA ONE, AND BREAST IMPLANT ISSUES

THURSDAY, NOVEMBER 15, 2001

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

The subcommittee met, pursuant to notice, at 2 p.m., in room 2123, Rayburn House Office Building, Hon. Michael Bilirakis (chairman) presiding.

Members present: Representatives Bilirakis, Wilson, Brown, Strickland, Barrett, Pallone, and Green.

Also present: Representatives Blunt and Lee.

Staff present: Brent Del Monte, majority counsel; Nolty Theriot, legislative clerk; John Ford, minority counsel; and Nicole Kenner, minority resident assistant.

Mr. BILIRAKIS. I call to order this hearing and, again, formally apologize to the panel and to the folks out there who are interested, but we just didn't really have any choice in the matter.

This is a hearing on raising health awareness through examining benign brain tumor cancer, breast implant health issues, hematological cancer research and access to breast cancer treatment for women receiving care through the Indian Health Service.

I would like to thank, again, all of our witnesses for coming today and for being so understanding and considerate. Their expertise on these important health issues are so very important. Two of the issues that we are discussing today focus on strengthening certain areas of the National Institutes of Health research programs. We will hear testimony highlighting the need for more research into the safety of breast implants. As we have all heard, many women have received breast implants and unfortunately suffer debilitating diseases that may have been linked to the procedure.

Testimony will also be presented on the need to improve our research efforts into leukemia and lymphoma cancers. Current Federal research into these deadly cancers falls well below the level that is afforded to other cancers, even though leukemia and lymphoma cancers will claim the lives of 60,000 people.

We will also learn about the lacking infrastructure for tracking benign brain tumors. Many brain tumors are diagnosed as benign. However, these tumors can and do have terrible health consequences for those who suffer from such illnesses. As we learned

this morning, surveillance is an important component in protecting the public's health, and I look forward to learning more about this issue.

Finally, we will hear testimony on an issue with respect to treatment for breast and cervical cancer. As many of you know, our subcommittee worked in the previous Congress to pass the Breast and Cervical Cancer Prevention and Treatment Act. I was pleased to support this effort and its enactment into law. A concern has been raised with implementation of the act. Specifically, women receiving care through the Indian Health Service may be excluded, something we certainly did not intend.

I look forward to hearing all the testimony today, and, again, would like to thank all the witnesses for appearing here today. And now I gladly yield to my good friend from Ohio, the ranking member of this subcommittee, Mr. Brown.

Mr. BROWN. Well, thank you, Mr. Chairman. Today's hearing will address—and welcome all of you as witnesses, thank you for your patience and sticking around and putting up with the idiosyncrasies of this institution. Today's hearing will address a number of important issues: a cancer registry for benign brain tumors and the need for additional research focused on breast implants as well as blood cancers. We are going to discuss the need for technical change to the Breast and Cervical Cancer Treatment Act we passed last year, which inadvertently omitted Native American women.

It is estimated that 35,000 individuals are diagnosed with malignant and benign brain tumors each year. Most registries collect data on malignant brain tumors but not on benign tumors. It might seem superfluous to collect data on people diagnosed with a nonlethal tumor, but experts contend that in order to understand this complex cancer, they must be able to track it in all forms—malignant as well as benign.

Because the causes of brain tumors are not well understood, studying ideology of benign brain tumors may improve our understanding of malignant tumors. My colleague, Congresswoman Lee, who just walked in, has introduced a Benign Brain Tumor Cancer Registries Amendment Act, H.R. 239, which will require all registries funded by the Government to collect both benign and malignant brain tumor data. And it is my understanding, Mr. Chairman, that once I am finished, that Ms. Lee would like to introduce the panelist from her—whom she knows.

The death of our colleague, Joe Moakley, earlier this year certainly raised the profile of leukemia and other blood cancers for those of us in Congress. An estimated 109,000 people in the U.S. will be diagnosed with blood cancers this year. These diseases will be the cause of death for an estimated 60,000 Americans in 2001, meaning that a child or an adult dies from a blood cancer every 9 minutes.

Our colleague, Mr. Crane, introduced legislation to expand and intensify NIH research on blood cancers and to establish a public information program in collaboration with the Centers for Disease Control and Prevention specifically for patients and their families. I am pleased our subcommittee is considering Mr. Crane's bill in honor of Joe.

I want to thank my colleague, Mr. Green, for his work developing legislation to heighten research in the area of breast implants. I am pleased to be a co-sponsor of that. This bill would recommend further studies into the risks of breast implants, providing women with more accurate and more complete information.

As you know, thousands of young women are getting implants each year. That number is expected to rise, yet neither they nor their parents have the information oftentimes that they need to fully assess the associated risks. This bill would require the study of a population not included in past studies: Breast cancer survivors who are seeking reconstructive surgery.

I have worked with the breast cancer community a great deal on the breast and cervical cancer issue, both enactment here and implementation in my State of Ohio, and recognize that for many women who have successfully beaten their cancer, the option of reconstructive surgery is a very important one. The least we can do is provide women with the most accurate information about the risks, so the decisions they make don't put their lives at risk a second time.

The last thing I wanted to briefly mention is a bill that my colleague, Tom Udall, has been working on to make a technical change to the Cancer and Cancer Treatment Act, to include this treatment service for Native American women. I hope the chairman and I can work together to bring this bill to the attention of leadership and bring it to the floor for a vote. These women should not have been excluded last year, and we should correct this anomaly as soon as possible. I thank the chairman.

Mr. BILIRAKIS. I thank the gentleman, and would the gentleman like to yield to Ms. Lee for her introduction?

Ms. LEE. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I might add that you are more than welcome to remain on the panel here and listen to the testimony if you'd like.

Ms. LEE. Thank you, Mr. Chairman. And I just want to thank you very much for holding this hearing and also for the committee's work on this very important issue. I would like to take this opportunity to introduce a constituent from Berkeley, California, Mr. Lloyd Morgan.

Now, Mr. Morgan will be testifying on the importance of H.R. 239, the Benign Brain Tumor Cancer Registries Amendment Act, which I am very proud to have sponsored. Mr. Morgan is an electrical engineer as well as a member of the North American Brain Tumor Coalition.

Mr. Chairman, let me just mention how I learned about this very important health issue. Mr. Morgan attended one of my town hall meetings in California where he had the opportunity to discuss this issue, not only with me but with those who were in the town meeting. He ask that I introduce a bill to address the problem of benign brain tumors not being included in the National Program of Cancer Registries, as his representative. And, Mr. Chairman, I think this is quite an example of how our democracy works.

We looked into it, we conducted our research, your staff has been very helpful, the entire committee has been helpful in assisting us to make sure that we were able to bring this amendment to you today. So I agreed to introduce this bill in order to help the medical

system, including public health agencies, scientific research labs and health system public policy groups, as well as patients with brain tumors.

Mr. Morgan will take the opportunity today to share his story as a survivor of benign brain tumor with the subcommittee. So I want thank you again, Mr. Chairman, for holding this hearing on the Benign Brain Tumor Cancer Registries Amendment Act. Thank you very much, and it is great to be here.

Mr. BILIRAKIS. I thank the gentlelady and thank her on behalf of all of us for your interest in this subject. And now I would yield to the gentlelady from New Mexico, Mrs. Wilson.

Ms. WILSON. Thank you, Mr. Chairman, and I appreciate your holding this hearing today and inviting testimony about breast implants. I wanted to thank one of my constituents who is here in the audience today, Anne Stansell, who brought to my attention this problem in this bill. And she survived cancer only to become seriously ill with symptoms attributed to her breast implants. And she has been a leader in New Mexico and across the country helping other women through breast cancer. I wanted to thank her for her work in helping women and also helping to educate me about the lack of information and the research that needs to be done.

I think the important message of this hearing today—and I thank all of you for your patience, as you've waited through a very long day and a prior testimony in this room—I think the important message is that women need more awareness about the possible side effects and the risks involved. No surgery or medical device is 100 percent risk-free, and no product is completely safe, because it is in high demand or because it is marketed effectively. People need to know what the risks are before they make a decision about whether to have implants.

I am very disappointed that we don't have anyone from FDA here, and I am not sure that the current FDA processes give an accurate picture of those risks. And I look forward to asking some questions of the FDA at a later time. Again, Mr. Chairman, I thank you very much for holding this hearing.

Mr. BILIRAKIS. I thank the gentlelady and thank her for being here. The members will be in and out; it is kind of, again, our way of life here. Mr. Pallone for an opening statement.

Mr. PALLONE. Thank you, Mr. Chairman. I wanted to speak in support of H.R. 1383, the Native American Breast and Cervical Cancer Treatment Technical Amendment Act of 2001. As was mentioned, this legislation makes a simple but extremely important technical change to the Breast and Cervical Cancer Treatment and Prevention Act to improve the coverage of breast and cervical cancer treatment for American Indian and Alaska native women.

Under the Health Insurance Portability and Accountability Act of 1996, HIPAA, credible coverage includes a reference to the Medical Care Program of the Indian Health Service. The reference to credible coverage in the law effectively excludes Indian women from receiving Medicaid breast and cervical cancer treatment, as provided under this act.

The Indian health reference to IHS tribal care was originally included in HIPAA so that members of Indian tribes eligible for IHS would not be treated as having a break in coverage simply because

they received care through Indian health programs, rather than through a conventional health insurance program. Thus in the HIPAA context, the inclusion of the IHS tribal provision was intended to benefit American Indians and Alaska natives, not penalize them. However, use of the HIPAA definition in the recent Breast and Cervical Treatment and Prevention Act has the exact opposite effect. In fact, the many Indian women who rely on IHS tribal programs for basic health care are excluded from the new law's eligibility for Medicaid. This not only denies coverage to Indian women, but the provision runs counter to the general Medicaid rule treating IHS facilities as full Medicaid providers.

While American Indian and Alaska native women have a higher incidence of breast and cervical cancer than the U.S. population generally, many Indian women with these conditions will be left with fewer resources to fight breast and cervical cancer because of their exclusion from the new Medicaid coverage option. The bill would resolve these problems by clarifying the term "credible coverage" that it shall not include—well, I am not going to go into all the details.

I just wanted to say that since a number of States are currently moving forward to provide Medicaid coverage under the State option, the need for this legislation is immediate to ensure that American Indian and Alaska native women are not denied from receiving life-saving breast and cervical cancer treatment. And I appreciate the fact that we are bringing this up today and hopefully can move it soon to the full House. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman. Mr. Green, for an opening statement.

Mr. GREEN. Thank you, Mr. Chairman. First of all, I appreciate you for calling this hearing on a number of bills, but particularly the issue of breast implant safety. As an original co-sponsor of the bill, along with Congressman Blunt, of H.R. 1961, I strongly believe that the Federal Government should do more to study the safety and efficacy of breast implants and to ensure that women have the facts they need to make informed decisions about implants.

I have been working on this issue now for 4 years, and it was brought to my attention by my constituent, Marlene Keeling, who is here today. Marlene has been a driven and tireless advocate for this cause and has done so much to raise the awareness about the potential dangers of breast implants. I would like to thank her for her hard work and for educating me on this important issue. I would also like to thank my colleague, Congressman Roy Blunt, who learned of this issue from his constituent, one of our panelists, Kim Hoffman.

Most people don't usually think of breast implants as a public health issue, but this is a serious issue that needs to be seriously examined. Silicone breast implants were never approved by the Food and Drug Administration, have significant complication rates. Women with implants often soften suffer hardening of the breast tissue, discomfort, scarring and disfigurement. Even more troubling, studies have shown that women with breast implants have higher rates of brain cancer, lung cancer, fibromyalgia, joint pain, fatigue and other symptoms.

Despite popular misconceptions, saline implants are not necessarily any safer. Saline implants, which consist of saline solution injected in a silicone envelope, were approved by the agency in 2000 despite alarmingly high complication and reoperation rates. In fact, from 1985 until January 2000, the FDA received 127,770 adverse reaction reports on silicone-gel-filled breast implants and 65,720 adverse reaction reports on saline-filled implants.

While these are startling statistics, there is still a great deal we don't know about the long-term safety of implants. That is because there haven't been many objective and comprehensive studies into the issue. As we will hear from one of our witnesses today, there is almost no research being performed on women who have implants for reconstruction following a mastectomy.

Mr. Chairman, I know there are many women in the breast cancer community who feel strongly that they need implants as part of their recovery process. And I don't believe they should be restricted from having that access, but we must ask how these implants are affecting mastectomy patients and whether there are higher rates of complications, problems detecting additional cancers or any other issues that women must know before they opt for implants. Mr. Chairman, these are very serious issues, and I am glad that—again, thank you for calling this hearing today, and I hope my colleagues will consider co-sponsoring H.R. 1961. I look forward to our committee hearing today.

Mr. BILIRAKIS. And the Chair thanks the gentleman. Mr. Blunt for an opening statement and to introduce Ms. Hoffman.

Mr. BLUNT. Thank you, Mr. Chairman. I want to thank you particularly for your leadership and joining with me and our fellow Commerce Committee member and our good friend, Gene Green, to bring this act, the Breast Implant Research and Information Act, before the Health Subcommittee for a hearing. Members of Congress are routinely inundated with statistics, and the topic of this bill generates its own list. More than 40,000 women are expected to die this year because of breast cancer, the second ranking cause of cancer deaths. It is estimated that 83,000 women had breast reconstruction following mastectomies last year, and almost 200,000 adverse reactions to implants have been reported to the FDA.

These are pretty big numbers, Mr. Chairman, but more importantly, behind each number is a face, a family, a friend and a fractured life. It is easy to be overwhelmed by such numbers. We can allow ourselves to become numb to just how big this problem really is. It is not so easy when we come face to face with people who these statistics represent.

Today, you will hear and I will and we will hear in this hearing from Kim Hoffman, from Southwest Missouri, who came to my office 3 years ago and shared her tragic experience of going from a successful business owner to a disabled person in a matter of months because of implants. She underwent six surgeries in 2 years, eventually lost her business, her home, her health, her pride because of what she believed at the time she made the decision was a routine medical decision. You will hear from Pam Noonan-Saraceni, who survived the trauma of cancer and the treatment that followed only to fall victim, ironically, to the implants she had hoped would allow her to return to a normal life. These women are

but two of the faces behind these huge numbers of women affected by this particular devastating problem.

There are many others who could share similar and tragic stories. Some of those are in the hearing room today, including actress Mary McDonough, who may be better known to many of us as Erin Walton on the TV series, "The Waltons." Mary is in the front row there, and you will all recognize her as you try to figure out who that might be from not only the Waltons but from appearances on "ER," "Ally McBeal," "Diagnosis Murder," "Walker, Texas Ranger." Her career was interrupted by lupus, which she attributes to implants.

You will also hear today from Dr. Diana Zuckerman, an academician with credentials from Yale, Harvard and George Washington University, who also worked as a staffer on Capitol Hill for over a decade to forge stronger programs on women's health. She brings a unique perspective on the Food and Drug Administration's oversight role in improving implants even when the agency found complication rates as high as 73 percent after only 3 years.

Mr. Chairman, the Breast Implant Research and Information Act improves women's health options in three critical areas. One is informed consent. This bill doesn't attempt to stop physicians from prescribing implants or from women seeking them. What it does do is to ensure that a women and perhaps other significant loved ones in her life make the decision to get implants, she has the best and most recent scientific research available to her. I have heard from woman after woman that has shared her decision on—that has based her decision, rather, on inaccurate information and general assurances, not on sound sciences. Individuals considering this surgery need to know about complication rates and the fact that these devices have been replaced periodically. Our medical community needs to do a better job in this area.

In light of the controversy surrounding implants, 2 years ago, the State of Missouri became the first State to require informed consent prior to implant surgery, including a 5-day waiting period and specific State-approved materials be given to the patient. Rather than creating a conflicting patchwork of State regulations, Congress can work to ensure that accurate portrayal of the risks associated with these implants, regardless of where the patient lives, are known to the patient.

Post-market research is the second this that this bill requires. When the FDA's Advisory Panel recommends approval of drugs or devices to the agency, they often do so with carefully worded conditions on follow-up studies. The truth is that the post-market research is rarely, if ever, reviewed to determine whether it is completed and whether the additional research reveals additional problems. When the pre-market panel improved saline implants, they also required continuing studies. This bill would require the FDA to report on the status of those recommendations every 6 months for 2 years after this bill is enacted.

The follow-up research conducted by the companies on their products deserves the same FDA scrutiny, which is paid to the research conducted on the initial approval of this device or other devices. Post-market research is especially important since there is increasing anecdotal evidence showing that significant implant

problems did not appear until the patient has had the implants for 6 years or more.

Coordinated activity is the third thing this bill does, as it utilizes the existing resources within the National Institutes of Health to bring together the work being done by seven different institutes and offices. Once lines of communications are open between the units, we expect there to be improved interdisciplinary research, either within the NIH itself or through outside research.

Mr. Chairman, women who are facing the trauma of breast cancer and mastectomy do not need to made a victim a third time because of inadequate information to make a decision, inadequate follow-up on the research and inadequate focus within the Government's own health agency. That is why this is so important, that is why Representative Green and I have responded to the stories we have heard and the constituents we have talked to and why we are so appreciative that you have decided to have this hearing today.

[The prepared statement of Hon. Roy Blunt follows:]

PREPARED STATEMENT OF HON. ROY BLUNT, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MISSOURI

Mr. Chairman: I want to thank you for your leadership in joining with me and fellow Commerce Committee member Gene Green to bring the Breast Implant Research and Information Act before the Health Subcommittee for a hearing.

Members of Congress are routinely inundated with statistics and the topic of this bill generates its own list. More than 40,000 women are expected to die this year because of breast cancer, the second ranking cause of cancer deaths. It is estimated that 83,000 women had breast reconstruction following mastectomies last year, and almost 200,000 adverse reactions to implants have been reported to the FDA. Those are significant numbers, but more importantly behind each number is face, a family and a fractured life.

It is easy to be overwhelmed by such numbers. We can allow ourselves to become numb to the enormity of the problem. It is not so easy when we come face to face with the people those statistics represent.

Today you will hear from Kim Hoffman from Southwest Missouri who came to my office three years ago and shared her tragic experience of going from a successful business owner to a disabled person in a matter of months because of implants. She underwent six surgeries in two years and eventually lost her business, her home, her health and her pride because of what she believed was a routine medical decision.

You will hear from Pam Noonan-Saraceni who survived the trauma of cancer and the treatment that followed, only to fall victim ironically to the implants that she hoped would allow her to return to a normal life.

These women are but two faces behind the numbers. There are many others who could share similar tragic stories. Some of those are in this hearing room today including actress Mary McDonough, who may be better known by many of us as Erin Walton on the TV series *the Waltons* but who has also appeared on *E.R., Ally McBeal, Diagnosis Murder* and *Walker-Texas Ranger.* Her career was interrupted by Lupus which she attributes to implants.

You will also hear today from Dr. Diana Zuckerman, an academician with credentials from Yale, Harvard and George Washington University who also worked as a staffer on Capitol Hill for over a decade to forge stronger programs on women's health. She brings a unique perspective on the Food and Drug Administration's oversight role in approving implants even when the agency found complication rates as high as 73% after only three years.Mr. Chairman, the Breast Implant Research and Information Act improves women's health options in three critical areas:

Informed Consent: This bill does not attempt to stop physicians from prescribing implants or from women seeking them. What it does do is to insure that when a woman, and perhaps other significant loved ones in her life, make the decision to get implants, she has the best and most recent scientific research available to her. I have heard from woman after woman that she based her decision on inaccurate information and general assurances, not on sound science. Individuals considering

this surgery need to know about complication rates and the fact that these devices have to be replaced periodically. Our medical community must do better.

In light of the controversy surrounding implants, two years ago the State of Missouri became the first state to require informed consent prior to implant surgery including a 5-day waiting period and specific state approved materials to be given to the patient. Rather than creating a conflicting patchwork of state regulations, Congress can work to ensure an accurate portrayal of the risks associated with these implants, regardless of where the patient lives.

Post Market Research: When the FDA's advisory panel recommends approval of drugs or devices to the agency, they often do so with carefully worded conditions on follow-up studies. The truth is that the post market research is rarely, if ever, reviewed to determine whether it is completed and whether the additional research reveals additional problems. When the pre-market panel approved saline implants, they also required continuing studies. This bill will require the FDA to report on the status of those recommendations every six months for two years after this bill is enacted.

The follow-up research conducted by the companies on their products deserves the same FDA scrutiny which was paid to the research conducted for the initial approval of their device.

Post market research is especially important since there is increasing anecdotal data showing that significant implant problems do not appear until the patient has had the implants for six years or more.

Coordinated Activity: This bill also utilizes the existing resources within the National Institutes of Health to bring together the work being done by seven different institutes and offices. Once lines of communication are opened between the units, we expect there to be improved interdisciplinary research either within the NIH itself or through outside research.

Mr. Chairman, women who are facing the trauma of breast cancer and mastectomy do not need to be made a victim for a third time because of inadequate information to make a decision, inadequate follow-up on research and inadequate focus within the government's own health agency. This bill will insure that our mothers, our wives, our sisters and our daughters will have the necessary information to make wise life changing medical decisions.

Mr. BILIRAKIS. And you can rest assured that I will continue to support that legislation, and hopefully move it through the process. Mr. Barrett for an opening statement? Thank you. Thank you for coming, Tom. As per usual, the opening statements of all members of the subcommittee will be made a part of the record.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. ROBERT L. EHRLICH, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MARYLAND

Mr. Chairman, thank you for holding this important hearing on legislative measures designed to address certain serious health conditions. I want to specifically call the Subcommittee's attention to benign brain tumors and the misnomer "benign" represents in this case.

There are several kinds of benign brain tumors, including meningiomas, a tumor of the lining of the brain; acoustic neuromas, affecting the acoustic nerve, often resulting in deafness; pituitary adenoma, affecting the pituitary gland; and pineal tumors, affecting the pineal gland.

These kinds of benign brain tumors and several others together represent about half of all brain tumors. Approximately 21% of children's brain tumors are benign, yet many of these are deadly. Today, there are an estimated 267,000 people with benign brain tumors across the United States, and many in Maryland.

Mr. Chairman, I first became aware of this issue when a Maryland resident, Mrs. Karen Wichman, of Ellicott City, came to me this summer in grief over the loss of her son, Nick, who passed away earlier this year. Nick Wichman was a healthy young boy who suddenly took ill, was diagnosed with an untreatable benign brain tumor, and died shortly thereafter. He received some of the best medical attention possible in the United States right in Maryland. Despite everything Nick had going for him, he was not able to defeat his benign brain tumor.

As a result of meeting Karen Wichman and hearing about Nick, I cosponsored H.R. 239, the Benign Brain Tumor Cancer Registries Amendment Act. This legislation will amend the Cancer Registry Act to include data collection of benign brain tumors. This data is important for our scientific community to collect, analyze, and

understand in order to research ways to reduce the incidence of benign brain tumors and effectively treat them once they occur. The data from this registry may one day be used to save lives.

As a member of the Speaker's Corrections Day Advisory Committee, chaired by Congressman Dave Camp (R-MI), I was pleased to see that it favorably recommended this legislation for the Corrections Calender this summer, and I understand that Congress may be expediting this legislation in this way in the near future.

I want to thank our witnesses who are here today to testify regarding all the important matters before us, and especially Mr. Lloyd Morgan, to discuss benign brain tumors and the need for this legislation. The passage of H.R. 239 won't save Nick Wichman, but it may help save others.

In closing, I ask all my colleagues to support H.R. 239, and to support the families and children who must wake up every day to face life-threatening benign brain tumors. Thank you.

PREPARED STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Thank you, Mr. Chairman, for holding today's hearing. In the present climate in which issues of bioterrorism and public health surveillance are at the forefront of everyone's mind, it is important to also press ahead with less prominent, but no less important, health care concerns. We will examine four health issues today: breast and cervical cancer in the Native American community; breast implants; benign brain tumors; and blood cancers. As many of the witnesses today will testify, these issues have received inadequate attention from the government, scientific researchers, and the medical community. The legislation that we consider today will potentially improve the health and well being of thousands of Americans each year.

H.R. 239 mandates the inclusion of benign brain tumors in cancer registries. Cancer surveillance conducted through state-based registries is designed to determine cancer patterns among various populations, monitor cancer trends over time, guide planning and evaluation of cancer control programs, help allocate health resources, advance health services research, and serve as the basis for an aggregated and centralized database of cancer incidence in the United States. Ignoring benign tumors may underestimate the occurrence of all brain tumors by at least 50 percent. Adding this important data will only increase data collection costs by one percent. This is a small price to pay for more accurate information.

H.R. 2629 will increase research and education for leukemia, lymphoma, and multiple myeloma to assure advances in the treatment and, we hope ultimately, a cure for those blood cancers. Blood cancers are responsible for 11 percent of all cancer deaths in the U.S. I am particularly pleased to note that this bill establishes the Joe Moakley Cancer Education Program within the Department of Health and Human Services. This program will be a most fitting tribute to our former colleague, who lost his gallant fight against leukemia earlier this year.

H.R. 1383, the Native American Breast and Cervical Cancer Treatment Technical Amendment Act of 2001, simply corrects the inadvertent exclusion of Native American women from Medicaid breast and cervical cancer treatment. The Health Insurance Portability and Accountability Act of 1996 unintentionally excluded them from receiving this life-saving care. This fix is overdue.

H.R. 1961, the "Breast Implant Research and Information Act," requires the National Institutes of Health (NIH) to report on the status of the existing breast implant research funded by such Institutes; the appointment of a coordinator regarding breast implant research; the establishment of either a study section or special emphasis panel for NIH to review breast implant research grant applications for quality control; and the conduct or support of research to expand the understanding of the health implications of both saline and silicone breast implants. It also requires the Food and Drug Administration to evaluate and report on postmarket evaluations of saline implant manufacturers' data, and to assist women in receiving accurate and complete information about the risks of such implants.

I look forward to working with my colleagues on these four bills and to hearing from the witnesses before us today.

Mr. BILIRAKIS. The witness list consists of Dr. Diana Zuckerman, Executive Director of the National Center for Policy Research for Women and Families; Ms. Kim Hoffman of Nangua, Missouri. Is that right?

Ms. HOFFMAN. Nangua.

Mr. BILIRAKIS. Close. Pamela Noonan-Saraceni from New Fairfield, Connecticut; Mr. Lloyd Morgan, the Board of Directors, Central Brain Tumor Registry of the United States and North American Brain Tumor Coalition; Dr. Dwayne Howell, President and CEO, Leukemia and Lymphoma Society; and Ms. Jacqueline L. Johnson, Executive Director of the National Congress of American Indians.

Ladies and gentlemen, I set the clock at 5 minutes. I certainly won't cut you off if you go past that, but I would hope that you would stay as close to it as you can. Your written statement is already a matter of the record, and so, consequently, we would hope you would complement it more than anything else. That being the case, we will start off with Dr. Zuckerman. Thank you and welcome.

STATEMENTS OF DIANA ZUCKERMAN, EXECUTIVE DIRECTOR, NATIONAL CENTER FOR POLICY RESEARCH FOR WOMEN AND FAMILIES; KIM HOFFMAN; PAMELA NOONAN-SARACENI; LLOYD MORGAN, BOARD OF DIRECTORS, CENTRAL BRAIN TUMOR REGISTRY OF THE UNITED STATES AND THE NORTH AMERICAN BRAIN TUMOR COALITION; DWAYNE HOWELL, PRESIDENT AND CEO, LEUKEMIA AND LYMPHOMA SOCIETY; AND JACQUELINE L. JOHNSON, EXECUTIVE DIRECTOR, NATIONAL CONGRESS OF AMERICAN INDIANS

Ms. ZUCKERMAN. Thank you very much, Mr. Chairman. Is this a good distance? It is working? I am Dr. Diana Zuckerman, President of the National Center for Policy Research——

Mr. BILIRAKIS. You might pull it closer. It is on? The light is not on, is it.

Ms. ZUCKERMAN. Okay. Is that working now?

Mr. BILIRAKIS. Yes.

Ms. ZUCKERMAN. Okay. Thank you. I am Dr. Diana Zuckerman, president of the National Center for Policy Research for Women and Families. I am especially grateful to have the opportunity to be here today, because 11 years ago, I was in a similar hearing room, only I was on that side of the table. Actually, it is a little easier on this side. Well, it wasn't even this room, but I was staffing the first congressional hearing on breast implants.

And on that day, I listened to courageous women talk about their terrible experiences with breast implants, and I wondered if their stories could possibly be true. At that point, about a million women had breast implants, but there was no research to tell us how often these implants caused health problems. There were just a few studies of rats and other animals, none of humans.

Eleven years later, there are studies of women, and it is now established that implants can cause serious complications, such as infections, which can sometimes be fatal, and the much more common problem of rupture and the need for additional surgery. And just a few months ago, two major new studies, conducted by the National Cancer Institute, reported that women who have silicone or saline breast implants are at increased risk of some kinds of cancer and at increased risk of death from brain cancer, lung cancer and other respiratory diseases. A third new study, conducted by

the FDA, found that women with leaking silicon jell breast implants are more likely to have several painful and potentially fatal autoimmune diseases.

These studies are very important, because unlike previous studies, every woman in these studies had implants for at least 6 years. The studies that had been conducted that had found no increased health risks had usually included women who had implants for just a very short period of time, sometimes just a few months or a few years. And as we all know, it takes a lot longer than that for cancer or other serious diseases to develop. So the new NCI and FDA studies are not conclusive, but they raise frightening questions about the long-terms risks of both silicone and saline breast implants.

The essential questions have not changed in the last 11 years. There are two: Do breast implants increase health problems; and No. 2, do women with implants die at a younger age than they otherwise would? And we especially need to know what are the health risks for women who have reconstruction with implants after mastectomies and to provide informed consent to all patients before they have decided whether or not to undergo implant surgery. And that is why H.R. 1961, the Breast Implant Research and Information Act, is so very important.

The number of American women and teenage girls that are getting implants for augmentation has more than doubled—more than doubled—in the last 3 years. Meanwhile, the FDA has not even bothered to look at the almost 200,000 adverse reaction reports that have been sent into them. And we are still listening to women with the courage to testify to Congress about their implant experiences. And many of the people in this room may still be wondering, can this be true what we are going to hear from them today? And if so, how often does this happen? It is time to stop wondering.

The studies that were conducted by the NCI were mandated by Congress. They would not have been conducted at all, they never would have been conducted if it weren't for congressional pressure, but even so, they did not include a single mastectomy patient, not one. It is too late to fix those studies, but it is absolutely essential that we do start a new study that is a study of mastectomy patients. We have learned from experience that that study won't be conducted unless Congress makes that happen, and it looks like we need a law to require it.

And, of course, all women, all women, mastectomy patients and augmentation patients, deserve informed consent. They deserve to know what the risks are when they are considering breast implants, and they especially deserve to know that there are these new NCI studies, the results of those studies and the FDA studies that show the potential of life-threatening diseases related to breast implants. So far that is not happening. Women today are not getting that kind of informed consent. And, again, it looks like it won't happen without your help.

I have two other very brief suggestions, really brief. The NCI and the FDA studies that have already been published should be continued. Almost all the women in those studies have had implants for at least 11 years by now. It had been 8 years at the time they were analyzed; now it is 11 years of research. And so we can learn

a lot more about the long-term risks of cancer and other diseases, and we can learn it for a lot less money just by continuing those studies. And, of course, because those studies don't include mastectomy patients, we still do need extra research on mastectomy patients.

And I would just ask that as this committee considers legislation to reform the FDA in the coming year, I urge you to include a provision requiring long-term safety data for implanted medical devices that are already on the market. Breast implants and many other medical implants are not like other medical products. There are women who have had breast implants for many, many years already out there, and they are available to be studied, and the FDA should be mandated to do so. Since implants are forever, basically, they are implanted forever, the FDA approval should be based on long-term safety data, not just a year or 2 or 3 of safety data.

In closing, I want to thank you for the privilege of testifying, and I especially want to thank Congressman Blunt and Congressman Green for their terrific staff and their terrific leadership on this issue. And I want to thank the other members of the committee and their staff—see, I was a staffer, you can tell—because you have listened to your constituents talking about these issues, and you have shown them great respect as they have described their implant problems.

Our non-profit think tank thanks you on behalf of our organization and the thousands of consumers who have contacted us about health problems linked to implants and other medical devices. Thank you very much.

[The prepared statement of Diana Zuckerman follows:]

PREPARED STATEMENT OF DIANA ZUCKERMAN, PRESIDENT NATIONAL CENTER FOR POLICY RESEARCH FOR WOMEN & FAMILIES

My name is Dr. Diana Zuckerman and I am president of the National Center for Policy Research for Women & Families. Our organization is a nonprofit think tank dedicated to improving the lives of women and families by explaining and disseminating medical and scientific research information.

I am honored to be on this panel with Congressman Roy Blunt and these courageous women, to talk about the need for H.R. 1961, a bill that will help to ensure and protect women's health and well-being.

The Breast Implant Research and Information Act calls for more research on breast implants. I am here to tell you why this bill is so essential.

Breast implants have been sold in this country for almost 40 years, but we still know very little about their long-term health risks. In fact, almost a million women had breast implants before the first epidemiological study was published about health risks. Before then, there were just a few studies of rats and dogs, but no published studies of human beings.

In 1990, as a scientist working on what is now the House Reform and Oversight Committee, I started an investigation of the FDA's regulation of breast implants. We found that the FDA had ignored the concerns of its own scientists by allowing the sale of breast implants without requiring that the manufacturers prove that implants were safe. As a result of our hearing, the FDA finally required the manufacturers to submit studies of silicone gel implants. Unfortunately, those studies were so badly designed that they could not prove whether or not implants were safe.

In response to pressure on both sides, the FDA did something they almost never do—they refused to approve implants but allowed them to stay on the market as a "public health need." I think the last two months have shown us what a true public health need is—and breast augmentation does not qualify. But, at the time, Congress went along with the FDA decision, but required the NIH to conduct long-term research.

There were no studies of women with implants in 1990, but quite a few epidemiological studies have been conducted since then. I have read all of them. Despite what you may have heard in the media, the research and the report by the Institute of Medicine does not conclude that implants are safe—to the contrary, they show many serious problems related to implants.

In fact, just a few months ago, three major new studies reported that women who have breast implants are at significant risk for several debilitating and fatal diseases.

One study, conducted by researchers at the National Cancer Institute (NCI) reported that women with implants were more likely to die from brain cancer, lung cancer, other respiratory diseases, and suicide compared to other plastic surgery patients.

A second study, also by NCI, reported that women with breast implants are more likely to develop cancer compared to other women their age.

Both of these studies were of women who had either silicone or saline breast implants for at least 8 years. In contrast, the studies showing no increase in disease for women with implants included many women who had implants for short periods of time—even as short as one month. Obviously, cancer and autoimmune diseases do not develop that quickly.

A third study, conducted by scientists at the FDA, found that women with leaking silicone gel breast implants are more likely to have several painful and potentially fatal autoimmune diseases. Implants were found to be increasingly likely to break as they got older, and most implants were broken by the time they were 10-15 years old. This study may provide an important clue: it is possible that illnesses reported by women with implants are a result of leaking implants—which would explain why most women do not have systemic health problems until after they have had implants for several years.

At the same time that these new studies were released, the plastic surgery organizations announced that almost 300,000 American women got breast implants last year, most of them for augmentation. Although they don't boast about it, their statistics also show that the number of teenage girls getting implants has more than doubled in the last 3 years.

These three new studies remind us that, although relatively few women become ill after having implants for a year or two, we need to be concerned about the long-term dangers. And women who are considering implants deserve to be accurately informed about the risks—what is known, and what is not known. And yet, hundreds of thousands of women are deciding to get implants because they mistakenly believe that implants are proven safe for long-term use.

The two studies conducted by NCI were mandated by Congress. They were designed to answer two essential questions:

1) do breast implants increase health risks and

2) do women with implants die at a younger age than other women?

These are still the essential questions and that is the purpose of H.R. 1961. I am especially pleased that this legislation requires studies of women with implants after mastectomies. It is unfortunately true that not one single breast cancer patient was included in the studies that the federal government has conducted thus far. I want you to know that Congress requested that mastectomy patients be included in those studies, but the head of NIH at the time, Dr. Bernadine Healy, refused. It's too late to fix those studies, but it is absolutely essential that studies of reconstruction patients be conducted as soon as possible. At this point, most of what we know is based on the manufacturers' own studies, which show that one in four reconstruction patients need to have at least one additional surgery within the first three years after getting saline implants, and that other complication rates are also extremely high. We need to know what happens after three years, and we need to tell breast cancer patients about these complications so that they can make an informed decision about what would be best for them.

In addition to new studies, it would be very cost-effective for the NIH to continue to study the breast augmentation patients in the NCI and FDA studies that I described a few minutes ago. At the time the NCI studied the women's medical records, they had implants for at least 8 years. They have now had implants for at least 11 years, so it is important to study what has happened—whether the cancer rates, autoimmune diseases, and death rates of women with implants have increased or decreased in the last three years.

Although I am especially concerned about the lack of information about the long-term safety of reconstruction, I am also concerned about the thousands of teenage girls that are getting breast implants every year. We don't know what will happen to those girls, but unfortunately neither they nor their parents realize how little is known about long-term risks. It is time we answered that question. And H.R. 1961

would help ensure that patients—and teenage patients' parents—know what the risks are well before they decide whether or not to get implants.

In conclusion, I want to thank the Committee for holding this hearing, and especially thank Congressman Blunt and Congressman Gene Green for their essential work on this legislation. And, I thank the Committee members who have supported this legislation and shown respect and support for their constituents who have courageously shared their experiences with implants. We need your continued help. If Congress doesn't require that these important studies be conducted by NIH, it is unlikely that they ever will be. And so, we're counting on this Committee to make sure that NIH moves forward as quickly as possible.

I hope the Committee will also undertake a careful review of the role of the FDA regarding the lack of long-term safety data on breast implants. Breast implants have been sold for almost 40 years, and yet the FDA has never required long-term safety data. They have not required that patients be informed of the risks of implants. Meanwhile, more than 127,000 adverse reactions have been reported regarding silicone gel implants and more than 65,000 for saline-filled implants—and yet the FDA has not even bothered to examine them. As this Committee considers legislation to reform the FDA in the coming year, I urge you to include a provision requiring long-term safety data for implanted medical devices that are already on the market. This is not like a new medical product: women who have had implants for many years are available to be studied, and the FDA should be mandated to do so.

I would be glad to answer any questions, and I invite staff to go to our website, www.center4policy.org, to read some of the medical and lay articles that we have written on the topic, and to link to FDA's consumer materials about breast implants.

Mr. BILIRAKIS. Thank you very much, Doctor. Ms. Hoffman.

STATEMENT OF KIM HOFFMAN

Ms. HOFFMAN. Mr. Chairman and members of this committee, thank you for giving me the opportunity to testify. My name is Kim Hoffman, and I am a breast implant recipient from Missouri.

As the watchdog of public safety for food, drugs and medical devices, the FDA has failed specifically in its duties by allowing a medical device with high complication rates to be marketed to American women by companies with dubious manufacturing practices.

Like Pam, who is here today, and thousands of other women, in 1995, I experienced numerous debilitating problems immediately after receiving silicone breast implants, manufactured by Mentor Corporation. To receive silicone implants after the moratorium in 1992, I was required to participate in a clinical study. Because data collected in this study could effect FDA's decision to approve the widespread use of this product——

Mr. BILIRAKIS. Kim, will you please pull that mike a little closer. I think it is important that we not miss any part of your story.

Ms. HOFFMAN. Okay. Because the data collected in this study—is that better? Okay—could affect FDA's decision to approve the widespread use of this product, I recognized the importance of accurately documenting my problems and including them in the study.

I reported my problems to my surgeon, but he ignored me. I obtained a copy of the study protocol and realized a number of study rules had been violated. I reported the violations and my physical problems to the manufacturer and to the FDA. Again, I was ignored. After numerous attempts to report my complications as a study participant, I received a form from my file at the manufacturer. It read, "Patient has no complaint."

Astonished by the apathetic responses I had received, and being from the "show me" State, I began my own investigation. I inter-

viewed several other study participants and found problems with their cases as well. I was able to talk to people who worked for the manufacturers and even a couple of industry whistle-blowers. From them I learned that not only were there problems with the study, but the companies were having major problems with quality control issues and were violating good manufacturing practices. These problems had gone on for years.

Informants alleged that there were problems with the implant design and gel suppliers; there were defects with the implants, valves, outer shell and gel. It appeared many of these problems had been concealed from the FDA. I reported this to the FDA, several people at the FDA, but there was no apparent action.

Disturbed by the lack of responsiveness at the FDA, in the summer of 1998 I put all of the information together and gave it to Congressman Gene Green, the FDA, the House Energy and Commerce Committee and eventually to Congressman Blunt. The FDA's copy was given to James Austin Templer, an FDA compliance officer who oversaw Mentor. He referred the information to the FDA's Office of Criminal Investigations, and in 1998 a criminal investigation was opened.

Throughout 1999, I continued to receive alarming information, which was given to Mr. Templer and then forwarded to the FDA's criminal investigators. Unfortunately, little was done, in spite of the shocking information which was uncovered and Mr. Templer's efforts to push the investigation forward. It became obvious to both of us that there were significant problems with the medical devices and the integrity of the manufacturing process. Furthermore, it appeared internal problems at the FDA were undermining consumer protection.

The situation became critical in 2000. The FDA had announced that saline breast implants would be considered for market approval in the spring, and Mentor Corporation would be submitting a pre-market approval application. The criminal investigation had gone nowhere, and regulatory actions had been put on hold because of the criminal investigation. In January 2000, in frustration and out of concern for American consumers, Mr. Templer tendered his resignation from a 12-year career at the FDA. He hoped his resignation would get the attention of the agency. In his resignation letter to the Commissioner, he urged the agency to conduct a thorough investigation of the allegations prior to the agency's approval of saline breast implants.

Unfortunately, in May 2000, the FDA approved saline breast implants anyway. The approval came in spite of Mr. Templer's recommendation, in spite of complications rates of over 70 percent for breast cancer patients in the first 3 years and in spite of an ongoing criminal investigation into Mentor, which remains open even today.

Sadly, consumers believe FDA approval of a product means that the product has been adequately studied and has been found to be safe and effective for its intended use. Clearly, this is not the case with this device. It is my fear that by ignoring the regulatory problems, the criminal allegations, the high complication rates and the recommendation of the FDA's own staff, the agency has lowered the bar for what is considered a safe and effective medical device.

Additionally, the ramifications of the FDA's decision could be widespread and ultimately affect other products and many American consumers.

It was this concept which disturbed Mr. Templer and me so deeply. Mr. Templer couldn't be here today; however, he asked me to advise the committee of his professional opinion. Mr. Templer writes, "Based upon information I was aware of as an FDA official, it does not surprise me that breast implant recipients are experiencing significant health consequences. I was aware of many quality control issues as well as situations where FDA employees illegally assisted an implant manufacturer. I reported these issues, but the FDA wanted to sweep the matter under the rug. In my opinion, the FDA has not adequately monitored the safety of breast implants nor have they investigated adequately the safety of breast implants. And in fact, they have looked the other way when credible allegations of criminal misconduct have been made. I urge the committee to take the actions necessary to protect the public health, because the FDA has clearly failed to do so."

In conclusion, I agree with Mr. Templer. It will take an act of Congress to get to the bottom of the breast implant debacle. However, Congress must insist that our country's watchdogs are doing their jobs. This bill will ensure the FDA has full oversight and will provide accountability. This bill will ultimately benefit women's health and could also impact FDA's oversight of all medical devices.

I want to thank Congressman Green and Congressman Blunt for their efforts and all the committee members who have supported H.R. 1961.

[The prepared statement of Kim Hoffman follows:]

PREPARED STATEMENT OF KIM HOFFMAN, PATIENT REPRESENTATIVE REGARDING BREAST IMPLANTS

Mr. Chairman and Members of this Committee: thank you for giving me the opportunity to testify. My name is Kim Hoffman. I am a breast implant recipient from Missouri.

As the watchdog of public safety for food, drugs and medical devices, the FDA has failed specifically in its duties, by allowing a medical device with high complication rates to be marketed to American women by companies with dubious manufacturing practices.

Like Pam, who is here today, and thousands of other women, I experienced numerous debilitating problems immediately after receiving my textured, silicone breast implants, manufactured by Mentor Corporation, in 1995. To receive silicone implants after the moratorium in 1992, I was required to participate in a clinical study. Because data collected in this study could effect FDA's decision as to whether the agency should approve the wide spread availability of the product, I recognized the importance of accurately documenting my problems and including them in the study.

I reported my problems to my surgeon. He ignored me. I obtained a copy of the study protocol and realized a number of study rules had been violated. I reported the violations, *and* my physical problems to the manufacturer, who was the sponsor of the study *and* to the FDA; again, I was ignored. *After* numerous attempts to report my complications as a study participant, I received a form from my file at the manufacturer; it read, "patient has no complaint."

Astonished by the apathetic responses I'd received, and being from the show me state, I began my own investigation. I interviewed several other study participants and found problems with their cases as well. I was able to talk to people who worked for the manufacturers and even a couple of industry whistle-blowers. From them I learned that not only were there problems with the study and the documentation of problems experienced by patients, but the companies were having

major problems with quality control issues and were violating good manufacturing practices. These problems had gone on for years.

These individuals alleged that there were problems with the implant design and gel suppliers; there were defects with the implants, valves, and outer shell; and there were inconsistencies in the gel used to fill implants. It appeared many of these problems had been concealed from the FDA. I reported this information to the FDA, *several people* at the FDA, but there was no apparent action.

Disturbed by the lack of responsiveness at the FDA, in the summer of 1998 I put all of the information together, information about the clinical trials and the manufacturing problems alleged by industry employees, and gave it to Congressman Green, the FDA, the House Energy and Commerce Committee, and eventually to Congressman Blunt.

The FDA's copy was given to James Austin Templer, a FDA compliance officer who oversaw Mentor Corporation, the manufacturer I had gathered the most data about. Mr. Templer referred the information to the FDA's Office of Criminal Investigations, and in 1998 a criminal investigation was opened.

Throughout 1999, I continued to receive alarming information, which was given to Mr. Templer and then forwarded to the FDA's criminal investigators. Unfortunately, little was done, in spite of the shocking information that was uncovered and Mr. Templer's efforts to push the investigation forward. It became obvious to both of us that there were significant problems with the medical devices and the integrity of the manufacturing process. Furthermore, it appeared internal problems at the FDA were undermining consumer protection.

The situation became critical in 2000. The FDA had announced that saline breast implants would be considered for market approval in the spring, and Mentor Corporation would be submitting a pre-market application (PMA) for approval of their products. The criminal investigation had gone nowhere and regulatory actions had been put on hold because of the criminal investigation. In January 2000, in frustration and out of a concern for American consumers, Mr. Templer tendered his resignation *from a twelve-year career at the FDA.* He hoped his resignation would get the attention of the agency. In his resignation letter to the commissioner, he, among other things, urged the agency to conduct a thorough investigation of the allegations, which had been made about the manufacturer and the study, *prior* to the agency's approval of saline breast implants. Unfortunately, the FDA again chose to look the other way.

In May 2000, the FDA approved saline breast implants. The approval came in spite of Mr. Templer's recommendation, in spite of complications rates as high as 43% for cosmetic patients and complication rates of over 70% for reconstruction patients (in the first 3 years), and in spite of an ongoing open criminal investigation into one of the manufacturers, which remains open even today.

Sadly, consumers believe "FDA approval" of a product means that the product has been adequately studied and has been found to be safe and effective for it's intended use. I'm not sure this should be concluded with this device. Unfortunately, the average consumer who might purchase this product will not have access to the information the FDA has ignored during the approval process, resulting in an inappropriate assumption of safety and effectiveness.

It is my fear that by ignoring the regulatory problems, the criminal allegations, the high complication rates and the recommendation of the FDA's own staff, the agency has *lowered the bar* for what is considered a safe and effective medical device. Additionally, the ramifications of the FDA's decision could be widespread and ultimately effect other products and many American consumers.

It was this concept which disturbed Mr. Templer and me so deeply. Mr. Templer couldn't be here today, however, he asked me to advise the committee of his professional opinion regarding this topic.

Mr. Templer writes, "Based upon information I was aware of as an FDA official it does not surprise me that breast implant recipients are experiencing significant health consequences. I was aware of many quality control issues as well as situations where FDA employees illegally assisted an implant manufacturer. I reported these issues, but the FDA wanted to sweep the matter under the rug. In my opinion, the FDA has not adequately monitored or investigated the safety of breast implants, and in fact, they have looked the other way when credible allegations of criminal conduct have been made. I urge the committee to take the actions necessary to protect the public health, because the FDA has clearly failed to do so."

I agree with Mr. Templer: it will take an act of Congress to get to the bottom of the breast implant debacle. However, Congress must insist that our country's watchdogs are doing their jobs. The passing of this bill is a great first step. H.R. 1961 will ensure the FDA has full oversight and will provide accountability. The

passing of this bill will ultimately benefit women's health and could also impact FDA's oversight of all medical devices.

I want to thank Congressman Gene Green for his steadfast leadership on this issue, and I would also like to thank my Congressman, Roy Blunt, for his support. I would also like to thank members of this panel who have co-sponsored H.R. 1961. We are grateful for the support of Representatives Sherrod Brown, Ed Bryant, Richard Burr, Frank Pallone Ted Strickland and Heather Wilson.

Thank you for your time today and I urge you to make it a goal to pass this bill in *this* Congress. Breast implants have been put in women's bodies for over 30 years; it's high time we understand the long-term effects of this product and insist that they be manufactured with integrity and in accordance with good manufacturing practices.

Mr. BILIRAKIS. Thank you. Thank you so very much. Ms. Noonan-Saraceni?

STATEMENT OF PAMELA NOONAN-SARACENI

Ms. NOONAN-SARACENI. Mr. Chairman and members of the committee, my name is Pamela Noonan-Saraceni. I am a breast cancer survivor who continues to endure the painful side effects from breast implants. I am very pleased to have this opportunity to be here with you today.

Despite over 30 years of use, breast implants remain a classic example of, "What we don't know can hurt us." The Institute of Medicine estimates by 1997 about 1.8 million American women had breast implants with nearly one-third of these women being breast cancer survivors. In 1999 alone, 83,000 women received implants following mastectomies. In the year 2000, over 200,000 women received breast implants for cosmetic reasons.

The FDA has never approved silicone implants and just recently approved saline implants for the first time. Little is known about the long-term effects of silicone and even less is known about saline, yet their popularity is growing with a new generation of young women who were led to believe that improvements have been made to these implants and therefore they are now safe.

I believe breast implants should be an option for women but a safe option, so the role of the Government cannot be overlooked. The bill that has been introduced by representatives Roy Blunt and Gene Green, H.R. 1961, Breast Implant Research and Information Act, calls upon the FDA to strengthen the informed consent documents given to patients in breast implants clinical trials. It directs the NIH to conduct research desperately needed on breast implants recipients, and it ensures better FDA oversight of device manufacturers.

To understand the need for this bill, I would like to tell you about my experience. I was diagnosed with breast cancer and had a radical mastectomy in 1978. I was just 25 years old at the time. I waited 5 years before I decided to have reconstructive surgery. At that time, I was active, I played tennis, I taught aerobics, and I jogged. I had grown tired of the inconvenience of the prosthesis shifting and falling out when I perspired. I thought I had done my homework on breast implants, but I was never advised of any health risks associated with the implants; in fact, I was told they would last a lifetime, and the complications were rare.

Within 3 months, I was back in the operating room. My body had formed a capsule around the implant, and the implant had shifted up to my collarbone. My symptoms began in the summer of 1990

when I experienced joint pain and chronic fatigue. Various doctors gave me a list of diagnoses. Eventually, I again had to wear a prosthesis over the implant, because I was again misshapen and lopsided. Finally, in 1994, which was 10 years after my initial reconstruction, I had surgery for the fifth time; this time to remove the breast implant.

My out-of-pocket medical expenses has totaled over $35,000. My husband and I are self-insured, and our insurance policy at the time carried an exclusion: I would not be covered for any illness or disability related to my reconstructive surgery. Apparently, the insurance company understood the health risk of breast implants, what they posed for women, and they were not willing to cover the costs.

I believe there are improvements that need to protect women considering implants. This bill is a tremendous step forward in safeguarding American women. First, informed consent must be strengthened. The informed consent agreement, written by the implant manufacturers, is the only required information women receive prior to surgery. This document contains inaccurate and misleading information. Furthermore, the informed consent agreement does not mention the effects of breast implants on future mammography. This is probably not a concern to most cosmetic patients, yet over 30 percent of breast tissue can be obscured by an implant, which can delay the early detection of breast cancer.

Until research is able to answer the long-term safety questions about breast implants, women, at the very least, need to be informed about what we do know: Chronic pain, hardening, infections and deformities, high rate of reoperations and ruptures, problems with insurance coverage, the fact that implants do not last a lifetime and will have to be replaced every 8 to 10 years and inaccurate mammography readings.

Second is the need for long-term studies. I hope 1 day there will be a cure for breast cancer, but until then the NIH should be obligated to conduct long-term research so badly needed on breast implants. Almost no research has been done to track mastectomy patients who suffer with local complications at a higher rate than other breast implant recipients. No woman should survive breast cancer only to experience chronic pain, infections or deformities from implants. The latency period for complications and ruptures has been widely recognized in the scientific circles, but the FDA only required manufacturers to follow women in the saline implant trials for 3 years. The agency recently announced manufactures of silicone breast implants are required to study patients for only 2 years in order to glean data for their market approval. These studies will not provide meaningful data on a long-term safety and efficacy of the implant and will not protect American women.

In conclusion, had I known the physical, emotional and financial hurdles I would have to overcome due to breast implants, I would have made a different decision. I would never have chosen implants. Despite the implant manufacturers' advertisements, breast reconstruction was not a part of my breast cancer recovery process; being cancer-free and feeling physically well enough to return to a normal life is. My experience and what I have learned from women across the country is my only breast implant expertise.

I would like to acknowledge the women who helped to bring this message to Capitol Hill today. We have Anne Stansell from New Mexico, Marlene Keeling from Texas, Mary McDonough from California, Lisa Hickey from Arizona and Kim. We feel a tremendous responsibility to increase awareness about the safety questions which still surround breast implants, and we thank you for your support in the passage of H.R. 1961. Thank you.

[The prepared statement of Pamela Noonan-Saraceni follows:]

PREPARED STATEMENT OF PAMELA NOONAN-SARACENI, PATIENT REPRESENTATIVE REGARDING BREAST IMPLANTS

Mr. Chairman and Members of this Committee: My name is Pam Noonan-Saraceni. As a breast cancer survivor who continues to endure the painful physical side-effects of silicone breast implants, I am pleased to have the opportunity to take part in this hearing.

Many of you here today may think the scientific and safety debate on breast implants is over and are wondering why breast implants are part of today's hearing. You believe this issue has reached its saturation point. But, breast implants remain a classic example of "what we don't know can hurt us."

Consider the number of women who have breast implants. The Institute of Medicine estimates that by 1997, 1.5 to 1.8 million American women had breast implants with nearly one third of these women being breast cancer survivors. In 1999 alone, nearly 83,000 women received implants following a mastectomy. In 2000, over 200,000 women received breast implants for cosmetic reasons.

Yet, in 1999, the Institute of Medicine concluded:

- First, reoperations and local complications are frequent enough to be a cause for concern and to justify the conclusion that they are the primary safety issue with silicone breast implants;
- Second, risks accumulate over the lifetime of the implant, but quantitative data on this point are lacking for modern implants and deficient historically;
- Third, information concerning the nature and relatively high frequency of local complications and reoperations is an essential element of adequate informed consent for women undergoing breast implantation.

And in 1997, the Mayo Clinic found that one in four women required additional surgeries within five years of implantation because of problems related to the implants. The rate was higher for mastectomy patients: one in three women.

Despite over thirty years of use, the Food and Drug Administration has never approved silicone implants and just recently approved saline implants for the first time. Little is known about the long term effects of silicone and even less is known about saline. Yet their popularity is growing with a new generation of young women who, in spite of the past controversy, are being led to believe that improvements have been made to these implants, and therefore, they are now safe.

I believe breast implants should be an option for women. But, a safe option. Therefore, the role of the government cannot be overlooked. There are a number measures that the federal government could implement to better protect women and preserve their health and their quality of life. These measures are encompassed in the legislation introduced by Representatives Roy Blunt and Gene Green. H.R. 1961, "The Breast Implant Research and Information Act," calls upon the FDA to strengthen informed consent documents given to patients in clinical trials for breast implants; directs the National Institute of Health to conduct independent research desperately needed on breast implant recipients; and ensures better FDA oversight of device manufacturers.

In order to better understand the need for this legislation, I would like to tell you a little bit about my personal experience. I was diagnosed with breast cancer and had a radical mastectomy in 1978. I was just 25 years old at the time. I waited 5 years before I decided to have reconstructive surgery. I was an active person. I played tennis, taught aerobics, and jogged. I had grown tired of the inconvenience of the prosthesis shifting and falling out when I perspired. I thought I had done my homework on breast implants prior to choosing the plastic surgeon to do my reconstruction. However, I was never advised of any of the health risks associated with the implants. In fact I was told repeatedly that they would "last a lifetime" and that "complications" were rare. Within 3 months of the initial reconstruction, I was back in the operating room. My body had formed a capsule around the implant and the implant had shifted up toward the collarbone. My symptoms of physical illness began slowly. In the summer of 1990 I began to experience joint pain and chronic

fatigue. This was six years after my being implanted. I have been to various doctors and specialists and have a list of various diagnoses. Before I had the implant removed in June of 1994 (10 years after the initial reconstruction), I had to wear a partial prosthesis over the implant. Capsular contracture had again become a problem and I was misshapen and lopsided. The explantation was the 5th surgery at my breast site.

To date, my out of pocket medical expenses total almost $35,000. My husband and I are self-insured. The insurance policy that we took out in 1991 had an exclusion. I was not covered for any illness or disabilities related to the reconstructive surgery. Apparently, the insurance companies understood the health risks breast implants pose for women and were not willing to bear the financial costs.

I believe there are several areas that need improvement in order to protect women considering breast implants. The Breast Implant Research and Information Act, introduced by Congressmen Gene Green and Roy Blunt, is a tremendous step forward to safeguarding American women.

First: Informed Consent Must Be Strengthened

Insufficient and inaccurate information has posed many problems for women in breast implant trials. Even the Institute of Medicine recognized that women are not being adequately warned of rupture, painful local complications and multiple surgeries.

The informed consent agreement drawn up by the breast implant manufacturers is the only required information women receive about the implants and the study prior to surgery. This document contains inaccurate data on rupture and contracture rates, the efficacy of the implants, the risks and complications, and the need for future reoperations. It understates the FDA's concern about the safety of silicone breast implants, which first led to the 1992 moratorium, and makes many misleading statements about the rate of complications following implantation.

Furthermore, the informed consent agreement does not mention the effects of breast implants on future mammography, which is particularly worrisome for breast cancer survivors. We live in fear of finding reoccurring cancer. Over 30% of the breast tissue can be obscured by the implant, which can delay the detection of cancer.

Until independent research is able to answer the long-term safety questions surrounding breast implants, women, at the very least, need to be informed about what we DO know:

- chronic pain, breast hardening, infections and breast deformity;
- the high rate of reoperations;
- the high rate of ruptures;
- problems associated with insurance coverage;
- the fact that implants do not last a lifetime and will have to be replaced every 8-10 years;
- inaccurate mammography.

Second: The Need for Long-Term Studies

The Breast Implant Research and Information Act directs the National Institutes of Health to conduct the independent research that is so desperately needed in this area. The lack of convincing data submitted by the manufacturers or the plastic surgeons on the incidence of device failure, implant rupture or gel bleed was of concern to the FDA in the early 1980s Bso much of a concern that an FDA panel headed by Dr. Norm Anderson recommended that silicone breast implants remain a Class III device, meaning their safety and efficacy was not proven.

Once product liability cases involving silicone breast implants became more and more common, the manufacturers began to pour money into new scientific research on breast implant safety. Dr. Anderson implored the manufacturers to put their money into an independent fund so that impartial scientists could decide which issues should be examined. His wish was not granted, and the ensuing research in large part ignored long term outcomes, incidence of device failure, the consequences of implant rupture, and the causes for tissue pain.

The latency period for breast implant complications and ruptures has been widely recognized in scientific circles. I had my implants for six years before my symptoms began to appear. But, the FDA only required manufacturers to follow women in saline implant trials for three years, and the agency recently announced that manufacturers of silicone breast implants will only be required to follow patients for 18 months in order to glean data for market approval. These studies will not provide meaningful data on the long-term safety and efficacy of the implant, and will do little to protect American women in the long run.

In its review of breast implant studies, the Institute of Medicine also concluded, "risks accumulate over the lifetime of the implant, but quantitative data on this point are lacking for modern implants and are deficient historically."

In May of 1999, University of Florida researchers published their analysis of more than 35 studies, which examined more than 8,000 implants. According to this analysis, silicone breast implant rupture rates were found to be 30% at 5 years, 50% at 10 years and 70% at 17 years. According to the researchers, past studies that have been cited in support of silicone breast implant safety have "paid almost no attention to the health consequences of local complications of pain, capsular contracture, disfigurement, chronic inflammation, rupture, silicone migration, and frequent surgical revisions." They conclude that the longer women have these devices in their bodies, the greater the risk of failure and numerous complications.

This study and the IOM review reinforce the need to study women for a long period to accurately assess the health effects of breast implants.

Furthermore, almost no research has been done to track mastectomy patients who suffer from local complications at a higher rate than other breast implant recipients.

I hope one day there is a cure for breast cancer. But until that day, the National Institutes of Health should be obligated to conduct the independent research so badly needed on breast implants. No woman should be put in a position of surviving breast cancer only to experience chronic pain, infections, or deformities from breast implants.

Conclusion

When I opted for reconstructive surgery using breast implants, I thought I had made an informed decision. I asked questions of my doctors; I read as much information as was available in 1983. I thought I was making a safe choice for myself. Almost immediately, I was back in the operating room. It took six years before I began to experience unusual and chronic pain in my joints. A series of doctors diagnosed me with several different illnesses, and I underwent two additional surgeries. Finally, ten years after my initial implantation, I had the implants removed and my symptoms began to improve.

Despite the breast implant manufacturers advertisements, breast reconstruction is not an essential part of the recovery process; being cancer free and feeling physically well enough to return to a normal life is. Had I known the additional physical, emotional and financial hurdles I would have to overcome due to breast implants, I would have made a different decision. I would have never chosen implants.

My personal story and what I've learned from the experiences of women like me across the country and around the world is my only breast implant expertise. I am grateful for the friendship and camaraderie of other implant women who have helped bring this message to Capitol Hill. I would like to acknowledge those who are attending today's hearing: Anne Stansell from New Mexico, Marlene Keeling from Texas, Mary McDonough from California, and Lisa Hickey from Arizona. We all feel a tremendous responsibility to increase awareness about the unanswered safety questions that still surround breast implants. My hope is that other women, when faced with the same choices, can make their decisions based upon better informed consent and independent research. Please support the passage of H.R. 1961.

Mr. BILIRAKIS. Thank you very much for that great testimony. Mr. Morgan.

STATEMENT OF LLOYD MORGAN

Mr. MORGAN. Thank you, Honorable Chairman Michael Bilirakis and the whole Subcommittee on Health, 5 of whom are among the 75 co-sponsors, and Honorable Representative Lee, the sponsor of H.R. 239, Benign Brain Tumor Cancer Registries Amendment Act, for allowing me to be here today.

On April 28, 1995, I went to lunch with a colleague from work. Without warning or prior symptoms, I had a 45-minute grand mal seizure. My wife was told, "You better get used to it, honey. He has between a few hours and a few days." I spent 11 days, 8 in critical condition, at the hospital. The surgery took 12 hours; I was off work for 4 months. The reason? I had a peach-sized benign brain tumor. Unlike most benign brain tumor survivors, I escaped with only a minor deficit.

Carla Brinegar had the same tumor. It was, like mine, completely removed by surgery. It has since reoccurred five times. She is now in a hospice in Sacramento, California, blind in one eye, unable to speak, unable to care for herself in anyway. This is a benign brain tumor. Jeff Licht had a pineal tumor in his brain completely removed. It has reoccurred twice. It is now inoperable and growing. He, too, has a benign brain tumor. The dictionary defines benign as harmless. All brain tumors are malignant by location.

I am an electronic engineer. I am trained to use data in order to understand how the world behaves. I quickly learned that most SSate cancer registries, including California, where I live, did not collect data on benign brain tumors because they are not labeled as cancer. I am not a person who sits back when confronted with a challenge. Last year, California corrected this oversight with the passage of assembly bill 48. My Congresswoman, Barbara Lee, picked up our cause. As a result, H.R. 239 was introduced in the House.

I am active in the North American Brain Tumor Coalition and I am a member of the Board of the Central Brain Tumor Registry of the United States. I attend several scientific conferences and patient symposiums each year. This week, I will be at the Society of Neuro-Oncology here in DC. But, please understand, I am here today, not as a member of any organization. I am here as a benign brain tumor survivor, and I am here on behalf of all brain tumor patients, especially those that have died from a benign brain tumor.

H.R. 239 amends the Cancer Registry Act to include data collection of benign brain tumors. It is non-controversial, has widespread support from the cancer surveillance community, brain tumor researchers and clinicians, patients and their families. Its cost is very small, an estimated $923,520).

The most common benign brain tumors are: Meningiomas, a tumor of the meninges, the lining of the brain. This is the tumor that I had and that Carla Brinegar has. Acoustic Neuromas, a tumor of the acoustic nerve. Often it results in deafness. Pituitary Adenoma, a tumor of the pituitary, or master, gland located within the brain. All too often it results in hormonal devastation. Pineal tumors, tumors of the pineal gland located within the brain. This is the type of tumor that Jeff Licht has. There are other benign brain tumors.

Benign brain tumors are estimated to number about half of all brain tumors. Approximately 21 percent of children's brain tumors are benign. Since primary, that is benign and malignant, brain tumors are the leading cause of cancer death in children, cancer registries already collect most of these benign children's tumors. Collecting data on all benign brain tumors will amount to less than 3 percent of all data collected by cancer registries.

For women, a meningioma, a benign brain tumor, is more deadly than breast cancer; 69 percent survival in 5 years compared to 84 percent for breast cancer. In Norway, where data is kept on benign brain tumors, the incidence rate for men has increased by 250 percent; for women 280 percent for 3 decades, between 1962 and 1992. Is this happening in the United States? We cannot know without data. Only with the data provided as a result of H.R. 239 will we

have the ability to recognize trends, the full scope of the problem, the potential cause, the best treatment options, as is done with cancer.

There are now an estimated 267,000 people with benign brain tumors, including Members of this Congress. I urge this subcommittee to pass H.R. 239. I urge the Energy and Commerce Committee to pass H.R. 239, and I certainly urge the House of Representatives to pass H.R. 239. I would also like to give a special thanks to Lynette Farhadian of Congressman Lee's staff for all the work she has done for us. Thank you so much. Do you have any questions?

[The prepared statement of Lloyd Morgan follows:]

PREPARED STATEMENT OF LLOYD MORGAN

Thank you Honorable Chairman, Michael Bilirakis and the whole Subcommittee on Health, 5 of whom are among the 75 cosponsors of HR239, the Benign Brain Tumor Cancer Registries Amendment Act, for allowing me to be here today.

On April 28th 1995 I went to lunch with a colleague from work. Without warning or prior symptoms, I had a 45-minute grand mal brain seizure. My wife was told, "You better get use to it, honey. He has between a few hours and a few days." I spent 11 days, 8 in critical condition, at the hospital. The surgery took 12 hours. I was off work for 4 months. The reason? I had a peach sized "*benign*" brain tumor! Unlike most "benign" brain tumor survivors, I escaped with only a minor deficit.

Carla Brinegar had the same tumor. It was, like mine, completely removed by surgery. It has since reoccurred 5 times. She is now in a Hospice, blind in one eye, unable to speak, unable to care for herself in anyway. This is a "*benign*" brain tumor!

Jeff Licht had a pineal tumor in his brain completely removed in 1993. It has reoccurred twice. It is now inoperable and growing. He, too, has a "*benign*" brain tumor.

The dictionary defines benign as harmless. **All** brain tumors are malignant by location.

I am an electronic engineer. I am trained to use data in order to understand how the world behaves. As soon as I came home from the hospital I tried to find the data for "*benign*" brain tumors. I quickly learned that most state cancer registries, including California, where I live, did not collect data on "*benign*" brain tumors because they are not labeled as cancer. I am not a person who sits back when confronted with a challenge. Last year California corrected this oversight with the passage of AB 48. My Congresswoman, Barbara Lee picked up our cause. As a result HR 239 was introduced in the House.

I am involved with various brain tumor organizations. I am active in the North American Brain Tumor Coalition (NABTC) and a member of the Board of the Central Brain Tumor Registry of the United States (CBTRUS). I attend several scientific conferences and patient symposiums each year (this week I will be at the Society of Neuro-Oncology's meeting, here in DC). But, please understand, I'm here today, not as a member of any organization. *I'm here as a "benign" brain tumor survivor.*

HR 239: What it does

HR 239 amends the Cancer Registry Act to include data collection of "*benign*" brain tumors. HR 239 is an ideal bill for Congress to pass this year. It is non-controversial, has wide spread support from the cancer surveillance community, brain tumor researchers and clinicians, patients and their families. Its cost is very small (an estimated $923,520). It will provide an accurate description of brain tumors in our country so that we can fight this enemy offensively. I am sure you seldom get an opportunity to correct such a tragic oversight without either controversy or significant cost.

"Benign" Brain Tumors

The most common "*benign*" brain tumors are:

- Meningiomas: a tumor of the meninges, the lining of the brain. This is the tumor that I had and that Carla Brinegar has.
- Acoustic Neuromas: a tumor of the acoustic nerve. Often it results in deafness.

- Pituitary Adenoma: a tumor of the pituitary (or master) gland located within the brain. All too often it results in hormonal devastation.
- Pineal tumors: tumors of the pineal gland located within the brain. This is the type of tumor that Jeff Licht has.
- There are other "*benign*" brain tumors.

"Benign" Brain Tumor Statistics

"*Benign*" brain tumors are estimated to number about half of all brain tumors. Approximately 21% of children's brain tumors are "*benign*". Since primary ("*benign*" and malignant) brain tumors are the leading cause of cancer death in children, cancer registries already collect most of these "benign" tumors. Collecting data on all "*benign*" brain tumors will amount to less than 3% of all data collected by cancer registries.

Meningiomas are 27% of all brain tumors, and 35% of all brain tumors in women. For women, this "*benign*" brain tumor is more deadly than breast cancer; 69% survival compared to 84%. In Norway, where data is kept on "*benign*" brain tumors, the incidence rate for men has increased by 250%; for women 280% for over three decades. Is this happening in the United States? We cannot know without data.

While 21 states do collect "*benign*" brain tumor data, the remainder do not. HR239 will correct this oversight.

There are now an estimated 267,000 people with "*benign*" brain tumors including members of this Congress.

I urge this Subcommittee to pass HR239. I urge the Energy and Commerce Committee to pass HR239. I urge the House of Representatives to pass HR239.

Thank you so much. Are there any questions?

Mr. BILIRAKIS. Thank you, Mr. Morgan. Dr. Howell. And we will have questions.

STATEMENT OF DWAYNE HOWELL

Mr. HOWELL. Good afternoon, Mr. Chairman and members of the committee. I appreciate the opportunity to testify today on the Hematological Cancer Research and Investment Act of 2001. I am Dwayne Howell, the president and CEO of The Leukemia & Lymphoma Society, and equally important, I am the parent of a child who died from leukemia in 1973, a time when research advances and the prospects for patient survival from a blood cancer were much more limited than they are today.

The society is a voluntary health agency, and we fund research into blood cancers and help patients through our 59 chapters around the country. We are, by far, the largest private funder of blood cancer research, with a budget this year of over $40 million.

The burden of the hematological cancers is usually underestimated. People think of leukemia, lymphoma, myeloma, and Hodgkin's disease as separate entities, and they measure the prevalence and the incidence of those diseases separately. But when together, blood cancers represent the fourth most common form of cancer. In 2001, almost 700,000 people are living with leukemia, lymphoma and myeloma, and this year, 110,000 people will be diagnosed with them and 60,000 will die from them.

Patients, their families, friends and caregivers applaud the efforts of Representatives Phil Crane, Marge Roukema, Mike Ferguson, and Vic Snyder to develop legislation to focus the Nation's blood cancer research and education programs, and we also appreciate the willingness of the subcommittee to consider this bill in 2001. This is a time of great challenge and also tremendous opportunity for blood cancer research, and a coordinated and strengthened program is essential.

The Federal Government currently makes a substantial investment in blood cancer research, an investment that is complemented

by private funders, such as The Leukemia and Lymphoma Society. But despite the strong commitment of public and private funders, the research effort can be improved. The Hematological Cancer Research Investment and Education Act would make improvements in the existing research program to enhance the fundamental understanding of blood cancers and accelerate the development of new therapies.

The act would also establish the Joe Moakley Cancer Education Program, an important educational initiative for patients and the public that would allow for coordination with existing private sector patient education and service programs. Patient service and education are a major focus of The Leukemia & Lymphoma Society, and we look forward to the Federal Government's involvement and collaboration in patient and public education.

The Leukemia and Lymphoma Society would like to express its deep appreciation for your decision to focus on the hematological cancer research and education bill in the midst of the great pressures facing Congress. Your prompt action to evaluate the legislation is critically important to individuals living with blood cancers and their families and friends. The opportunity for research advances and the necessity for educating patients about those advances confront us now, and this act will help us respond to those challenges.

We have reason to be hopeful. Our substantial investment in basic research has enhanced knowledge of the nature of these cancers and contributed to major advances in treatment. Genetic and molecular analyses of hematological cancers are identifying targets for drug development, and this work has yielded a groundbreaking new therapy for chronic myelogenous leukemia, or CML. We hope this new therapy, a signal transduction inhibitor called Gleevec, is the first of other similar drugs that are targeted to intercept a cellular malfunction that leads to cancer. There are other promising approaches to treatment of blood cancers, including cancer vaccines, employing immunotherapy, laboratory-designed monoclonal antibodies that target therapy to tumor antigens and leave the normal cells in tact, and the use of an antibody to carry a radioactive isotope or toxin to the cancer cells.

The investment in research on the blood cancers will yield benefits beyond improvements in treatments for these cancers. The advances in understanding and treatment of blood cancers have also contributed to enhanced therapies for other forms of cancer. Chemotherapy drugs that were developed for treatment of leukemia, for example, are now saving the lives of individuals with solid tumors. Molecular therapies, such as Gleevec that I just mentioned, has also been beneficial and is saving the lives of patients with gastrointestinal tumors. Support for hematological cancers benefits all cancer research and has the potential to improve the lives of many cancer survivors.

On behalf of the hundreds of thousands of leukemia, lymphoma and myeloma survivors and their families, friends and caregivers, we would like to thank you for your attention to hematological cancer research and education. We look forward to committee approval of this bill, and we approve your efforts to advance this bill. Thank you.

[The prepared statement of Dwayne Howell follows:]

PREPARED STATEMENT OF DWAYNE HOWELL, PRESIDENT & CEO, THE LEUKEMIA & LYMPHOMA SOCIETY

Good afternoon, Mr. Chairman and Members of the Committee. I appreciate the opportunity to testify today on the Hematological Cancer Research Investment and Education Act of 2001. I am Dwayne Howell, the President and CEO of The Leukemia & Lymphoma Society. The Society is a voluntary health agency that raises funds to support research on the blood cancers and provides services to individuals with blood cancers and their families. In fiscal year 2001, we committed $36 million to hematological cancer research, including major grants to support specialized centers of research excellence in blood cancers, and we hope to fund research totaling almost $40 million in fiscal year 2002. Through our 59 chapters, we support patients and their families around the country.

The burden of the hematological cancers, including leukemia, Hodgkin's disease, non-Hodgkin's lymphoma, and multiple myeloma, is often underestimated. However, if these diseases are taken together, they represent the fourth most common cancer. In 2001, almost 700,000 are living with hematological malignancies. In this year, approximately 110,000 individuals will be diagnosed with leukemia, lymphoma, and myeloma, and more than 60,000 will die from these cancers.

These individuals, their families, friends, and caregivers applaud the efforts of Representatives Phil Crane, Marge Roukema, Mike Ferguson, and Vic Snyder to develop legislation to focus the nation's blood cancer research and education programs and we also appreciate the willingness of this Subcommittee to consider this bill in 2001. This is a time of great challenge and also tremendous opportunity for blood cancer research, and a coordinated and strengthened research program is essential. The obstacles of educating patients, their families, and the public regarding the blood cancers grow as our knowledge of the diseases deepens and the range of treatment options expands, and a public-private partnership in that educational effort is crucial.

The Hematological Cancer Research Investment and Education Act of 2001 authorizes an initiative to intensify and coordinate blood cancer research efforts at the National Institutes of Health (NIH) and the Joe Moakley Cancer Education Program within the Department of Health and Human Services. These programs will facilitate advances in the treatment of blood cancers and the education of patients and the public regarding blood cancers.

The federal government currently makes a substantial investment in blood cancer research, an investment that is complemented by the research support of The Leukemia & Lymphoma Society and other private research organizations. Despite the strong commitment of public and private funders, the research effort can be improved with more funding and greater coordination. The Hematological Cancer Research Investment and Education Act would make improvements in the existing research program to enhance the fundamental understanding of blood cancers and accelerate the development of new therapies.

The Act would also establish the Joe Moakley Cancer Education Program, an important educational initiative for patients and the public that would allow for coordination with existing private sector patient education and service programs. Patient service and education are major areas of focus for The Leukemia & Lymphoma Society, and we look forward to the federal government's involvement and collaboration in patient and public education.

The Leukemia & Lymphoma Society appreciates the tremendous responsibilities and pressures that face the Congress as it attempts to respond to the events of September 11, and we would like to express our deep appreciation for your decision to focus on the hematological cancer research and education bill in the midst of these pressures. Your prompt action to evaluate this legislation is critically important to individuals living with blood cancers and their families and friends. The opportunity for research advances and the necessity for educating patients about those advances confront us NOW, and the Hematological Cancer Research Investment and Education Act will help us respond to those challenges.

Over the last half-century, researchers have made impressive advances in the treatment of some forms of leukemia and Hodgkin's disease. In fact, many cite these diseases as success stories of cancer research. There has been much less progress in the treatment of non-Hodgkin's lymphoma, multiple myeloma, and some forms of leukemia. Particularly troubling is the fact that the death rate for non-Hodgkin's lymphoma has increased by 45% from the time period between 1973 and 1998 and the death rate for multiple myeloma has increased by more than 32% in the same time period.

Despite these troubling statistics, we have reason to be hopeful. Our substantial investment in basic research has yielded enhanced knowledge of the nature of hematological cancers and contributed to advances in treatment. Genetic and molecular analyses of hematological cancers are identifying targets for drug development, and this work has yielded a groundbreaking new therapy for chronic myelogenous leukemia, or CML. We hope this new therapy, a signal transduction inhibitor called Gleevec, is the first of other similar drugs that are targeted to intercept a cellular malfunction that leads to cancer. There are other promising approaches to treatment of blood cancers, including cancer vaccines employing immunotherapy to enhance the recognition and destruction of cancer cells; laboratory-designed monoclonal antibodies to use the specificity of an antibody directed against a tumor antigen to target therapy to the tumor, sparing normal cells; and the use of an antibody to carry a radioactive isotope or toxin to the cancer cells.

The investment in research on the blood cancers will yield benefits beyond improvements in treatments for these cancers. The advances in the understanding and treatment of the hematological cancers have also contributed to enhanced therapies for other forms of cancer. Chemotherapy drugs that were developed for treatment of leukemia, for example, are now saving the lives of individuals with solid tumors. Support for hematological cancers benefits all cancer research and has the potential to improve the lives of many cancer survivors.

To ensure that we realize the benefits of our investment in basic research and continue to make advances in the treatment of blood cancers, there must be a strong partnership between the private and public sectors. A special panel of researchers convened by the National Cancer Institute (NCI), called the Leukemia, Lymphoma, and Myeloma Progress Review Group (LLM PRG), has developed a comprehensive set of recommendations for hematological cancer research. This ambitious plan reflects lengthy deliberations of a group that included researchers, government officials, industry, and patient advocates and sets an aggressive course for hematological cancer research, with a special emphasis on partnerships between the private and public sectors. The Hematological Cancer Research Investment and Education Act will help us realize the goals of the PRG report, which are concentrated on accelerating the development of new therapies for leukemia, lymphoma, and myeloma.

On behalf of the hundreds of thousands of leukemia, lymphoma, and myeloma survivors and their families, friends, and caregivers, we would like to thank you for your attention to hematological cancer research and education. We look forward to Committee approval of this bill, and we appreciate your efforts to advance this bill.

Mr. BILIRAKIS. Thank you very much, sir. Ms. Johnson?

STATEMENT OF JACQUELINE L. JOHNSON

Ms. JOHNSON. I am honored to be here today on behalf of the National Congress of American Indians, which is the largest national organization of tribal governments in this Nation, to discuss with you an issue that is of great concern to our Health Committee. And at the last mid-year session of the National Congress of American Indians, we passed a resolution supporting the inclusion of the Native American women in the Native American Breast and Cervical Cancer Treatment Technical Amendment Act.

I also would like to begin by thanking Mr. Udall of New Mexico and the co-sponsors of this act for taking the initiative to put forward this corrective action, and I might also note that there are written statements also in support of the inclusion of the Native American women by not only Tom Udall, J.D. Hayworth, J.C. Watts, American Cancer Society and the National Native American Indian Health Board.

It is our—as we know, in the original passage of the act, the HIPAA Act, there was a reference to include Indian health care that was not originally included in the HIPAA Act so that members of the tribes that were eligible for Indian Health Service and not necessarily under insurance coverage could be considered eligible for this important provision, which also dealt with the fact that

there are many times tribal members who have received health services under Indian Health were not necessarily—would not be subject of pre-existing conditions and long waiting periods when seeking health insurance.

Thus, in the HIPAA context, the inclusion of the Indian health tribal provision was intended to benefit American Indians and Alaskan natives, and, unfortunately, as you heard earlier by Mr. Pallone and by the statement of the chairman, in fact the act had the opposite effect. And rather than in benefiting the American Indian women, it works to penalize them from receiving coverage under the Breast and Cervical Cancer Treatment and Prevention Act. In fact, many Indian women who rely on the Indian Health Service tribal programs for basic health are excluded within the new law eligibility for Medicaid. Not only does this definition deny coverage to Indian women, but also the provision runs counter to the general Medicaid rule that allow Indian Health Service facilities to be full medical providers.

In summary, I would just like to also note that as a Native American woman whose family has breast cancer in their direct line and who all my family receives services under the Indian health care service provisions, I know that this is a deep concern to not only Native American women, Indian Health Board but certainly to my family, additionally. We support the technical amendment that clarifies, for the purposes of this Breast and Cervical Cancer Treatment and Prevention Act, that credible coverage shall not include the Indian Health Service funded care so that American Indians and Alaska native women can be covered by Medicaid for breast and cervical cancer treatment.

And with that, I would like to thank you for your support in including the Native Americans to correct, which I am sure was not intentional but an oversight of the committee, and I am sure that the right things will be done. Thank you. Goonesh Shish.

[The prepared statement of Jacqueline L. Johnson follows:]

PREPARED STATEMENT OF JACQUELINE JOHNSON, EXECUTIVE DIRECTOR, NATIONAL CONGRESS OF AMERICAN INDIANS

Good Afternoon Chairman and distinguished committee members. It is an honor to be invited to provide testimony before the House Energy and Commerce Committee, Subcommittee on Health. I am Jacqueline Johnson, Executive Director of the National Congress of American Indians (NCAI). As the oldest and largest national Indian advocacy organization in the United States, NCAI is dedicated to advocating on behalf of our member tribal governments on a broad range of issues affecting the health, welfare, and self-determination of Indian Nations. I greatly appreciate the opportunity to make comments on H.R. 1383, the Native American Breast and Cervical Cancer Treatment Technical Amendment Act of 2001, and ask that this statement be included in the hearing record.

I would like to begin by thanking Mr. Udall of New Mexico and the cosponsors of H.R. 1383 for taking the initiative to correct language in the Breast and Cervical Cancer Treatment and Prevention Act so that Indian women will not be denied treatment for breast and cervical cancer.

NCAI member tribal governments strongly endorsed the inclusion of Indian women in the Breast and Cervical Cancer Treatment Program through a resolution passed earlier this year at its midyear session. This bill makes an extremely important yet simple technical change to the "Breast and Cervical Cancer Treatment and Prevention Act" (P.L. 106-354) that will improve the coverage of breast and cervical cancer treatment for American Indian and Alaska Native women.

The Breast and Cervical Cancer Treatment and Prevention Act gives states the option to extend coverage to certain women who have breast or cervical cancer who have been screened by programs operated under Title XV of the Public Health Serv-

ice Act (the National Breast and Cervical Cancer Early Detection program) and who have *no* "creditable coverage."

The Health Insurance Portability and Accountability Act of 1996 (HIPPA) established the term "creditable coverage." Under HIPPA, the term "creditable coverage" is defined to include a reference to the medical care program of the Indian Health Service (IHS). *In short, the reference to "creditable coverage" in the Breast and Cervical Cancer Treatment and Prevention Act effectively excludes Indian women from receiving Medicaid breast and cervical cancer treatment as provided for under the Act.*

The Indian health reference to IHS/tribal care was originally included in HIPPA so that members of Indian Tribes eligible for IHS would not be treated as having a break in coverage (and thus subject to pre-existing exclusions and waiting periods when seeking health insurance) simply because they had received care through Indian health programs, rather than through a conventional health insurance program. Thus, in the HIPPA context, the inclusion of the IHS/tribal provision was intended to benefit American Indians and Alaska Natives.

Unfortunately, use of the HIPPA definition of "credible coverage" in the recent "Breast and Cervical Cancer Treatment and Prevention Act" has the exact opposite effect, and rather than benefiting American Indian women, it works to penalize them from receiving coverage under the Breast and Cervical Cancer Treatment and Prevention Act.

In fact, the many Indian women who rely on IHS/tribal programs for basic health care are excluded from the new law's eligibility for Medicaid. Not only does the definition deny coverage to Indian women, but the provision runs counter to the general Medicaid rule treating IHS facilities as full Medicaid providers. Without this important correction, the many Indian women impacted by breast and cervical cancer will be left without the resources needed to reverse this trend because of their exclusion from the new Medicaid coverage option.

H. R. 1383, would remedy these problems by clarifying that, for purposes of the "Breast and Cervical Cancer Prevention and Treatment Act," the term "creditable coverage" *shall not* include IHS-funded care so that American Indian and Alaska Native women can be covered by Medicaid for breast and cervical cancer treatment.

Improving the health of Indian women in Indian Country is an important component of NCAI's health agenda. I am confident to say that NCAI supports H.R. 1383 as an important technical amendment to ensure that American Indian and Alaska Native women receive life-saving breast and cervical cancer treatment. We look forward to working with this committee to improve the health and the well-being of Indian people. Thank you once again for the opportunity to provide this statement in support of H.R. 1383, the Native American Breast and Cervical Cancer Treatment Technical Amendment Act of 2001.

Mr. BILIRAKIS. Well, thank you, Ms. Johnson. And it clearly was an oversight; certainly was not intended. You are correct there.

Well, there is so much. Mr. Morgan, you mention in your written testimony that 21 States presently collect data on benign brain tumors.

Mr. MORGAN. Yes.

Mr. BILIRAKIS. So I guess my questions are: What is done with this data, and has the collection of the data led to improvements in public health? Because you emphasize the collection of the data and it should be listed on the registry, and I tend to agree with you. I am just wondering what the positive effect of that would be. Explain.

Mr. MORGAN. Yes. The 21 States that do collect, three of those States only began in—or the legislation was only passed in the last year, which includes California. The registry data, in general, is used to determine incidence of morbidity, treatment outcomes and so on. And within the States, I presume that that is being done. Within the United States, there is no national data base, except from a small non-profit that I am a member of the board of, the Central Brain Tumor Registry of the United States. And the reason that we know, for example, that the mortality 5-year survival rates for women with meningiomas is lower than breast cancer is be-

cause that data allows that to come together from the States, and that is based on, I think, 12 States. Does that answer your question?

Mr. BILIRAKIS. I guess I am looking for a little more than that. The collection of the data, in other words, how does it directly help in terms of improvements in public health? What is it? Is there a determination of environmental factors that might lead to——

Mr. MORGAN. Exactly. In order—I mean the overall concept of collecting the data not only allows you to understand what kinds of treatments have what kinds of effects and so on, but in the end the true desire is to determine the etiology, the cause. And without the data, there is no way to look. There is nothing to go looking for.

Mr. BILIRAKIS. All right. Great. That is what I figured, but I just wanted to hear it from you.

Dr. Howell, I understand that less than 5 percent of Federal funds for cancer research are spent on blood cancers, and yet, as I understand it, blood cancers account for about 11 percent—might be more—of all cancer deaths in the United States. So give me your opinion. Have you looked into the NIH research, and do you feel that they are neglecting blood cancer research?

Mr. HOWELL. Well, the NIH estimate of 5 percent of the outlay for cancer research going toward blood cancers is that, an estimate. I can't dispute or agree with that estimate. I can say this: That there has been good work done by the National Cancer Institutes and other institutes, and we are on the edge of a time now when research investment will save lives. Gleevec, a non-toxic, genetic therapy, developed just recently, has borne that out. And the point I would make is that research by the NIH, that kind of investment, and by private funders, such as WE, will result in lives saved now, and the promise is greater than it has ever been.

Mr. BILIRAKIS. So you are satisfied that generally—nobody is really ever satisfied, because we never think enough money goes into research—but as far as the NIH funding for research is concerned, that it is basically doing the job?

Mr. HOWELL. The NIH is launching good programs. We would like to see greater investment at the NIH and among private funders as well, because that extra investment is what is needed to leverage this increased scientific understanding that might help.

Mr. BILIRAKIS. This committee, has hearings as you can imagine on a number of different sicknesses and illnesses, many of which many of us have never even heard of. And, of course, we have had Muhammad Ali and just so many others here pleading for more money for Parkinson's research, for instance.

What we try to do here in the Congress is—and, really, I think we have been pretty cooperative. We just feel we are an ivory tower, and we don't really know how much money should go into research for Parkinson's against the owners of that illness. Therefore, we leave it up to NIH to make that determination, although every once in a while we will write a letter and ask them for a greater emphasis, regarding a particular illness.

I just wanted you to know that that is basically a policy that we establish here, because, who are we to tell them? We like to think, too, as you have indicated, that when they are right on the verge

of a breakthrough, then they can focus more dollars there, and how can we tell them where those dollars should go?

Mr. HOWELL. Well, I should say, Mr. Chairman, that the National Cancer Institute convened a Progress Review Group on blood-related cancers and worked with that group and agreed that this was an areas where focus and emphasis would have a strong return on investment, based on the therapies and the discoveries that have come to light recently. So I don't think we are in dispute with the National Cancer Institute or the National Institutes of Health that more investment here is timely.

Mr. BILIRAKIS. Yes, sir. Thank you. Ms. Hoffman, Ms. Saraceni, your stories are just—well, they trouble us; there is no question about that, particularly Ms. Hoffman. But I do know that my colleagues are going to concentrate on those particular areas. And I would now yield to Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman, and I do have some questions on the other issues, but this is the first time we have been able to do this, and I thank you again for having hearing. I would like to first ask Ms. Noonan-Saraceni, you mention in your testimony that there is little research being done on the effects of implants on women who use them for reconstruction following a mastectomy, but we know that more than 70 percent the mastectomy patients experience some complications. Can you comment on the situation and your concerns about the lack of research, as a breast cancer survivor?

Ms. NOONAN-SARACENI. As a breast cancer survivor, I mentioned earlier that I am more ill now than I was prior to. I just basically have statistics that there has not been any breast cancer patients in the NIH studies, so from there the statistics are basically what has been sent in from women that we have done—the manufacturers.

Mr. GREEN. If Ms. Hoffman or Dr. Zuckerman would comment on it.

Ms. ZUCKERMAN. Yes. Let me just mention the complication rate of over 70 percent is based on the manufacturers' own studies. The only studies that have been conducted were conducted in order to get approval for saline breast implants. And so when the studies were submitted to the FDA a couple of years ago, they provided data on just a few hundred, I think it was about 300, breast cancer survivors who had used implants, and their complication rates for Magan and Mentor, the two manufacturers, were over 70 percent. But those are the only studies, and they did not look at illnesses. So when we say there is no research on mastectomy patients, we mean that there is research on complications, what are called local complications, such as infection, but not on systemic diseases, such as cancer, autoimmune disease or other diseases.

Mr. GREEN. Okay. Dr. Zuckerman, one of the things the legislation calls for is improved informed consent for patients so they know exactly what the risks are for implants before they get them. Can you tell our committee, for the record, a little bit about the current information provided to implant patients and why it is not sufficient?

Ms. ZUCKERMAN. Sure. Basically, the doctors really have total freedom to provide the information that they see fit. One of the in-

teresting developments of recent years is that plastic surgeons are frequently requiring patients to sign forms that basically give away their legal rights but don't necessarily give them much in the way of informed consent rights. And so when the FDA approved saline breast implants in the year 2000, the Advisory Committee specified that it was absolutely essential that patients be given informed consent, better information about risks. The FDA did not require the surgeons to do that, and so it really is up to the surgeons.

Most of the information that is available is available from, basically two different sources: One is the manufacturers themselves. They do have package inserts, just the same kind of inserts that you might see when you buy cold medication, for example, written in the same teeny tiny type that people can't read. In addition to that, in the case of implants, the package insert is given to the surgeon. The surgeon is the person who buys the implant, not the patient, and so there is not a requirement to give that information directly to the patient. So that is one potential source of information that patients may see but don't necessarily get to see. And the other is information from the FDA itself. They do have a patient brochure which is quite good but is not totally up to date, does not include information from these new studies showing increased risks of cancers, for example, and increased risks of autoimmune diseases.

So the short answer is currently there is no requirement, and that means that some doctors do a great job of providing information about risks, and other doctors provide very poor information or no information practically at all.

Mr. GREEN. Okay. In your testimony, you point out that Congress has already told NIH once that they need to perform a study on breast implants, including a study on the breast cancer survivors. And there is some reluctance, I guess, from the NIH's own behalf to perform the study. Can you comment on why you think there is that resistance to getting this information the first time around and what we can do in the future to really find out this need?

Ms. ZUCKERMAN. Sure. It was really shocking to me, as a congressional staffer at the time, that Congress would ask that something be done and it would just be ignored like that. And, basically, the person who was the head of NIH was Bernadine Healy who was the first woman head of the NIH. She just refused to include mastectomy patients in the study. I think it was because including cancer patients makes the study more complicated and makes it more expensive. You have to deal with things like some of the patients get chemotherapy and some get radiation and some don't, things like that. It does make a study more expensive.

My training is in epidemiology, so I really understand research design, but on the other hand, this is a very important group of women. So even though the study might have cost more, might have been more complicated, I don't think anybody in this room thinks that breast cancer patients don't deserve to have studies to find out whether implants are safe for them. So I think that if—I hope that if the Congress this time, well, first of all, puts it in a bill as opposed to, I think in a letter to Bernadine Healy, I think that having it in legislation will make a big difference, hopefully.

Mr. GREEN. Thank you. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I am contemplating maybe a brief second round, I might add at this point. These good people have waited a long, long time for us to get back here to get started. The least we could do is give them an opportunity to communicate to us. Mr. Blunt to inquire.

Mr. BLUNT. Thank you, Mr. Chairman. Thank you again for holding this hearing. Let me ask, first of all, Dr. Zuckerman, what do you think that the average person when they get the safe and effective determination from FDA would assume that means?

Ms. ZUCKERMAN. Well, if they are like everybody I know, they assume that it means that a product is really truly safe. I think one of the shocking things to me is that when you have a product that is really cosmetic—implants are a cosmetic product; they don't save lives. They may improve the quality of life for some women, particularly women after a mastectomy, but they are not life saving. And so you would think the standard would be higher. But in this particular case, saline breast implants were approved despite a very high complication rate. Silicone gel breast implants have never been approved at all.

So I think that patients do assume that if they are sold even in this country, they must be safe and especially if they are approved, they must really be safe. And in this case, I was at the Advisory Committee meeting when experts were looking at the data, and they were saying things like, "Well, I guess they are safe if you define safe as not killing people," which I don't think is a good standard for a cosmetic device.

Mr. BLUNT. I might ask you, Ms. Hoffman, the same question. When you were told these were safe and they are FDA approved as safe and effective, what did you assume that meant?

Ms. HOFFMAN. I was told not only that they were safe but they would last a lifetime, so I assumed that they would not cause me to have to have additional surgery. I did not know that they would cause me to not be able to work or to become uninsurable. I was put on disability, I lost my businesses, I lost my health insurance, and now I have trouble getting health insurance. Even women who have removed their breast implants have trouble getting health insurance. It is as thought the health insurance companies know something that the rest of us don't, because we are excluded. I would say those——

Mr. BLUNT. Would you say it is fair—did you rely on what the doctor told you at that point or did you really rely on the FDA? At the point you were making this decision, did you even think to ask, "What does the FDA say?"

Ms. HOFFMAN. Really, at that time, I didn't know very much about the FDA. I relied solely upon my searching.

Mr. BLUNT. Ms. Noonan-Saraceni, what did you rely on when you decided to have this done, in terms of advice?

Ms. NOONAN-SARACENI. Well, as you know, I was 25 years old when I had the cancer, so I was 30 when I went to have the reconstructive surgery done. At the time, I went to three different plastic surgeons. At no time, from any of the plastic surgeons, was I ever told there was any complications or any health risks. In fact, I was told, "Well, you could probably get hit by a mack truck and the im-

plant will survive." But, again, I didn't know to even look to the FDA or even to see if there was a record on the FDA at that point, because I mean at that point in my life, I thought doctors were God and they didn't make mistakes.

Mr. BLUNT. I guess, going back to your testimony, you probably felt like you were hit by a Mack truck——

Ms. NOONAN-SARACENI. Yes, I did. Thank you.

Mr. BLUNT. [continuing] during part of that. Ms. Hoffman, how did the FDA respond to your complaints that your surgeon and the manufacturer were ignoring the complaints you were making to them? What did the FDA do when you contacted them?

Ms. HOFFMAN. They were dismissive. They did not follow up. My plastic surgeon remains a clinical investigator in the clinical trials today.

Mr. BLUNT. He remains what? Your plastic surgeon he or she remains what?

Ms. HOFFMAN. A clinical investigator. He continues to enroll patients in this study in spite of the fact that he did not report my complications to be included in the study.

Mr. BLUNT. So you assumed you were going to be part of a study, because he was doing that, and you were not included in that study?

Ms. HOFFMAN. By law, I had to be part of a study to receive silicone breast implants after the moratorium in 1992. And as part of the protocol of the study, any complications that I experienced were mandated to be reported by the plastic surgeon who was the clinical investigator. Those were to be reported to the sponsor, to the manufacturer and included in the study data. And that did not happen in my case.

Mr. BLUNT. Dr. Zuckerman, you watched this approval process. How do you think FDA could have improved what they did in the follow-up? I know that is maybe too broad a question, but give us some thought as to what you—where you think FDA made their most significant mistakes in those two processes?

Ms. ZUCKERMAN. Sure. I would be delighted to answer that question, but how much time do you have?

Mr. BLUNT. Well, not much probably is the answer to that.

Ms. ZUCKERMAN. Right. Well, a couple of things. One was that the Advisory Committee made a lot of suggestions about what they thought needed to be done, and they actually asked—their hope was that the FDA would have to—I'm sorry, that the manufacturer would have to provide more data and better data before implant approval or non-approval would be decided. But the FDA instructed the Advisory Committee that all they could advise was yes or not. And then they said, in a way that I thought was quite biased, "And you know, if you say you don't want to approve these, they are going to have to be removed from the market immediately." So it seemed to me quite a biased arrangement where the instructions were clearly headed toward one direction, which was approval.

The other thing was the Advisory Committee said things like, "Girls under the age of 18 should not be able to have breast implants, because they are too young and they have never been tested on anybody that young," and they made other kinds of restrictions, and the FDA officials never instructed the Advisory Committee

that these were instructions that they could not follow, that they didn't have—FDA didn't have the authority to make the kinds of caveats that the Advisory Committee was making.

But perhaps the biggest issue of all was the fact that the FDA made its—that both the Advisory Committee and the FDA afterwards made decisions based on just 3 years of data. When you have an implanted device that is going to be in somebody's body for a lot longer than 3 years, I think it is very dangerous to make an approval based on only 3 years, especially when there are all these problems in just the first 3 years.

Mr. BLUNT. I guess you could see the follow-up there. You know, you can't, obviously, assuming it is a safe—that it truly is safe and effective, you wouldn't want to go an entire lifetime before you approved it to anybody else, but I think I see your point.

Mr. Chairman, I have got one other meeting that I have got to go to. If I could ask one more question, not to interfere with the second question.

Mr. BILIRAKIS. Without objection, please proceed.

Mr. BLUNT. You mentioned, I think in your testimony, that the number of young women, women under 18, has risen dramatically who are having these implants done. Do you have some idea how hard is that to get done if you are under 18? Do you have to have parental consent in every State? What do you find out? I assume, in most cases, for young girls, this is augmentation, but I don't know. Could you talk to us a little bit about that?

Ms. ZUCKERMAN. Yes, absolutely. Any surgery for anybody under the age of 18 has to have the approval of a parent, whether it is breast implants or anything else. Because there is no real teeth in this whole issue of informed consent, we are particularly concerned that 17, 16-year old girls really don't have the information that they need to make these decisions, and the parents aren't necessarily given that information either. So the number of teens getting breast implants for augmentation—I am only talking about augmentation—has more than doubled in the last 3 years, and there is a lot of advertisements for breast implants in magazines that teenage girls read.

So there is a lot of pressure, of course, and I have a 14-year old daughter. Anybody who has a teenager knows there is a lot of pressure to look a certain way. It is a very vulnerable time, and I think it is very dangerous to be having ads and other pressures on these girls without having the kind of information about risks that they need. I am not even sure you could convince a 16-year-old girl anyway, but at least that their parents could use.

Mr. BLUNT. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman. Ms. Johnson, how many Native American and native Alaskan women, in terms of percentage, I suppose, receive health care under the Indian Health Service?

Ms. JOHNSON. I am not sure of that number. I certainly could get that to you. I know as far as number of women who would be affected by this technical amendment, there is about 90 to 100 Native American women who are in this category of breast or cervical cancer on an annual basis.

Mr. BILIRAKIS. Ninety to 100 on an annual basis.

Ms. JOHNSON. Yes.

Mr. BILIRAKIS. Well, let me ask you then, this is more of a general, generic question, I guess. How accessible to these women is Indian Health Service as against other health—whether it be Medicaid or whatever?

Ms. JOHNSON. Okay. Actually, Native Americans rely on Indian Health Service as their primary service provider, period.

Mr. BILIRAKIS. They rely on it.

Ms. JOHNSON. Excuse me?

Mr. BILIRAKIS. Yes. They rely on it.

Ms. JOHNSON. They rely on upon it as the primary service provider, whether the tribe itself is a self-governance tribe and actually compacts with Indian Health Service to provide their services or they are a direct service tribe where the Indian Health Service provides the service directly. And the reason why this has become such an issue for us is because when you are compact tribe and you provide your own Indian Health Service—you take on your own responsibility for Indian Health Service, the pot of money at Indian Health is non-existent or very, very small for any kind of major health issues that come to you, that affect you. And the tribe has to—once that allocation is gone for that year, the allocation is gone, and there is no more money. It doesn't matter what the circumstances are without getting special approval from Indian Health Service.

Mr. BILIRAKIS. Well, then why do we have then separate Indian Health Services? We are talking about good people who are Americans. I mean why is not the health services that are available to the American people, in terms of Medicaid, Medicare, whatever the case may be, why is that not just available to them? Why is it we have separate Indian Health Services?

Ms. JOHNSON. Well, there is a number of things. Part of it is—some of it is in the treaty rights with the government-to-government relationship to provide——

Mr. BILIRAKIS. I know, but that goes way back to the——

Ms. JOHNSON. Right.

Mr. BILIRAKIS. Yes.

Ms. JOHNSON. And because of a lot of the areas of our communities, the remoteness of our villages and the reservation boundaries, to get adequate coverage like the general public gets provided would probably if the private was trying to provide it, it would be non-existence totally. So the Federal Government provides this service to us, and I have to say as a person who has received Indian health care all my life until I came to DC, in fact that was a real interesting experience.

Mr. BILIRAKIS. Yes. Apparently, it has treated you pretty well.

Ms. JOHNSON. Yes. They treated us pretty well. And my tribe is actually a compact tribe, where we actually provide, through a contract with Indian Health Service, our own care. And it wasn't until recently that when we were fully Medicaid-eligible, when we actually could apply for—when we had tribal members who were insurance-eligible, many of our jobs and occupations don't have health care coverage unless you are with the Federal Government on a reservation. So the provision of insurance and insurance coverage

is limited, and therefore Indian Health Service picks up the gap in those provisions.

Mr. BILIRAKIS. I guess I can see where there would be a gap there; obviously, there is. We know that there is a lot of uninsured out there, and so that would be beneficial. Is the quality—maybe the benefits, are the benefits basically comparable in terms of what is available? I shouldn't say quality. I would like to think the quality is——

Ms. JOHNSON. There is tremendous shortage in health care. Even in Indian Health Service, the care providers—you know, the lines are always long, you have long, long waits for surgery or other issues related to that. Tribes are very challenged by having to make decisions about what is a priority. Prevention versus treatment is a major issue, because when you have to prioritize your limited health resources, it goes more to treatment. We do very little in the ways of prevention. As you know, diabetes and other things are majorly affecting and sweeping through our communities in substantial numbers that we don't have—we have to travel long, long distances for any kind of treatment. Blood transfusions are non-existent, mammograms——

Mr. BILIRAKIS. Well, my time is up, you have separate Indian health care, and I have always wondered—I understand that back in the days before Medicaid and Medicare, which are all relatively recent, that Indian health care would have been certainly the thing back then, but I just wonder today if that is a good idea, and look at the gap that we are talking about here as a result of this legislation.

Well, all right. It is a subject, though, that I have always wondered about, and I am certainly not sitting here saying I am against Indian health care, but I just wonder if that really the best for the Native Americans today, considering today's circumstances? If you have anything on that, please write me a memo or something.

All right. Does the gentleman have anything?

Mr. GREEN. No, no other questions.

Mr. BILIRAKIS. We generally have written questions that we would like to submit to the panelists after the hearing and request responses in writing from you, and we would appreciate your, of course, being amenable to furnish those answers to me. And I would like to hear from Ms. Johnson regarding my question, in general.

Mr. GREEN. I was just going to see if we could leave the record open for a number of days, whatever the requisite that we have.

Mr. BILIRAKIS. Yes, that is customary the record is open. And you have been very helpful. I know I have learned an awful lot. Thank you very much. The hearing is adjourned.

[Whereupon, at 5:18 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

JOINT PREPARED STATEMENT OF HON. TOM UDALL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW MEXICO; HON. J.D. HAYWORTH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ARIZONA; AND HON. J.C. WATTS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OKLAHOMA

Mr. Chairman: Thank you for including H.R. 1383 in your hearing today on raising health awareness. These are very important issues and we thank you for the opportunity to offer this joint statement on our legislation.

On Tuesday April 3, 2001, the three of us joined by Representatives Dave Camp, Dale Kildee, Patrick Kennedy, Rosa DeLauro, and Sherrod Brown introduced the "Native American Breast and Cervical Cancer Treatment Technical Amendment Act of 2001." This legislation makes a simple but extremely important technical change to the "Breast and Cervical Cancer Treatment and Prevention Act" (P.L. 106-354) to improve the coverage of breast and cervical cancer treatment for American Indian and Alaska Native women.

The Breast and Cervical Cancer Treatment Act which Congress passed last year gives states the option to extend coverage to certain women who have been screened by programs operated under Title XV of the Public Health Service Act (the National Breast and Cervical Cancer Early Detection program) and who have no "creditable coverage." The term "creditable coverage" was established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Under the HIPAA definition, creditable coverage includes a reference to the medical care program of the Indian Health Service (IHS). In short, the reference to "creditable coverage" in the law effectively excludes Indian women from receiving Medicaid breast and cervical cancer treatment as provided for under this Act.

The Indian health reference to IHS/tribal care was originally included in HIPAA so that members of Indian Tribes eligible for IHS would not be treated as having a break in coverage (and thus subject to pre-existing exclusions and waiting periods when seeking health insurance) simply because they had received care through Indian health programs, rather than through a conventional health insurance program. Thus, in the HIPAA context, the inclusion of the IHS/tribal provision was intended to benefit American Indians and Alaska Natives, not penalize them.

However, use of the HIPAA definition in the recent "Breast and Cervical Cancer Treatment and Prevention Act" has the exact opposite effect. In fact, the many Indian women who rely on IHS/tribal programs for basic health care are excluded from the new law's eligibility for Medicaid. Not only does the definition deny coverage to Indian women, but the provision also runs counter to the general Medicaid rule treating IHS facilities as full Medicaid providers.

This legislation would resolve these problems by clarifying that, for purposes of the "Breast and Cervical Cancer Prevention and Treatment Act," the term "creditable coverage" shall not include IHS-funded care so that American Indian and Alaska Native women can be covered by Medicaid for breast and cervical cancer treatment. Since a number of states are currently moving forward to provide Medicaid coverage under the state option, the need for this legislation is immediate to ensure that American Indian and Alaska Native women are not denied from receiving life-saving breast and cervical cancer treatment.

In addition to enjoying support of 112 of our colleagues, H.R. 1383 is also supported by the American Cancer Society and the American College of Obstetricians and Gynecologists. We would like to ask that their letters of support be included in the record.

Mr. Chairman, this legislation is a simple yet critical change that will help many American Indian and Native Alaskan women enjoy longer, healthier lives in spite of cancer. There is absolutely no reason why these women should be denied treatment for breast and cervical cancers. However, this is precisely what happens because of the definition of creditable coverage, combined with the fact that not all American Indian and Native Alaskan women have access to breast and cervical cancer treatment at I.H.S. health facilities. H.R. 1383 will ensure that American Indian and Native Alaskan will receive the treatment they need and deserve.

Again, thank you for allowing us the opportunity to offer our statement for the record today. We hope the committee will see the merits of this legislation that is critically important to many American Indian and Native Alaskan women.

PREPARED STATEMENT OF CHRISTOPHER CONWAY, PRESIDENT, MENTOR CORPORATION

Dear Mr. Chairman, thank you for this opportunity to submit testimony on behalf of Mentor Corporation to the Committee on the safety and efficacy of breast implants. As a leading global medical device company, we address a wide variety of health-related needs, including incontinence, prostate cancer, impotence, and aes-

thetic and reconstructive surgery. Mentor Corporation manufactures breast implants for purposes of breast reconstruction and breast augmentation.

We share the Committee's concern that the best studies, information and facts be available to the public. We believe like the Committee that women have the right to know the risks and benefits of any medical procedure and device they might choose. Nevertheless, we have serious concerns about HR 1961 and do not believe that as currently drafted this legislation will achieve the Committee's goals.

The bill does not accurately reflect the history or status of breast implants in the United States. The findings are based largely on anecdote and poorly constructed and discredited studies and ignore the conclusions of the National Academy of Science's own Institute of Medicine study and other findings by several multidisciplinary panels of internationally-recognized scientists and physicians. Among the many findings, the IOM panel found that breast implants are safe and do not pose serious health risk for women. The studies also show that women can safely breast feed their babies, receive adequate breast care, including mammography and experience no greater risk for breast or other cancers than women without implants.

HR 1961 also ignores the federal regulations and requirements for breast implants. Premarket approval for saline implants requires rigorous research and study that does not stop with the approval of the product. We are required to conduct and submit reports on a 10-year-post-approval study to assess the long-term clinical performance of this device. Continued approval of our product is also contingent on our compliance with the FDA statutes and regulations for medical devices including regular inspections and reports.

Finally, the legislation does not recognize the plethora of unbiased information currently available to breast implant patients, including our company's patient information booklet, which contains a discussion of the risks of breast implants and the materials widely available on the FDA's new breast implant web site.

We believe this testimony will provide the Committee with a more balanced perspective on the safety of breast implants by reviewing the status of past and ongoing research, the FDA's regulatory approval and oversight process for breast implants, and the unbiased information currently available to women considering implants.

THE HISTORY OF SALINE AND SILICONE BREAST IMPLANTS [1]

There have been continued advances in the manufacture and regulation of breast implants over the last decade, including a greater scrutiny by the government and its scientific agencies, as well as by several multidisciplinary panels of internationally-recognized scientists and physicians. There are two general types of breast implants approved for marketing, saline-filled and silicone gel-filled, both of which our company offers to women meeting certain criteria. Saline-filled implants have an external silicone shell and are filled with sterile saline (salt water) by the doctor at the time of surgery. Silicone gel-filled implants have an external silicone shell but are pre-filled with silicone gel.

Saline Filled Implants

Saline implants have been available to women for more than 25 years. The FDA published a proposal in 1993 and a final rule in 1999, calling for safety and effectiveness data for saline-filled implants. Saline implants are available for breast reconstruction surgery and to women 18 years and older for breast augmentation.

The FDA granted premarket approval (PMA) for saline implants in May 2000 to Mentor, following their extensive review of the very large body of safety and efficacy data. Among our detailed submissions to the FDA—which involved more than 400 binders (approximately 750,000 pages)—were numerous preclinical studies, including chemical, toxicological, mechanical and manufacturing data. The submission also included results from clinical studies documenting the types and rates of local complications, as well as benefits, experienced by patients. These data are provided in both physician and patient labeling. The FDA also provides this information (including 3-year cumulative risk rates) on its public web sites.

Silicone Gel-Filled Implants

Silicone gel-filled implants are available for limited use. In 1992, the FDA approved our company's adjunct study for silicone gel-filled implants for reconstruction and revision only. In 2000, the FDA approved our "core gel" study (or IDE study) for breast augmentation, reconstruction, and revision for a specified number of patients at a limited number of sites. Mentor first began manufacturing breast implants in 1984.

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[1] See "Chronology of FDA Breast Implant Activities," attached.

STUDIES ON THE SAFETY OF BREAST IMPLANTS

Over the past decade, there has been very extensive further documentation of the safety and efficacy of breast implants that comes from a range of sources, including:

- Over 17 in-depth epidemiology studies (including many conducted by the leading medical and scientific institutions in this country) that have addressed long-term safety concerns such as potential immune effects or cancer
- Numerous clinical studies conducted by Mentor, including the saline prospective study, the adjunct study and most recently Mentor's core gel study
- Extensive preclinical studies conducted by Mentor using state-of-the-art methods
- Clinical studies conducted by outside organizations
- A wealth of studies in peer-reviewed published literature
- Findings of scientific expert panels, including the Institute of Medicine, the National Science Panel and the International Review Group

Institute of Medicine Study on Silicone Implants [2]

Because of issues regarding the safety of silicone implants, Congress asked the Department of Health and Human Services in 1997 to sponsor a study on silicone breast implants. HHS appointed the Institute of Medicine, part of the National Academy of Sciences, to conduct an independent and unbiased review of all past and ongoing scientific research regarding the safety of silicone breast implants.

IOM established a thirteen-member committee of distinguished medical, scientific and academic experts to conduct this study of both augmentation and reconstruction patients. The committee set out to evaluate past and ongoing studies of the relationship, if any, between implants and systemic disease; evaluate the complications during or after implant surgery; assess the biologic and immunologic effects of silicone and other chemical components of breast implants; assess the impact of breast implants, if any, on the offspring of women with implants and on breastfeeding; and assess the accuracy of mammograms. The committee studied and reviewed thousands of published scientific reports, citing almost 1,200 references in the text of the report, 80% of which are from peer-reviewed literature. It also studied selected industry research reports on silicone breast implants and heard presentations from the public, including representatives of consumer groups, researchers, and women with silicone breast implants.

The committee's work resulted in a 440-page report (published in book form in 2000) with the following findings:

- There is no evidence that silicone implants are responsible for any major diseases of the whole body.
- There is no plausible evidence of a novel autoimmune disease caused by implants.
- There was no increase in either primary or recurrent breast cancer in women with breast implants. Some studies even suggest lower rates of breast cancer in implanted women.
- The major issues with implants are local, but not life-threatening, complications. These include, implant removal, ruptures, deflations, capsulare contracture, disfigurement, infection and pain. *(Note: Mentor's recently completed Saline-Prospective Study already has, and its Core Gel Study currently underway will, provide detailed incidence rate data for these local complications.)*
- There is no danger in breast-feeding.
- No studies of women with breast implants show increases in cancer deaths because of mammographic diagnostic delay.
- Implants are not lifetime devices; risks accumulate over time, and many women should expect to have more than one implant.

National Science Panel and International Review Group Studies on Silicone Implants

The National Science Panel, commissioned by the coordinating judge (Judge Pointer) for the federal breast implant litigation, and The International Review Group, commissioned by the British Minister of Health both in 1998, also reviewed, analyzed and critiqued the scientific literature pertaining to the possible link between silicone breast implants and connective tissue disease. The unanimous findings of both reports showed that breast implants constructed from or filled with silicone do not constitute any significant risk for connective tissue disease.

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[2] See the Institute of Medicine "Information for Women about the Safety of Silicone Breast Implants," attached.

Adjunct and Core Gel Studies on Silicone Implants

Silicone gel-filled breast implants are currently available to women through an adjunct study and a "core gel" study, both of which are FDA-approved for our and at least one other company. These studies ensure that close attention is being given to the safety and efficacy of silicone gel-filled implants.

The adjunct study, FDA-approved in 1992, was developed to make silicone-gel filled breast implants available for reconstruction and revision patients to collect short-term complication data. Eligible women include those who have had breast cancer surgery, a severe injury to the breast, a birth defect that affects the breast, or a medical condition causing a severe breast abnormality and those who needed to have an existing implant replaced for medical reasons. Each woman in the adjunct study is required to have informed consent. Also Institutional Review Boards, composed of scientists, health professionals and community members who do not have a bias as to the outcome, oversee this study.

The core gel study is an IDE (investigational device exemption) study, which means it has been reviewed and approved by the FDA to ensure the data is meaningful and that patients are not exposed to unreasonable risks. This study was FDA-approved in 2000 for breast augmentation, reconstruction and revision for a specified number of patients at a limited number of sites. Generally, the IDE study data is used as the basis for a future PMA application to market the device for the clinical indications studied. Each woman who participates in an IDE study must give informed consent. Also an Institutional Review Board (IRB), composed of scientists, health professionals and community members who do not have a bias as to the outcome, oversee the study.

Saline Prospective Study

Our company's Saline Prospective Study, submitted to the FDA in 2000 as part of the PMA approval process, was a 36-month prospective study (with IRB oversight) that assessed all complications with breast implants as well as quality of life measures. It included both augmentation and reconstruction patients. Among the findings were:

- Risks were consistent with those reported in the medical literature for similar devices and indications.
- Augmentation patients have low risk.
- While reconstruction patients are at higher risk, they have greater potential emotional and physical benefits.
- Patients needing surgery on an existing implant experience similar or somewhat higher complication rates than surgery for primary implants.
- Despite some possible complications, patients report high levels of satisfaction and improved quality of life.

FEDERAL REGULATIONS AND REQUIREMENTS FOR SALINE BREAST IMPLANTS

The FDA has outlined rigorous conditions of approval for saline-filled breast implants that we must comply with in order to ensure continued approval of the PMA. One such condition is a 10-year post-approval study to assess the long-term clinical performance of the device. All patients enrolled in the Saline Prospective Study are asked to enroll in this post-approval study. Safety data must be collected annually out to 10 years. In addition, our company along with the other company with PMA approval must conduct a focus-group study to obtain immediate feedback on the patient brochure, "Making an Informed Decision," for both augmentation and reconstruction patients. We must also conduct a retrieval study, which must collect visual examination, physical and histological data on removed implants to determine reason for failure. Mechanical testing (i.e., fatigue rupture and shelf-life) is also required to collect additional information.

Continued approval of our PMA is also contingent upon:

- Submission of annual post-approval reports
- Adverse reaction and device defect reporting
- Various other reporting requirements under the FDA Medical Device Reporting Regulation

In addition, the FDA conducts regular inspections at our company and manufacturing facilities to make sure that we are in compliance with applicable FDA statutes and regulations. The FDA provides reports of these inspections to us once the inspection is closed. In addition, the FDA routinely performs investigations of companies to examine allegations by individuals of possible wrongdoing. HR 1961 includes references to such an investigation. The FDA should be allowed to adequately perform an investigation without outside interference.

MAKING INFORMED DECISIONS ABOUT BREAST IMPLANTS

Our company believes that women have the right to complete and accurate information about the potential health risks and advantages of breast implants in order to make informed decisions. In the past five years, there has been a dramatic increase in the information available for women considering implants from a variety of sources, including:

- Patient information brochures created by our company that lay out among other information risks, contraindications, questions to ask a surgeon about reconstruction and augmentation and the FDA MedWatch contact to report problems.[3]
- FDA's Breast Implant Information Page (http://www.fda.gov/cdrh/breastimplants) provides a breast implant customer handbook and other information that allows the customer to differentiate between breast implant labels and access information about possible complications, recent studies on breast implants.
- FDA's MedWatch (http://www.fda.gov/medwatch/index.html) or (1-888-463-INFOFDA) is available if a patient feels she has experienced a serious problem(s) related to her breast implants, she should have her health care professional report the problem(s) to the FDA.
- Online copies of the IOM, NSP and IRG reports are available to the public and can be obtained on the following web sites:
  - IOM: http://www.nap.edu/catalog/9618.html
  - NSP: http://www.fjc.gov/BREIMLIT/SCIENCE/report.htm
  - IRG: http://www.silicone-review.gov.uk/
- Junk Science web site (http://www.junkscience.com/) provides an extensive list of links to informative, recent newspaper articles concerning the current medical status and social opinion of breast implants. Many of the stories highlight the fact vs. fiction/ myths vs. reality aspects of breast implants.

In conclusion, I thank the Committee for the opportunity to submit testimony in order to ensure that a balanced record exists on the safety of breast implants. In order to create a fair record of the history of breast implants, I ask the Chairman to include the following documents for the record:

- Chronology of FDA Breast Implant Activities
- Institute of Medicine "Information for Women About the Safety of Silicone Breast Implants"
- Mentor's "Saline-Filled Breast Implant Surgery: Making an Informed Decision"

Thank you.

[3] See Mentor's "Saline-Filled Breast Implant Surgery: Making an Informed Decision," attached.