DEPARTMENT OF HEALTH AND HUMAN SERVICES
ASSISTANT SECRETARY FOR PLANNING AND EVALUATION
OFFICE OF HEALTH POLICY

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Date: 2-14-94

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Number of Pages (Including Cover): 4

Comments: Thanks!

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

The Honorable Richard E. Neal
House of Representatives
Washington, DC 20515

Dear Mr. Neal:

Thank you for your inquiry about coverage for mammography screening under the Health Security Act. I share your concern that women have appropriate access to these services.

The Health Security Act covers screening mammography for asymptomatic women over 50 with no cost sharing. Mammograms for diagnostic purposes, such as when lump is present, will be covered for women of all ages, subject to cost sharing as specified in the woman's plan.

The schedule of covered screening mammography for asymptomatic women outlined in the Act is consistent with the best science available regarding the efficacy of this service. A substantial volume of scientific information has become available regarding the effectiveness of breast cancer screening by mammography over the last several years. As a result of a nearly year-long review process, the National Cancer Institute (NCI) recently released a statement concerning breast cancer screening:

> There is a general consensus among experts that routine screening every 1 to 2 years with mammography and clinical breast examination can reduce breast cancer mortality by about one-third for women ages 50 and over.
>
> Experts do not agree on the role of routine screening mammography for women ages 40 to 49. To date, randomized clinical trials have not shown a statistically significant reduction in mortality for women under the age of 50.

A copy of the complete NCI statement is enclosed.

The NCI review process actually began in 1991 with the planning of a major international workshop to review clinical trials of mammography. In February 1993, NCI convened an International Workshop on Breast Cancer Screening, where the results of eight randomized clinical trials were reviewed. The workshop conclusions reinforced the advisability of screening for women ages 50 to 69 and stated that the effects of screening in women ages 40 to 49 do not demonstrate a statistically significant

reduction in mortality to date. Between May and December 1993, scientific data from clinical trials, including the workshop results, were reviewed by a number of scientific organizations, health groups, and advisory boards. At the conclusion of these reviews, NCI issued the above statement.

Screening intervals from 12 to 33 months were examined in the trials. Yet the benefits of screening--mortality reductions of 30-35 percent--were similar across these trials for women aged 50 to 69 years. There was little evidence to show that shorter screening intervals were more effective in reducing breast cancer mortality. At this time, scientific experts have not yet reached a consensus on the precise interval for screening. The new information provided by the NCI to the public reflects this finding and the importance of regular screening at intervals that range from 1 to 2 years.

I believe it is fair to say that the most important screening issue we face today is encouraging women 50 years of age and older to undergo regular breast screening by mammography and clinical breast examinations. Screening every one to two years will reduce the death rate by about one-third in women over 50. It has been reported in a number of studies that a substantial proportion of women in this age group are not having regular mammograms at all. The overwhelming weight of clinical trial results, however, assures us that these are the very women who will benefit most from screening. Therefore, in order to encourage use of this potentially life-saving technology, the Health Security Act covers biennial mammography screening to women over the age of 50 without cost-sharing.

We recognize that the periodicity of covered clinical preventive services may not be appropriate for all individuals. The bill provides that women of any age who are classified as "high risk" (e.g., first degree relative with breast cancer) by the National Health Board would be covered for more frequent mammography screening with no cost sharing. Any other women who require medically necessary or appropriate mammography would also be covered with cost-sharing depending upon the choice of plan. Furthermore, the Board may also revise the clinical preventive services package as indicated by advances in scientific knowledge.

The Health Security Act represents an opportunity to significantly improve the health status of women and to increase their access to affordable quality health care. Thank you for

sharing your concerns and allowing me the opportunity to share current knowledge concerning the effectiveness of screening mammography. Please let me know if I can be of further assistance.

Sincerely,

Donna E. Shalala

Enclosure

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503

SPECIAL

January 18, 1994

LEGISLATIVE REFERRAL MEMORANDUM

LRM #I-1878

TO: Legislative Liaison Officer -

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FROM: JANET R. FORSGREN (for) B Pellicci
Assistant Director for Legislative Reference

OMB CONTACT: Robert PELLICCI (395-4871)
Secretary's line (for simple responses): 395-7362

SUBJECT: HHS Proposed Testimony RE: HR 3600, Health Security Act

DEADLINE: NOON January 20, 1994

COMMENTS: Hearing before the House Committee on Energy and Commerce on Wednesday, January 26th. The hearing will focus on women's health under the Health Security Act.

OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President, in accordance with OMB Circular A-19.

Please advise us if this item will affect direct spending or receipts for purposes of the the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

CC:
Nancy-Ann Min
Gene Sperling
Ira Magaziner
Jennifer Klein
Bob Boorstin
Jason Solomon
Jack Lew
Chris Jennings
Steve Richetti
Greg Lawler
Melanne Verveer
Len Nichols
David Kleinberg
Barry Clendenin
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Linda Blumberg
Shannah Koss
Janet Forsgren

LRM #I-1878

RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

If your response to this request for views is **simple** (e.g., concur/no comment) we prefer that you respond by **faxing** us this response sheet. If the response is **simple** and you prefer to call, please **call the branch-wide line** shown below (NOT the analyst's line) to leave a message with a secretary.

You may **also respond** by (1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); (2) sending us a memo or letter; or (3) if you are an OASIS user in the Executive Office of the President, sending an E-mail message. Please **include** the LRM number shown above, and the **subject** shown below.

TO: Robert PELLICCI
Office of Management and Budget
Fax Number: (202) 395-6148
Analyst/Attorney's Direct Number: (202) 395-4871
Branch-Wide Line (to reach secretary): (202) 395-7362

FROM: _____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

SUBJECT: HHS Proposed Testimony RE: HR 3600, Health Security Act

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No objection

_____ No comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of _____ pages, attached to this response sheet

DRAFT Jan 13, 1994
5:45 pm

To Be Released Upon Delivery

DRAFT

STATEMENT OF

Dr. Samuel Broder
Director
National Cancer Institute
National Institutes of Health
Department of Health and Human Services

before the
Subcommittee on Health and the Environment
House Committee on Energy and Commerce

Representative Henry Waxman, Chairman

January 26, 1994

Statement of Dr. Samuel Broder

National Cancer Institute

Good morning, Mr. Chairman, and Members of the subcommittee. I am Dr. Samuel Broder, Director of the National Cancer Institute (NCI). Thank you for the opportunity to appear before you today to discuss the NCI's position, and the scientific basis for that position, on screening for breast and cervical cancers, two areas critical to women's health.

Cancer is the second leading cause of death among women in the United States. In 1994, about 250,000 women will die of all cancers combined, about 46,000 dying of breast cancer. It is the most common cause of death from any cause in women aged 40-44. The incidence of breast cancer is increasing and has been increasing since 1973. Although there are now slight decreases, the situation is dire. Since 1987, breast cancer incidence, fortunately, has reached a plateau and has actually decreased slightly. Some of the increase in incidence over the 1980s is attributed to increased detection due to mammography; the longer term increase is less well understood. We do not believe that the increase can be fully understood without more basic research.

Turning to cervical cancer, in 1993, 13,500 American women were diagnosed with this disease and 4,400 died. Fortunately, the incidence of invasive cervical cancer and the death rate have decreased in the United States over the past several years, because the Pap screening test can detect the pre-malignant or in situ stage. This early stage can be effectively treated, and yet even here, there are problems as sometimes the cells captured are

not the atypical ones, and beyond that some women are not being screened and among those who are screened some are not being treated. The Pap test, developed by George Papanicolaou, has been used since the 1940's. This test, like others, has limitations. Sometimes the cells are imperfectly gathered, nor are all tests read and interpreted accurately. NCI has worked to improve the reading of the Pap test and has introduced the "Bethesda system" which has clarified and standardized reporting. But the Pap test is an excellent tool, even when its limitations are taken into account. Here there is good progress from basic research to report on a vaccine against cervical cancer. The ability to create such a vaccine grew out of years of research on viral carcinogenesis.

The issue of mammography is an area of intense polarization between various groups at this time. The polarization has occurred not because of fundamental differences--we all share the concern that women are dying of breast cancer--but because we have different perspectives on this problem. The key question before us all is how to go about reducing the devastating toll of breast cancer and cervical cancer. The NCI is a science institution, a biomedical research institution committed to generating the knowledge needed to reduce the suffering and death from cancer. While at times there have been bursts of enthusiasm for research advances that promised to cure cancer, we all recognize that cancer has not been cured. Today, there are exciting developments on many fronts, particularly in basic research, but as we discuss these achievements, we must acknowledge that cancer poses an awesome research and therapeutic challenge. We must have no illusions on this point.

As a scientific organization, we know that opinions and practices may require adjustments or fundamental changes as we learn more facts about normal biology, more about the cancer cell and have more opportunity to assess diagnostic tools and treatments. At the same time, we have seen that yesterday's "incurable and fatal" disease can be tomorrow's medical triumph, and that a disease that terrorizes one generation can be only dimly remembered by the next generation. Two principles need to guide us wherever possible: the consensus of scientific peer groups and clinical trials as the instrument for consensus wherever possible.

Each of us has a role to play in this enormously important effort to save the lives of American women. I believe that NCI's role is the generation of knowledge, the sharing of that knowledge and translation of scientific knowledge into clinical reality at the community level. We could not advocate a treatment being continued if followup clinical trials showed that its benefits were initially overstated, that in truth, it brought no reduction in deaths in the real world. By the same rules, we must adhere to what we have learned about the value of mammography for women in various age groups. After a process of scientific evaluation, after extensive review of data from a number of clinical trials, after internal and external debate, and most important of all, after seeking the input and advice of our most respected non-governmental experts, we have an obligation to share the results of this process with the women of America. We owe it to them to provide the most accurate information available about screening and treatment of breast and cervical cancer at a point in time. In the case of mammography, a routine program of screening will definitely save lives. This technology has been proven in randomized clinical trials for women over age 50, and moreover there is a

clear and unmistakable consensus on this point. For women under 50, neither condition applies at this time.

One point must be emphasized: this discussion does not address diagnostic mammography, where a doctor and woman are joined in following symptoms or other indications, such as a lump, pain, or swelling, of a possible malignancy. That is a different situation entirely. Here, in this discussion, we are focusing on the concept of screening in women who are free from known signs or symptoms.

It is important to note that mammography is only one of several technologies being examined by NCI. For example, a large clinical trial, the Prostate, Lung, Colorectal, and Ovarian (PLCO) trial, has begun to evaluate screening tests in these cancers. This study will assess the predictive value of the widely used test for prostate specific antigen (PSA) and less used technology such as ultrasound, CA 125 or flexible sigmoidoscopy. In women, for instance, the study is designed to determine if screening with pelvic examination plus serum CA 125 and transvaginal ultrasound can reduce deaths from ovarian cancer. Thus, for tests such as PSA, we are not recommending its adoption as a routine screening tool until clinical trials and a scientific consensus permit us to do so.

The rank-and-file scientists who work in the National Cancer Program, both intramural and extramural, are superb and they are a dedicated group of men and women. They are working to find new ways to prevent, detect and treat breast and cervical cancer. NCI supports

research aimed at locating important genes and genetic processes in breast cancer. Research is being carried out on specific inherited gene abnormalities and certain familial predispositions to breast cancer including benign proliferative breast disease; the Li-Fraumeni syndrome, in which family members inherit a mutation in the p53 tumor suppressor gene, located on the short arm of chromosome 17; and early-onset familial breast cancer, linked to abnormalities also on chromosome 17 referred to as Breast Cancer-1 or BRCA-1.

Collaborations with the National Center for Human Genome Research are designed to elucidate genetic information about breast cancer. On December 2, 1993, we were pleased to announce the finding of a gene for colon cancer that also appears to play a role in ovarian, uterine and several other cancers. When genes are found, tests can be developed to show which women are at risk. Sometimes the genetic discovery will aid in developing vaccines or new prevention strategies.

At times, conditions not typically thought to fall within a definition of women's health are of surpassing importance. Thus, the gene for Ataxia-Telangiectasia when carried by an otherwise normal woman can predispose her to radiation damage and breast cancer. As carcinogenesis studies progress, this information could be used to counsel women at high risk to avoid certain environmental exposures and to undertake individualized programs of screening and prevention. We are looking specifically at breast cancer and the interaction of various occupational and environmental hazards in the NCI Long Island Breast Cancer Study

Project. This will provide information not only for New Yorkers, but for women everywhere.

Genetic discoveries will yield new molecular tests that might have high specificity. We are not waiting for these events to occur. We are working to refine our knowledge of the tools we have, including mammography and Pap tests. We are encouraging the development of new digital mammography techniques, which would also allow transmittal of images for consultation or diagnosis by specialists. New imaging techniques are being used to more accurately guide biopsies and surgery. Other methods are borrowing from space or defense department technology. None of us is content. All of us know that cancer is the second leading cause of death among women in the United States and we know the suffering caused by this disease.

NCI research has shown that the impact of cancer in general on minority and underserved populations is disproportionately great. This impact is certainly felt in breast and cervical cancer incidence and mortality rates. Even where incidence rates are lower for African-American women than for white women, as is the case with breast cancer in women ages 40 and over, the mortality rates of African-American women are higher. Cervical cancer incidence rates for African-American women are about twice the rates for white women, and mortality rates are about three times the rates for white women.

Screening and access to screening are only one aspect of this very complex situation, one that tangles economic issues, educational issues, access to screening and diagnosis and access to treatment with many other variables including genetic and environmental ones. Mammography has seemed to be a successful way to introduce some underserved women into the medical system. In some ways, it has become a metaphor for concern about breast cancer, even a way a woman could express her determination to protect her health. But mammography was never designed to do all that--it is a medical tool. Mammography was designed to screen for breast cancer and where it is efficient and there are other benefits, that is all to the good. Thus, for women over 50, mammography is an established screening tool. But there is extreme disagreement concerning women under age 50. Therefore, in this setting, we must state what we know and what we do not know.

A word about the history of NCI recommendations is in order. In 1987 the NCI developed Working Guidelines for the early detection of cervical and breast cancers. These guidelines provided the American public with a summary of the state of knowledge at the time.[1] The guidelines regarding screening mammography for breast cancer detection (which can be defined as a regularly performed mammogram for a woman with no presumptive evidence or symptoms of breast cancer) were as follows:

[1] It is important to stress that none of these guidelines pertain to diagnostic mammography, which is performed as a result of a clinical suspicion (such as a lump or nipple discharge). In the setting of a clinical suspicion, whether because of symptoms or physical findings, mammography is generally a necessary medical tool.

♦ The screening process should begin by age forty and consist of annual clinical examination with screening mammography performed at one to two year intervals.

♦ Beginning at age fifty both clinical examination and mammography should be performed on an annual basis.

♦ Physicians should encourage women to perform monthly breast self-examinations.

At the time these guidelines were developed, evidence for screening was strongest in women ages 50-69, although the Health Insurance Plan (HIP) of Greater New York clinical trial had shown a reduction in cancer deaths due to screening in a group of young and older women all mixed together. The above guidelines were considered working guidelines with the intent to revisit them should any new information become available.

Similarly, the working guidelines for cervical cancer screening developed in 1988 are as follows:

♦ All women who are or who have been sexually active or who have reached the age of 18 years should have an annual Pap test and pelvic examination.

♦ After a woman has had three or more consecutive, satisfactory, normal annual examinations, the Pap test may be performed less frequently at the discretion of her physician.

Over the ensuing six years there has been no new information to contradict the basic meassage of the original guidelines on cervical cancer and the consensus among scientists has held firm. Over the last two to three years, however, several events have led to an ongoing re-evaluation of the breast cancer screening guidelines:

♦ First, an NCI-supported meeting entitled "Forum on Breast Cancer Screening in Older Women" was convened in April 1992. Among the recommendations was the following: "There was enough direct evidence to support a recommendation for universal screening in women sixty-five to seventy-four years of age. Because of the lack of direct evidence regarding screening efficacy and because of increasing occurrence of multiple chronic diseases in women seventy-five years of age and older, the Forum concluded that clinical judgment was necessary to weigh the relative benefits of comorbidity and screening effectiveness for the individual patient in this age group ... Regarding the interval for mammography and clinical breast examination, the Forum concluded that there was no evidence to choose one interval over another, since apparently equally effective intervals have ranged from twelve to thirty-three months."

♦ Second, the Canadian National Breast Screening Study of screening women in their forties, published in November 1992, did not show a mortality benefit ascribed to mammography after seven years of follow-up. Dr. Anthony Miller presented a preliminary analysis of this study in closed session to the Board of Scientific Counselors of the NCI's Division of Cancer Prevention and Control (DCPC) as far back as October 1991.

♦ Third, an overview analysis of five randomized screening trials conducted in Sweden in the 1970's was reported early in 1993. The study found that the largest reduction of breast cancer mortality, roughly one-third, was observed among women aged 50-69 at randomization. Among women aged 40-49 at randomization, no satistically significant difference was observed.

I would like now to briefly discuss the process by which NCI came to the specific change under discussion today, but before doing so, I want to put to rest the concern that the NCI's position is influenced by political considerations or expediency.

This process was, in one way, initiated in 1991. It was obvious that there was a need to evaluate the new information in the context of the large body of evidence which had evolved since the landmark Health Insurance Plan (HIP) study of thirty years ago. Following a pre-publication, closed briefing in the Fall of 1991 on the Canadian mammography study, NCI began planning a major international workshop of breast cancer screening that was held in

February 1993. Many of the scientists who performed the studies, as well as researchers in breast cancer screening fields, participated in this workshop. Results from all eight published randomized clinical trials of screening mammography were reviewed. At that workshop an overview analysis, a meta-analysis, was presented by New Zealand investigators of all the randomized screening trials in the world. This analysis raised questions regarding the benefit of screening women between the ages of 40-49. This workshop was open to both the press and the public. At that time, NCI provided information and resources to the media, interested voluntary, advocacy and health professional organizations, and the public, on the mammography screening studies that were being reviewed.

The final report of the workshop concluded:

- First, "The randomized trials of women ages 40-49 are consistent in showing no statistically significant benefit in mortality after 10-12 years of follow-up. .... For this age group, it is clear that in the first 5-7 years there is no reduction in mortality from breast cancer that can be attributed to screening. There is an uncertain and, if present, marginal reduction in mortality at about 10-12 years. Only one study provides information on long-term effects beyond 12 years, and more information is needed."

- Second, "For women ages 50-69, the evidence presented at the Workshop strengthens the scientific observation that screening leads to reduced breast

cancer mortality. Every study presented found a protective effect for women in this age group. .... The Swedish studies suggest that a screening mammogram as infrequent as every 33 months reduces breast cancer mortality, at least in a population with a high compliance rate and in a setting with high-quality mammography. These data raise the possibility that a screening interval of every 12 months may not be necessary in this population."

♦ Third, "Women in their 70's are a high risk group for breast cancer. The currently available clinical trial data for these women are inadequate to judge the effectiveness of screening because the numbers of women were small, the compliance was poor, and the screening episodes were too few."

The Workshop charge was to critically review and summarize the scientific evidence, not to develop guidelines per se. In response to this analysis, NCI staff began the process of reviewing our Working Guidelines in the context of the new information. NCI has a responsibility to provide accurate, clear information to the public-based on scientific evidence. This information clearly held an important public health message for all women and health care professionals.

Subsequently the following process has taken place:

♦ During the period from May through August 1993, the NCI PDQ Editorial Board, consisting of both NIH and non-NIH researchers, reviewed and endorsed Workshop results; the NCI staff developed draft guidelines/recommendations which were reviewed by the NCI Executive Committee; NCI staff also met with the American Cancer Society (ACS) to discuss principles underlying the NCI draft guidelines.

♦ In September 1993 the draft guidelines were reviewed and discussed by PHS agencies and selected participants from the February 1993 International Workshop on Breast Cancer Screening; NCI staff met with the ACS Breast Cancer Subcommittee, the National Cancer Advisory Board, and with individual members of the DCPC Board of Scientific Counselors to discuss proposed guidelines.

♦ During October 1993, NCI disseminated draft guidelines and other materials to agencies involved in earlier guidelines and voluntary advocacy groups, with a request for written comments and attendance at the upcoming October 21 meeting of the NCI DCPC Board of Scientific Counselors.

♦ On October 21, 1993, the guidelines were reviewed by the DCPC Board of Scientific Counselors, who passed a motion recommending that the existing recommendations for women 50 years and over be maintained, and that for women under age 50 NCI provide a summary of existing evidence and data and suggest that

these be discussed with each woman's physician or health care provider. In effect, the Board wanted to present the facts, without the pronouncement of a guideline.

♦ On November 22-23, 1993 the National Cancer Advisory Board passed the following motion: "Recognizing that there is controversy on the effectiveness of mammography for women under the age of 50 that calls for more research, the members of the National Cancer Advisory Board recommend that the National Cancer Institute defer action on recommending any changes in breast cancer screening guidelines at this time."

♦ On December 3, after careful consideration of the conflicting advice of scientific experts, NCI released the following statement summarizing our position on breast cancer screening:

> "There is a general consensus among experts that routine screening every 1 to 2 years with mammography and clinical breast examination can reduce breast cancer mortality by about one-third for women ages 50 and over.
>
> Experts do not agree on the role of routine screening mammography for women ages 40 to 49. To date, randomized

clinical trials have not shown a statistically significant reduction in mortality for women under the age of 50."

The process has been open and candid. We have extended our outreach to many diverse groups, both scientists and consumer advocates. We have heard from women's advocacy groups who strongly oppose the use of routine mammography in women under 50 and those who with equal force hold the opposite view. NCI has been intensively reviewing the state of the science regarding mammography screening efficacy for at least two years. After the Workshop conclusions were clear, NCI conducted surveys and focus groups with women and health care professionals to anticipate issues which might help to prepare health professionals and the public for such changes.

Results from the surveys and focus groups indicated that women clearly understand that scientific debate on health issues is sometimes unavoidable.

The NCI maintains communication with many voluntary, advocacy and health professional organizations in the areas of cancer prevention, early detection, and treatment. NCI has redoubled its efforts to stay in close communication with these organizations and to assist where possible in minimizing the confusion that often occurs when recommendations change. And yet, we sometimes must differ even while we may at the same time respect and admire those who disagree with us.

On December 3, 1993, NCI released the new mammography statement and simultaneously communicated with all its own units including the Cancer Information Service--which answers inquiries via the toll-free 1-800-4-Cancer telephone number, the National Black Leadership Initiative on Cancer, the National Hispanic Leadership Initiative on Cancer, the Appalachian Leadership Initiative on Cancer; the Cancer Centers Public Affairs Network; and the Centers for Disease Control and Prevention to determine the strategies and tools needed to convey NCI's breast cancer screening messages in light of the latest scientific review. NCI immediately began updating its own publications and developing a consumer brochure that explains the new position on breast cancer screening for woman 40 and over.

The NCI Division of Cancer Prevention and Control is planning a meeting of organizations within the Public Health Service to determine how best to work together on this issue and to organize an ad hoc committee of NCI staff as a first step to develop effective strategies to educate physicians and other health care providers on the new NCI mammography statement.

Perhaps most importantly, NCI staff will continue to meet with breast cancer advocacy groups and voluntary organizations, such as the American Cancer Society (ACS), to clarify issues, identify common ground--and there is common ground--foster cooperation, and explore joint communication efforts, where this is possible.

Mr. Chairman, I welcome your interest and the interest of this Committee and the Congress in this issue. Please allow me to repeat myself: Each of us has a role to play in this

enormously important effort to save the lives of American women. This dialogue on mammography is part of the effort. NCI must generate and assess knowledge and then assist in translation of scientific knowledge into the care given at the community level. Science is not separate from life, it is our effort to understand life. NCI's recommendations must be based on scientific evidence to the greatest extent possible, and they must change as new information becomes available. Thank you, Mr. Chairman, for this opportunity to testify. I would be pleased to answer any questions you or other members of the committee may have.