

BREAST CANCER SCREENING RECOMMENDATIONS

HEARING

BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

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BREAST CANCER SCREENING RECOMMENDATIONS

WEDNESDAY, DECEMBER 2, 2009

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

The subcommittee met, pursuant to call, at 10:07 a.m., in Room 2123 of the Rayburn House Office Building, Hon. Frank Pallone, Jr. [Chairman of the Subcommittee] presiding.

Members present: Representatives Pallone, Dingell, Eshoo, Green, DeGette, Capps, Schakowsky, Baldwin, Matheson, Christensen, Castor, Sarbanes, Space, Sutton, Braley, Waxman (ex officio), Shimkus, Shadegg, Blunt, Pitts, Rogers, Wilkins Myrick, Burgess, Blackburn, Gingrey and Barton (ex officio).

Staff present: Ruth Katz, Chief Public Health Counsel; Purveen Kempf, Health Counsel; Sarah Despres, Health Counsel; Jack Ebeler, Health Advisor; Stephen Cha, Professional Staff; Anne Morris, Professional Staff; Bobby Clark, Professional Staff; Alvin Banks, Special Assistant; Elana Leventhal, Professional Staff; Katie Campbell, Professional Staff; Virgil Miller, Professional Staff; Andy Bindman, Robert Wood Johnson Fellow; Ryan Long, Minority Chief Health Counsel; Brandon Clark, Minority Professional Staff; and Chad Grant, Minority Legislative Analyst.

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

Mr. PALLONE. The subcommittee is called to order, and I will first recognize myself.

The subcommittee is meeting today to review the new breast cancer screening recommendations issued by the U.S. Preventive Services Task Force just a few weeks ago. By now, I am sure everyone in this room is familiar with the new guidelines or at least we are familiar with the controversy surrounding them. From what I have heard from my constituents, friends, family members and academic institutions in my district, there are a lot of questions, frustration and confusion around these new recommendations. The controversy that was ignited by the report may be eclipsing what the report actually says, and this is the reason why I am holding this hearing today. It is time for all of our questions to be answered. We want a clear understanding of what the report did and didn't say and what others have to say about the report.

We also want to understand the process used by the task force. Should they operate, for example, with more transparency? Do they get sufficient input from stakeholder groups? Do they consider different opinions? And I have invited the U.S. Preventive Services Task Force to speak directly about their work. It is my hope that we will all walk out of this room later today with a better understanding of how these recommendations came about, how they should be viewed and what exactly they mean. We want to get these answers. We want to know as much as we can because women and their doctors deserve to know what is best.

I also want to hear from organizations, advocacy groups and medical experts. We don't want the task force's report to stand alone if there are different opinions. I know that some of the frustration is due to the fact that this recommendation was seemingly made with little input from these groups. That may be a problem with process as well as a problem with the substance of the report, and they will have a platform and a voice today.

The United States is at the forefront of medical research and innovation. Investment in science has led to the development of early detection methods for certain cancers. It has led to treatments and cures for diseases once considered a death sentence, and it is important that all of this new medical information is used to empower physicians and their patients when making medical decisions. This information should be used to help patients and their doctors. It should not be used, and I stress, it should not be used as an excuse to deny needed care. Scientific studies enable patients and their physicians to make more-informed decisions about what is best for them in any given situation. These studies should be one of many tools. Patients and their doctors should have access to as much information as available. They should have informed conversations. But the decisions about mammography for women in their 40s should remain with women and their doctors.

There is a lot of disagreement in the medical community about when exactly to begin using mammography screening for breast cancer. Studies have shown that mammograms save lives while at the same time others have highlighted the risks associated with the test. For example, an article published in the New York Times just yesterday cites a new study that indicated that the risks associated with yearly mammograms can actually put high-risk women at an even greater risk to develop breast cancer in their lifetime, though at the same time the study also cautions that more research is needed to make a more conclusive recommendation. And it appears to me that the takeaway message from all this is that more research is needed and there is already quite a bit of disagreement within the community as to what is best for the patient. But remember, our goal is to provide the best ways of preventing, detecting and treating breast cancer. All the studies, reports and recommendations should be used with that goal in mind. And I also believe that we do not want this study or any other study to be used as an excuse by insurance companies or others to deny mammograms or treatment that would help women. And again, the decision should be between the women and their doctors, not with the insurance companies. Essentially we want stakeholders today and the task force and all groups to be heard. We want people to under-

stand whatever recommendations are made and what the implications are from these recommendations.

So I want to thank the witnesses that are here today for coming on relatively short notice.

At this time I would recognize our ranking member, our temporary ranking member, I guess, the gentleman from Missouri, Mr. Blunt.

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

Mr. BLUNT. Well, I thank you, Mr. Chairman, and Mr. Deal will be here at some point during the hearing. I am glad to substitute for him in this chair for a little while today. I certainly thank you for holding this hearing on the recent recommendations on breast cancer screening. I think there will be large agreement from the committee and concern about those recommendations.

These new guidelines or these new proposed guidelines have caused a great deal of confusion for women and their families. The U.S. Preventive Services Task Force no longer recommends routine mammograms for women between the ages of 40 and 49 yet this group accounts for about one out of six instances of breast cancer. I believe it is a huge mistake to send a message to women and their families and health care providers that an early alert system is not beneficial or may not be beneficial. As a cancer survivor myself, I am very interested in hearing from members of the task force on why these recommendations were formalized, how they were finalized and then communicated to the public because I know how important screening was for me on two different cancers on two different occasions as part of my annual physical.

As we all know, health care reform has been a hot topic for this Congress. In a time when we have been talking about encouraging more prevention in the health care arena, these recommendations run counter to almost every other discussion that we are having. I am also concerned about how these recommendations could be interpreted should the House-passed health care bill become law. I find it unlikely, or at least questionable that the government-run health benefits advisory committee would propose including services in the central benefits package that another government-appointed board has recommended are not necessary.

Mr. Chairman, I think this is an important hearing. I congratulate you for holding it. I look forward to working with you and our ranking member, Mr. Deal from Georgia, on the subcommittee as we work to figure out how and why these confusing recommendations were made.

Mr. PALLONE. Thank you, Mr. Blunt.

Next is our chairman, Mr. Waxman, the gentleman from California.

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

Mr. WAXMAN. Thank you, Chairman Pallone, for holding this important hearing.

Today we are going to talk about an issue about which people have strong views: which women should be routinely screened for breast cancer and when. It is a question that resonates with every person in this room. We all know someone, a family member or friend, who has received a breast cancer diagnosis. In some instances, this may be a younger woman in the prime of her life. Indeed, just a few weeks ago, this subcommittee heard powerful testimony from a member of our own Congressional family, Representative Wasserman Schultz, about her diagnosis and treatment for breast cancer at age 40.

The new guidelines for breast cancer screening that were recently issued by the U.S. Preventive Services Task Force have placed this issue front and center again. I emphasize the word “again” because this is not the first time recommendations about the use of mammography and breast self-exams have been revisited by the task force or NIH or any number of cancer-related research or advocacy groups. Just as we have seen with prostate cancer screening, immunization schedules and even last week cervical cancer screening as well as numerous other services, new information or new interpretations of old information often result in a change in what the experts tell us works at all or works most effectively at all, and this is how it is supposed to be. As the science of medicine evolves, so too should the recommendations on the best use of that science. I believe that is what the U.S. Preventive Services Task Force set out to do in making a review of its 2002 mammography guidelines: to take a fresh look at what has been learned over the last several years and based upon that body of work to provide its best professional judgment on what doctors and their patients should consider when they are making decisions about breast cancer screening. While that judgment may be contentious, I have no doubt it was driven by science and by the interpretation of science and not by cost or insurance coverage or the ongoing health care reform debate. I am also confident that these recommendations are just that—recommendations, and that the task force would not expect them to be used to take the place of a considered opinion of a physician and a patient.

As we will hear shortly, there is a deep divide about these guidelines among other experts that I believe together with the task force share the primary goal of ensuring the best possible care for women. We want to learn more about those differing views today and understand better exactly what the task force has proposed and why, but in the end, what must prevail is a set of recommendations that is evidence based, backed by science and supported by experts in the field. American women and their doctors deserve and are entitled to nothing less to inform their decisions, not to make them but simply to inform them. I hope that will be our sole focus here today.

I look forward to hearing from all of our witnesses and thank them in advance for their testimony. Thank you, Mr. Chairman.

[The prepared statement of Mr. Waxman follows:]

**Chairman Henry A. Waxman
Hearing on "Breast Cancer Screening
Recommendations"
December 2, 2009**

Thank you, Chairman Pallone, for holding this very important hearing.

Today we are going to talk about an issue about which people have strong views: Which women should be routinely screened for breast cancer and when. It is a question that resonates with every person in this room. We all know someone -- a family member or friend -- who has received a breast cancer diagnosis. In some instances, this may be a younger woman, in the prime of her life. Indeed, just a few weeks ago, this Subcommittee heard powerful testimony from a member of our own congressional family -- Representative Wasserman Schultz -- about her diagnosis and treatment for breast cancer at age 40.

The new guidelines for breast cancer screening that were recently issued by the U.S. Preventive Services Task Force have placed this issue front and center . . . **again**. I emphasize the word “again” because this is not the first time recommendations about the use of mammography and breast self exams have been revisited – by the Task Force or NIH or any number of cancer-related research or advocacy groups. Just as we have seen with prostate cancer screening, immunization schedules, and even last week, cervical cancer screening, as well as numerous other services, new information or new interpretations of old information, often result in a change in what the experts tell us works at all or works most effectively of all.

And this is how it is supposed to be. As the science of medicine evolves, so, too, should the recommendations on the best use of that science.

I believe that is what the U.S. Preventive Services Task Force set out to do in undertaking a review of its 2002 mammography guidelines – to take a fresh look of what has been learned over the last several years, and based upon that body of work, to provide its best professional judgment on what doctors and their patients should **consider** when they are making decisions about breast cancer screening. While that judgment may be contentious, I have no doubt it was driven by science and by the interpretation of science – and not by cost or insurance coverage or the ongoing health reform debate. I also am confident that these recommendations are just that -- recommendations -- and that the Task Force would not expect them to be used to take the place of a considered opinion of a physician and patient.

As we will hear shortly, there is a deep divide about these guidelines among other expert groups that, I believe together with the Task Force, share the primary goal of ensuring the best possible care for women. We want to learn more about those differing views today and understand better exactly what the Task Force has proposed and why. But in the end, what must prevail is a set of recommendations that is evidenced-based, backed by science, and supported by experts in the field. American women and their doctors deserve -- and are entitled to -- nothing less to inform their decisions -- not to make them, but simply to **inform** them.

I hope that will be our sole focus here today. I look forward to hearing from all of our witnesses and thank them in advance for their testimony.

Mr. PALLONE. Thank you, Chairman Waxman.
Next is the gentleman from Illinois, Mr. Shimkus.

OPENING STATEMENT OF HON. JOHN SHIMKUS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. SHIMKUS. Thank you, Mr. Chairman, and I hate to disappoint Mr. Waxman but this will not be our sole focus today because this is the canary in the coalmine. This is what we get when we have government intervention starting to dictate health care policy decisions and this will not be taken outside the context of H.R. 3962, which will then set up a government system and will eventually ration care, and when you have government commissions setting policy instead of a doctor and a patient relationship, you get this. So don't be surprised if we do not focus on how this is just one small example of how health care will be delivered in this country pretty soon, 2013, and definitely in 10 or 15 years. We will be able to point out in H.R. 3962 the ratings of A and B in the essential benefits package and the highest rating of C, women would not receive access to regular mammograms until the age of 50. One estimate finds rationing of care like this would result in 50,000 preventable deaths from women who go undiagnosed. H.R. 3962 does give the Secretary the ability to add benefits but only after getting approval to do so from a new bureaucracy that is created called the Health Benefits Advisory Council. Will the new Health Benefits Advisory Committee take into account cost when making decisions? Will the committee make recommendations another government board like the task force has said shouldn't be covered? When mammograms and other services aren't covered by government, where will people turn? In Canada, we know those people can turn to the United States market. In the U.K., they are allowed to purchase their own private plan, this creating a two-tiered system.

Under H.R. 3962, we create the same tiered system for the rich, one for the rich and one for the poor. The Secretary can approve additional benefits to be covered or enhanced and a premium plan is to be offered in the exchange. These plans will cost more money and in 2013, 2014, anyone receiving subsidies to help them afford insurance can only purchase a basic plan. How will these people receive coverage? So here is proof the government will have the ability to come between you and your doctor and that we won't need a single payer to get there. The government-run public option will allow them the same ability to ration care, and I yield back my time.

Mr. PALLONE. The gentlewoman from California, Ms. Eshoo.

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

Ms. ESHOO. Thank you, Mr. Chairman, for holding this very important hearing today. I want to welcome the witnesses, the members of the task force, the National Breast Cancer Coalition, the American Cancer Society and the Susan Komen Foundation here today as well, and to thank you all for your work.

I will place a full statement in the record, but there are a couple of points that I would like to make at this moment, and that is, number one, I think that if we wander away from science, from evidence-based science in our country, then it will be a march to folly. Sometimes we debate, and we should, and question the scientists and how they arrived at the conclusion that they have come to, but science is something that has been honored by the American people for a very, very long time. We have come through a period of time where science was not honored by the Congress. It was political science that drove it, and scientists within the government were muzzled and we paid a big price for it. Certainly the task force and coming out with their information, I wish there were maybe a better communications plan. I think a lot of people were simply not prepared all of a sudden to be hearing what the task force came out with. But now is the sober and the prudent time to examine what the task force has come out with and why and where that may take us.

Now, on the issue of national health insurance, of course our Republican friends are going to try and drag this into that but I remember too many times where they were too slow to take up the call to reform, to bring services to women, especially poor women, in the fight against breast cancer. So today is a most important hearing and we need to remain, I think, devoted and dedicated to solid science in our country and to pay heed to that, and I think that that really drives to the core of what we are here today for and God help us if we don't. This is not about anybody's political science as much as members are tempted to drag that into it, and I might say that insurance companies, private insurance companies have long made decisions about who they want to insure and what they will cover, and women and their complicated bodies have been left out of so many of those decisions and not covered by them and that is why we have engaged in a whole new debate and hopefully we will be successful with our efforts to remain all of that.

So, Mr. Chairman, thank you. Thank you for having the scientists, the experts that are here today for us to query, to understand better and their recommendations and that with that we will be far more confident about the discussion and the debate that they brought forward, so thank you.

Mr. PALLONE. I want to thank the gentlewoman.
The gentleman from Texas, Mr. Burgess.

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

Dr. BURGESS. Thank you, Mr. Chairman.

I agree with the gentlelady's previous statement that the fight against cancer knows no ideological or partisan lines, and I am certain the doctors who will be testifying before us today would agree with that. Cancer is a disease that all Americans fear and one that is all too often very, very close to home. We have learned in this committee that cancer is a complex disease, still has no cure but efforts geared towards prevention, early detection and treatment have made significant gains. We start there because as we embark upon this hearing, we must remember not to embrace policies that would undo the successes that we have enjoyed. I agree, we should

not make this partisan but the 2,000-page gorilla in the room is the bill that this House passed 2 weeks ago, and if things were just to stay as they are now, then the task force recommendations would be just that, recommendations. Doctors would be free to accept them or reject them. But what we have written in the legislative language may take some of that freedom away from doctors and may take some of that freedom away from patients as well.

Cancer strikes roughly one-third of all women in the United States and 13,000 Texans are expected to be diagnosed with breast cancer this year, so we come to these new recommendations made by the United States Preventive Services Task Force and they have made some pretty dramatic statements regarding breast cancer screening. Now, the whole concept of not participating in a monthly self-exam, well, okay, maybe that is a good thing but I cannot tell you as a physician practicing obstetrics and gynecology for 25 years in north Texas the number of new cancers that were brought to my attention by the patient herself who found something on exam. In fact, the young OB/GYN physician learns very early in their course not to question the patient's clinical judgment when they come in and tell you something is wrong because very likely something is wrong. We are all happy when the tests show that in fact there was no problem but more often than not there is going to be something there that does deserve further scrutiny.

Now, we had these task force recommendations come up 2 weeks ago and I went home to Texas, and on my desk waiting for me was a periodical called OB/GYN News, not necessarily a peer-reviewed scientific journal but articles of the day which are of interest to practicing OB/GYNs are discussed and they had a story that ironically was the day before the task force recommendation came out that said headline, breast cancer deaths higher without routine screening, and this was from a report given to the American Cancer Society out in San Francisco and a rather startling statistic that Dr. Katie reported to this group that 345 breast cancer deaths, which was nearly three-fourths of the total, were in women who were not regularly screened. Women who were regularly screened had 25 percent of the cancer deaths. Women who did not have regular screening, 75 percent of the cancer deaths. I think that is trying to tell us something and I think again the 2,000-page gorilla in the room is this new brave new world of health care which Congress is going to dictate how things are happening and the recommendations of the United States Preventive Task Force now carry the weight of law, if you will, under the auspices of the Secretary of Health and Human Services or whoever the health care commissar is that they designate.

So I thank you for having this hearing. I think it is extremely important. I think it is extremely timely. I look forward to the testimony of our witnesses. Dr. Brawley, always good to see you. And I will yield back the balance of my time.

Mr. PALLONE. Thank you, Mr. Burgess.

The gentlewoman from California, Ms. Capps.

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

Mrs. CAPPs. Thank you, Chairman Pallone, for holding this hearing.

I am so pleased that you and we all have responded quickly to the release of the task force's recommendation because there has been a lot of confusion underscoring the value of having hearings like this in our House of Representatives. I have just returned, as we all have, from our Thanksgiving break and I was with my family, and in fact as an aside, received my own annual mammogram during that time. I can assure you that the message is out there but I am afraid it is not necessarily the accurate one. So I am looking forward to hearing in great detail today how the task force arrived at its conclusions and what the recommendations really mean in a practical sense.

Unfortunately, there are people who have completely twisted what the task force is, what the task force does and what its recommendations mean. The scare tactics I have witnessed since the release of the recommendations have been deplorable, quite frankly. The recommendations are based on scientific findings. This is so important to underscore. Now, we know there is not always consensus within the scientific community or within the advocacy community, both groups so important to us in setting public policy, but we in Congress owe it to our constituents and the public to listen to what a reputable group of experts in evidence-based medicine and prevention have to say.

Furthermore, we owe it to them to refrain from engaging in partisan rhetoric about what these recommendations mean. The United States Preventive Services Task Force issues guidelines for a whole range of preventive services. They do not make coverage determinations for insurance companies, public or private, and ultimately all decisions should be made between patients and their health care professionals. The task force's website affirms that their purpose is to present health care providers with information about the evidence behind each recommendation, allowing clinicians to make informed decisions about implementation. At the end of the day, this is information that clinicians should use to make decisions in consultation with their patients and nothing more.

So I look forward to hearing in greater detail what the task force concluded and how they arrived at these conclusions, and I hope we can stop with the false accusations.

Before I yield back, Mr. Chairman, I ask unanimous consent to enter a letter from the Partnership for Prevention into the record. The partnership is a group of reputable organizations, the American Academy of Family Physicians, Nurse Practitioners, Physicians Assistants and on and on, there is about 10 of them, and they are calling attention to our committee on the three most common misstatements that have appeared in the media, one being that that the task force recommends that women age 40 to 49 not receive mammograms, this is nowhere in the report, that the intention of the task force was to reduce cost, this is nowhere in their analysis, and that they are not qualified. These are some of the misstatements out in the public that this task force is not qualified to make recommendations or that they have other agendas in play,

and I ask that the letter be made part of the record, and I yield back.

Mr. PALLONE. Without objection so ordered. Thank you, Ms. Capps.

[The information follows:]

The Honorable Tom Harkin
Chairman
Health, Education, Labor and Pensions Committee
United States Senate
SD-428
Washington, DC 20510

The Honorable Michael B. Enzi
Ranking Member
Health, Education, Labor and Pensions Committee
United States Senate
SH-835
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The Honorable Max Baucus
Chairman
Finance Committee
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SD-219
Washington, DC 20510

The Honorable Charles E. Grassley
Ranking Member
Finance Committee
United States Senate
SD-219
Washington, DC 20510

Dear Senators:

The recent mammography recommendations from the U.S. Preventive Services Task Force have brought unprecedented attention to this quasi-governmental, independent body. For the last quarter century, the Task Force has played a vital role in determining which clinical preventive services are effective in improving health and saving lives while avoiding harms from unproven services. We are committed to ensuring that the Task Force continues to play this important role long into the future.

The recent revision of the mammography recommendations has resulted in numerous inaccurate and unfounded attacks on the Task Force. We want to set the record straight about the recommendations and about the Task Force itself. The three most common misstatements that have appeared in the media are that:

- The Task Force recommends that women aged 40 – 49 not receive mammograms.
- The Task Force recommendations were intended to reduce costs by reducing the number of mammograms women will receive.
- Members of the Task Force are not qualified to make scientific recommendations, or they have other agendas at play.

Allow us to address each of these.

Misstatement #1: The Task Force recommends that women aged 40 – 49 not receive mammograms.

The Task Force found that, for women in their 40s, weighing the health benefits against the health risks of mammography did not justify a broad recommendation that all women in that age group receive mammograms on a regular or routine basis. However, the Task Force realized that the balance between benefits and harms (physical and psychological) of mammograms will be different for each woman depending on family history, other illnesses, and levels of anxiety about her health. The reason for that is that the benefit-risk calculation for women in their forties is much less clear than it is for older women. Women in their forties with no identifiable risk factors are much less likely to have breast cancer than those aged 50 and above with no risk factors. Moreover, mammograms in this age group have a much higher likelihood of generating false positives than in older women. False positive tests result in additional x-rays, unnecessary biopsies and other invasive procedures and treatments, as well as significant anxiety among women and their families.

For this reason, the Task Force does not recommend that all women in this age group automatically start receiving mammograms at age 40. Rather, it simply recommends that those women and their healthcare providers have a full discussion about the potential pros and cons of screening. This allows the patient to incorporate information about her family history, overall health, and personal values and preferences along with the best scientific information into the decision-making process. The result is an empowered patient who is able to make an informed decision about whether or not to be tested. In fact, many women may choose to continue mammography because they value the small chance that they might benefit, but other women may choose to defer beginning mammograms until the balance of benefits and risks is more favorable.

The Task Force does support routine screening for women aged 50 – 74 because the evidence is strong that the benefits clearly outweigh the potential risks. For mammography as well as for other preventive services, the Task Force supports shared decision-making between women and their healthcare providers.

Misstatement #2: The Task Force recommendations were intended to reduce costs by reducing the number of mammograms women will receive.

The Task Force never uses cost as a reason to recommend against a service that has been proven to be effective. In its review of the evidence about breast cancer screening, the Task Force had a single objective – to determine how to maximize the health of women. Every medical procedure has benefits and potential risks. Any scientific review of a screening test must therefore carefully weigh the health benefits and harms, especially when applying it to a broad population of healthy people. The Task Force followed this well accepted approach in considering a variety of breast cancer screening strategies.

The Task Force uses explicit criteria to formulate its recommendations about the effectiveness of preventive services. These criteria are clearly delineated on the Task Force's web site, which can be viewed at <http://www.ahrq.gov/clinic/prevenix.htm>. For each preventive service it reviews, the Task Force assesses the quality of the scientific information, estimates the magnitude of benefits and harms, reaches consensus about each service's net benefit, and issues a recommendation.

Misstatement #3: Members of the Task Force are not qualified to make scientific recommendations, or they have other agendas at play.

The U.S. Preventive Services Task Force was first convened by the Public Health Service in 1984. Since its inception, it has been recognized as the authoritative source for determining the effectiveness of clinical preventive services, and its methods have been adapted by guidelines groups worldwide. Most members of the Task Force are experienced clinicians (doctors, nurse practitioners, and nurses) as well as experts in prevention research.

While this small group of distinguished health care professionals and researchers is largely unknown to the general public, its work is well known to clinicians in preventive and primary care practice. Because of the rigor and objectivity of its research, the Task Force's recommendations have often been endorsed by the major primary care specialty societies in the U.S., giving patients access to a wide range of effective preventive services. The preventive services recommended by the Task Force have prevented hundreds of thousands, if not millions, of premature deaths and averted needless harms.

Members of the Task Force are appointed by the Agency for Healthcare Research and Quality within the Department of Health and Human Services. Current members have been appointed under Republican and Democratic Administrations, and they were nominated because of their expertise in prevention, primary care, and evidence-based medicine without regard to political views or influence. They operate under strict rules to prevent conflict of interest.

The Task Force has no direct role, and has not sought a role, in setting policy such as insurance coverage. The timing of the current recommendation in relation to health care reform is entirely coincidental. All Task Force recommendations must be updated at regular intervals. The decision to update the previous Task Force recommendations was made several years ago before current reform proposals were even conceived. The timing of release was dictated by when the process of careful peer review of the recommendations and supporting scientific paper were completed.

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The U.S. Preventive Services Task Force was established as an independent body to apply rigor and objectivity to the analysis of clinical preventive care – even on issues that arouse passions and political posturing. The misstatements we have noted are evidence of both of these dangers, and the Task Force is our best defense against both. Our common goal is for preventive services to improve the health of all Americans. We believe the Task Force is the best way to ensure we're guided toward that goal by recommendations of experts who are guided by science, and only by science.

Thank you for the opportunity to share our views.

Sincerely,

American Academy of Family Physicians
American Academy of Nurse Practitioners
American Academy of Physician Assistants
American College of Physicians
American College of Preventive Medicine
American Journal of Preventive Medicine
American Medical Association
American Public Health Association
National Association of County and City Health Officials
Partnership for Prevention
Public Health Institute
Trust for America's Health

Mr. PALLONE. Next is the gentleman from Georgia, Mr. Gingrey.

OPENING STATEMENT OF HON. PHIL GINGREY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Dr. GINGREY. Mr. Chairman, I thank you.

We have heard already some comments from the Democratic side regarding the danger of ignoring science if we go down that road. I don't think we are talking about Newton's third law here, by the way. We are not talking about exact science. We are talking, I think, about an opinion, a judgment that is made by the United States Preventive Services Task Force, 15 or so members, based on looking at a lot of studies. I will tell you as a practicing OB/GYN physician, like my colleague from Texas, Dr. Burgess, I have spent 26 years practicing medicine. In that specialty, I am a very proud member of the American College of Obstetrics and gynecology and a board-certified fellow, and we take our recommendations from that organization and from the standard of care in the community, my community, the greater Atlanta area, of what is best practices, and the American public and particularly the American women, they know who the American Cancer Society is. They know who the Susan G. Komen for the Cure organization is. So many of them help raise money for that organization but very few of them have ever heard of the United States Preventive Services Task Force or in what department they are embedded and how much power they have and how much authority they have, Mr. Chairman. They will find out pretty darn soon, and I would refer them to pages in both the House and the Senate bill, the Senate bill of course pending, the House bill 3962, and let them just connect the dots and to see the power that this organization, this U.S. Preventive Services Task Force, no matter what they call it, to tell physicians basically that this is not an A or B recommendation, this is a C recommendation. Well, Mr. Chairman, if the President had followed through, if the Congress had followed through on the President's recommendation of having meaningful medical liability reform in these pending health care bills, then maybe physicians like myself would not have to worry too much if we decide to follow the United States Preventive Services Task Force guideline and not order a mammogram for our patients between the ages of 40 and 49 or not recommend it to them that they do breast self-examination, and we miss a diagnosis of cancer and they died from that disease. Or on the other hand, if we decided to ignore the recommendation and we did the mammogram and a lump was detected or a suspicious marking on the mammogram, the patient had a needle biopsy, it turned out to be benign, but unfortunately, she developed a breast abscess and then the physician gets sued for not following the recommendations and doing something that is, quote, unnecessary. So you put doctors in an untenable position and you put their patients at risk of death.

So I can't wait to hear from Susan G. Komen and from the American Cancer Society and obviously from the Preventive Services Task Force and the others on the panel. Mr. Chairman, with that, I will yield back.

Mr. PALLONE. Thank you.

The gentlewoman from the Virgin Islands, Ms. Christensen.

**OPENING STATEMENT OF HON. DONNA M. CHRISTENSEN, A
REPRESENTATIVE IN CONGRESS FROM THE VIRGIN ISLANDS**

Mrs. CHRISTENSEN. Thank you, Chairman Pallone.

Given the confusion and the uncertainty the updated recommendations on screening for breast cancer by the U.S. Preventive Services Task Force has elicited, this hearing I hope will bring some clarity which I feel is needed on both sides, and I thank you for holding it.

I have only read the executive summary but I have several questions like why now. Did the task force not foresee the reaction that has occurred, and why was it just released as an article as important as it is and now in a briefing with press and stakeholder organizations. As an African American woman who has had friends and family diagnosed in their 20s, their 30s and 40s, many with no known risk factors, some with good outcomes and others who died because of the aggressive of their disease, and as a physician who knows the pain of caring for women who came with very late stage carcinomas like the 24 black women who are going to be reported on shortly diagnosed in this city by Dr. Wayne Frederick, the head of the cancer center at Howard, in a recent 18-month period, 24. I am not pleased to say the least with the report not specifically addressing those of who die most often from this disease.

Mammograms are not perfect and perhaps least so in the 40 to 49 age group, but as part of the full armamentarium, it is the best we have today. We have never told women that mammograms are all that there is. As Dr. Frederick of Howard said, and Ms. Luray and Dr. Brawley will attest, in prevention, our main concern ought to be the gaps in outcomes and the lack of access of many women to mammograms, exams and other screening and diagnostic modalities, and while is most evident in the uninsured, copays create almost equal barriers to women with insurance, and neither is the federal government doing enough. As an example, the Virgin Islands scored very high on the breast and cervical cancer grant application but was never funded. There is inadequate funding to meet the need.

Until every woman has access, you can well imagine that we will not welcome, I will not welcome, anyway, these kinds of narrow recommendations. What is next? Colonoscopy screening for cancer screening? It probably saved my life, and not having one has caused me to lose too many friends. The task force is independent, which I consider a good thing. It is also very important to base decisions and recommendations like these on science, but the task force is not as diverse as it needs to be to adequately and appropriately address the health care needs of all Americans. The recommendations may have been very different or at least more expansive if some of the recommendations that the American Cancer Society offered had been accepted. They are similar to ones that we recommended for H.R. 3962.

But I welcome all of the panelists today and I look forward to the testimony.

Mr. PALLONE. I thank the gentlewoman.

The gentleman from Pennsylvania, Mr. Pitts.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. PITTS. Thank you, Mr. Chairman, for convening this hearing.

On November 16, the U.S. Preventive Services Task Force released its updated breast cancer screening recommendations for women in the general population. Several of the recommendations have since caused widespread confusion and concern, primarily its recommendations for women age 40 to 49. The task force recommended against routine screening mammography in women age 40 to 49 but did say that certain patients in this age range based on individual factors should be screened. This is a change from the task force's 2002 recommendation that all women age 40 and older receive screening mammography every 1 to 2 years.

The U.S. Preventive Services Task Force was first convened by the Public Health Service in 1984 and since 1998 it has been sponsored by the Agency for Health Care Research and Quality, a division of the Department of Health and Human Services. It is instructive, therefore, to pay attention to what the Secretary of Health and Human Services had to say about the task force recommendations. On November 19, Secretary Kathleen Sebelius said, "My message to women is simple: mammograms have always been an important lifesaving tool in the fight against breast cancer and they still are today. Keep doing what you have been doing for years. Talk to your doctor about your individual history, ask questions and make a decision that is right for you." Basically she told women to ignore the task force recommendations. The good news for women age 40 to 49 is that they can talk to their doctors and determine whether or not routine mammograms are best for them. The bad news is that if the House-passed health reform bill, H.R. 3962, becomes law, a woman in that age range may not be allowed to have a mammogram. The House-passed reform bill renames the U.S. Preventive Services Task Force the Task Force on Clinical Preventive Services. As part of the bill's essential benefits package, preventive services including those services recommended with a grade of A or B by the Task Force on Clinical Preventive Services must be covered, but according to the task force's just-released recommendations, routine mammograms for women age 40 to 49 received only a grade C. Should the health reform bill become law, the new task force will make recommendations to the Health Benefit Advisory Committee which will determine what is and is not covered in the essential benefits package. I think we should ask ourselves how likely it is that one government board, the Health Benefits Advisory Committee, will recommend including services in the essential benefits package that another government board, the task force, has recommended not be covered.

It is important to note that all private plans in the exchange will have to meet the essential benefits package but they cannot exceed it. A private insurer cannot add additional benefits above and beyond what the government requires in the essential benefits package except to premium plus plans and then only if the added benefit is approved by the health benefits commission. So, for example, if the essential benefits package did not coverage routine mammograms for women age 40 to 49, insurance plans would be forbidden

from covering them. My State of Pennsylvania requires that all plans cover mammograms for women age 40 to 49. If this bill were to become law and the Secretary were to adopt these breast cancer screening recommendations as is as part of the essential benefits package, Pennsylvania would either have to change its benefit mandate law or reimburse the government for the added cost of screening this population. These recommendations should be a wake-up call that government-run health care will come between patients and their doctors.

I look forward to hearing our distinguished witnesses. Thank you, and I yield back my time.

Mr. PALLONE. Thank you, Mr. Pitts.

The gentlewoman from Florida, Ms. Castor.

OPENING STATEMENT OF HON. KATHY CASTOR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Ms. CASTOR. Thank you, Mr. Chairman, very much for the hearing today because it not only gives us an opportunity to further understand the recommendations as to breast cancer screening but it affords us an opportunity to raise awareness about the real issue involving women's health in America and that is access to care, plain and simple.

For women in America, access to care, affordable health care, including screenings of all kinds, eclipses the debate over what age women and their doctors should begin routine mammograms. For millions of women across America, this debate has no application whatsoever. They are not receiving screenings at age 50, they are not receiving screenings at age 60. They simply do not have access to affordable health care because our health care system in this country is broken.

It is very basic. We know that if you do not have affordable health care you are less likely to receive the vital preventative screenings that women with insurance have. The American Cancer Society reports that in my home State of Florida, if you don't have health insurance, you are simply not going to receive any screening whatsoever. Women in this country just do not have access to affordable care. Maybe one-quarter of women in the State of Florida that do not have health insurance will receive some mammogram during age 40 to 60, and it is much worse if you are African American or Latina. The disparities in screenings, diagnosis and treatment exist and I think this is the critical issue that Donna Christensen has raised that really deserves a great deal of attention and debate and it is the proper place for our outrage over women's health in America because regardless of your insurance status, if you are African American, you are 1.9 times more likely to be diagnosed with an advanced stage of breast cancer than white women and Hispanic women are almost 1-1/2 times more likely to be diagnosed than white women.

So the real concern here and the proper place for our outrage is access to care in and of itself. Our broken system prevents millions of women in America from even being part of this debate over screening. Fortunately, due to the efforts of many over the past year, we are on the road to correcting this problem, and I hope that we can focus on the true issues of our broken health care system

in America that affects, yes, breast cancer screening but really is the heart of the problem in our fight to making America a healthier country. Thank you.

Mr. PALLONE. I thank the gentlewoman.

Next is the gentleman from Michigan, Mr. Rogers.

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

Mr. ROGERS. Thank you, Mr. Chairman.

You know, science is a whole host of disciplines and math is one of them, and when you look at what the task force recommendations have done, it is absolutely disingenuous to say cost didn't play a role in it. Let me quote you from the American Cancer Society: "The task force says that screening 1,339 women in their 50s to save one life makes screening worthwhile at that age yet the task force also says that screening 1,904 women ages 40 to 49 in order to save one life is not worthwhile." When you look at their executive summary, clinical breast examination specifically talks about costs. The principal cost of a CBE is the opportunity cost incurred by clinicians and the patient encounter. Clearly, cost is a consideration. They did it with digital mammography. Digital mammography is more expensive than film mammography and talks about the cost-benefit analysis of that as they work their way through. Magnetic resonance imaging—magnetic resonance imaging is much more expensive than either film or digital mammography. To say that cost was not a factor in this is not being honest. It is just not. It clearly was the reason, and to say, well, they don't have any authority. Wait until that insurance company comes out and says well, we based it on this task force, a government task force recommendation says I don't have to pay for mammography for a woman between the ages of 40 and 49. That is where we are going.

As a matter of fact, in your 2,000-page bill, that is exactly what you do. The Health Benefit Advisory Committee is created to do exactly that. And how do we know that? Because the National Institute of Clinical Effectiveness, the NICE board in Great Britain, is the very organization that limits things like Pap smears. They raised it from 23 to 25 for young women. Why? Why did they do it? Because science told them? No, to save money. And what the math part of your science equation is, we think that we are willing to accept that more women will be diagnosed later on in later stages of cancer. We are willing to accept a higher mortality rate to save money. That is what this report says and that is what we are getting ready to foist on the American people. That is not a scare tactic. That is reality, and it happens in Great Britain and it happens in Canada and it happens in France, and what we are saying is, we can and should do better.

I am a cancer survivor because of early screening. I know Mr. Blunt is a cancer survivor because of early screening. Why we would foist this kind of an ugly system and hide behind the fact that we will have more deaths, more mortality because of cancer because of it is beyond me. What we are saying is, this 2,000-page bill and its 118 new boards, commissions and other government agencies that will dictate your health care policy is wrong and we

can and we should by these women in their 40s do much better, and I would yield back the remainder of my time, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Rogers.

Next is—I am having a hard time seeing who is here. The gentlewoman from Illinois, Ms. Schakowsky.

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

Ms. SCHAKOWSKY. Thank you, Mr. Chairman, for moving so quickly to convene a hearing on the recommendations of the U.S. Preventive Services Task Force. I appreciate it.

This committee has talked a lot about the need for evidence-based science over the last year but it is important, particularly when it comes to something as critical as breast cancer screenings that we do look carefully into the justification for these recommendations and their ramifications for individual women. Many of my constituents have questions, as do I, and I look forward to asking them. But I do want to say right now that this is not something that should become a political football or, in my view, an attack on the need for health reform that guarantees access to comprehensive health care for women. We all want to ensure women, especially women threatened with life-threatening diseases like breast cancer and make sure that they have access to the health care that they need without preexisting-condition exclusions, gender rating denials that exist today.

But among the questions that have been asked is, how do we reduce the number of unnecessary screens while ensuring that we do not provide disincentives for mammograms that will save women's lives? How do we empower women to ask for a screening when they suspect a problem? How do we build on what we know today to ensure that are getting the research and science around breast cancer prevention and treatment right? What improvements are needed to obtain more accurate screens? How do the grades provided by the task force mesh with its recommendation that doctors and their patients be allowed to make individual choices, particularly when it comes to high-risk women? And how do we make adequate insurance coverage or high cost sharing don't prevent barriers to screening and all appropriate follow-up care? Women across the country are concerned about getting access to mammograms and other essential services, and women's groups across the Nation have endorsed comprehensive health reform for this very reason: because they know that millions of women's lives depend on it.

I am eager to hear from our witnesses and discuss the task force's recommendation and again, Mr. Chairman, thank you for having this hearing. I yield back.

Mr. PALLONE. Thank you.

The gentleman from Arizona, Mr. Shadegg.

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

Mr. SHADEGG. Thank you, Mr. Chairman, and I want to also thank you for holding this hearing so quickly on this important topic. I believe I have mentioned to this committee before that my

older sister is a 20-year breast cancer survivor so I have a keen interest in this topic.

The breast cancer treatment guidelines released on November 16th by the U.S. Preventive Services Task Force have created a firestorm across the country, giving rise to concerns about women's access to lifesaving screening. Some have commented that these recommendations are merely guidelines for insurance companies and government officials trying to assess the relative value of mammography, clinical breast exams and breast self-exams. In a written statement, Health and Human Services Secretary Kathleen Sebelius said the guidelines had caused a great deal of confusion and worry among women and their families across this country and stressed that they were issued by "an outside, independent panel of doctors and scientists who do not set federal policy and don't determine what services are covered by the federal government." I am here to tell you today and to tell every woman in America that under this bill, H.R. 3962, which has already passed this Congress, that statement will not be true. Indeed, under this bill, the recommendation of this task force would become binding law, and if so, it would be devastating to access to mammograms and nothing short of catastrophic for women's health in this country.

In their recent report, mammograms for women age 40 to 49 were given a grade of C. Under this bill, any procedure given a grade of less than A or B cannot be covered by the public plan. So the women that my colleague worried about who have no access to care today for mammograms could not legally get mammograms once this bill becomes law. The panel also found insufficient evidence to determine it is worth screening over the age of 74. Again, because the grade was neither an A nor a B, it was an I, insufficient, under this bill those women could not get mammogram screening legally under any public plan.

But it is important to understand precisely how far this bill goes. Because it does not just prohibit mammogram screening if this were the finding of this same task force after H.R. 3962 becomes law, it would prohibit private insurers, make it illegal for private insurers to provide mammogram coverage to women in these age groups. That is what the law says. Let me explain. Under the House bill, private insurers can offer four plans: one, a basic plan; two, an enhanced plan; three, a premium plan; and four, a premium plus plan. Under section 303 of H.R. 3962, women purchasing insurance under the first three categories, basic, enhanced or premium, would not be allowed to purchase because the insurance company would not be allowed to offer a policy covering mammogram services. That is right, it would be illegal for a private insurance company in any one of those first three categories, basic, enhanced or premium, to offer coverage for mammograms because mammograms were not given either an A or a B rating.

With regard to the top category, premium plus, an insurance company could offer coverage for mammograms but if and only if the health choices commissioner specifically allowed the policy to cover mammograms. Now, I don't suspect that many of my colleagues on the other side of the aisle understand that aspect of this bill and I hope that before this bill or anything like it were to become law, they would study it closely and recognize what is wrong

with it. Certainly having the government prohibit people who choose to be able to buy mammogram coverage is not what was intended by the authors of this legislation but in fact that is what the bill does. The government would prohibit millions of women from buying coverage for mammograms. The government would forbid private plans from offering mammogram coverage to millions of women. Poor and middle-class Americans by force of law would be prohibited from getting mammogram coverage under the insurance exchange—

Mr. PALLONE. The gentleman is 2 minutes over.

Mr. SHADEGG [continuing]. Created in this bill.

I thank the gentleman for his indulgence and hadn't realized I had gone over time. Thank you.

Mr. PALLONE. Thank you.

The gentleman from Maryland, Mr. Sarbanes.

OPENING STATEMENT OF HON. JOHN P. SARBANES, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MARYLAND

Mr. SARBANES. Thank you very much, Mr. Chairman, for holding this hearing. I expect we are going to hear a lot about rationing today from the other side. To me, the discussion today isn't about rationing, it is about being rational in looking at all of the evidence that is available to us and making smart decisions about what kind of treatment we should deploy and what kind of coverage there should be, and I think the jury is out on this. That is why we are having the hearing. There have been recommendations that have been put forward. They appear to me to be based on very extensive studies, research and science, and I think we ought to approach them with an open mind.

I am glad we are having this hearing. I think this is exactly the kind of thing we should be doing, and the fact of the matter is that as science advances, it causes us to revisit treatment, and that is a good thing. Now, there may be other considerations at play here. One of them is clearly the high attention that there is to mammography screening and the education effort that has gone on with women across this country to make them more sensitive to this as a screening tool, so all of those considerations ought to be fed into the mix and I would expect that the Secretary of HHS will be considering all of those things going forward. But to put our head in the sand and not look at the science, it seems to me would be a serious mistake. So we ought to review these recommendations with a sober and dispassionate consideration. I think that is what we are called upon to do. I would assume that that is what the Health Benefits Advisory Committee would do in receiving recommendations from any other government body. The notion that one—we have this theme again as well today, the notion that one government body will accept without any kind of independent judgment or review the recommendations of another government body, I don't think makes any sense. I think the Health Benefits Advisory Committee will look at all the factors in determining what ought to be the policy when it comes to treatment.

So I think that this is a good conversation to be having and I thank the commission for putting the recommendations forward,

for basing them on science, and now we are going to have to consider those in the light of many, many factors in judging how to move forward. So I look forward to the testimony of the witnesses and I yield back my time. Thank you.

Mr. PALLONE. I thank the gentleman.

The gentlewoman from Tennessee, Ms. Blackburn.

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

Mrs. BLACKBURN. Thank you, Mr. Chairman, and I want to say thank you so much to our witnesses for being here. I am really appreciative of the opportunity for us to have this hearing today and I have a formal statement I will submit for the record, but I do want to make a few comments as we begin this.

This is an issue of tremendous concern to me. I think that all of us are concerned about the welfare and the health of women. We are concerned about what you all as the task force brought forward. Sure, we are concerned about the science, and I want to discuss with you that science, where you drew that from and your process. I also want to explore with you your task force structure and look at the linkages that you bear and what would happen if H.R. 3962 were to be passed and read into law. You all have a portfolio of 105 topics. That gets to the heart of the issue because when you start reading on H.R. 3962 on page 1,296 in Title 3 and you look at section 2301 of this bill, the decisions you make do end up having the weight of the law placed behind them, and when you read specifically on pages 1,317 and 1,318, you see exactly what is going to happen with your recommendations. And then you go in and you look at how it becomes the standard of the law, so I encourage everyone to take this bill then and read it and read that title. Look at section 3101. Look at section 2301. Go back and look on pages 110 to 112 at how what you do and how you give priority and preference to certain treatments and certain categories is going to carry the weight of law.

Now, it is concern to me when I hear statements made by Members of Congress that we are going to deploy certain treatments or certain health care. That ability should rest with the patient and their physician. We do not need a bureaucrat in that exam room. And yes, indeed, when you read this bill, we do have concerns that it will lead to rationing because the decisions appear that they are being made on cost and not on health care.

So I welcome you all. I appreciate your time. We are going to have a lengthy number of questions. And Mr. Chairman, I yield the balance of my time.

Mr. PALLONE. I thank the gentlewoman.

Chairman Dingell, the gentleman from Michigan.

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

Mr. DINGELL. I flew back this morning from Michigan hoping to have a rather informed hearing on a very important point. I find that I have come back to listen to some fairy tales coming from the

other side of the aisle and I find myself offended by the lack of attention that my Republican colleagues have given to the health bill and I find myself very much offended to listen to the kind of distorted logic and reasoning with which I am being afflicted as I enter this room. I have great affection and respect for my friends on the other side of the aisle and I am willing to assume that their behavior this morning in making the comments I am hearing about these recommendations and how they will play with the bill is bot-tomed on a lack of attention, study, knowledge or diligence in understanding either the bill or the recommendations of the U.S. Pre-ventive Services Task Force.

It has been a little bit like listening to the fairy tales of the Brothers Grimm, but to set the record straight, I want my col-leagues to understand the bill does not in its provisions behave as my Republican colleagues would have us believe. It does not use these kinds of recommendations to suppress treatment or interfere with the relationship between the patients and the doctors. This is the kind of scare tactics that I have heard from that side of the aisle always with great personal offense. They talked about how we are going to pull the plug on Grandma, how we are going to push euthanasia forward, how we are going to deny health care to de-serving people because of this legislation. These recommendations that we are going into this morning are recommendations, nothing more, and to say anything different than that is either to transmit the grossest kind of carelessness or, and I hope this is not the case, just plain outright deceit.

It is time for us to look at these recommendations are they are: the recommendations of a scientific panel created to make advice on what is the best medical practice and how we can see to it that we best protect our women with regard to things like Pap smears and mammograms.

Now, I will yield to no one on either subject because this com-mittee and the Oversight Subcommittee when I was chairman of each were responsible for seeing to it that both mammograms and Pap smears were made in the safest way for the benefit of patients. I lost my mother to cervical cancer and I lost lots of friends to breast cancer and other things, and I am grossly affronted by the statements that I have heard coming from the other side in which they tell us how these recommendations and the health bill on which we are working so hard are going to deny women mammo-grams, proper mammography and Pap smear and other needed services. That is offensive. It is just plain wrong. It is absolutely false. And I would urge my friends on the other side to take a look at the bill, to read it carefully, and if they need any assistance in understanding what the bill does, I will be happy to volunteer to provide time so that they may come to have a better understanding of what the bill does and they may then make more-informed state-ments on these matters.

We need to deal with our health problems in a responsible way. We need to see to it that we address the honest defects which are in the bill but not to manufacture a lot of fears and faults which do not exist. I am affronted, Mr. Chairman, and I hope that this record and this hearing will correct some of the unfortunate mis-apprehensions and misstatements that have been flowing thickly

from the other side of the aisle this morning. I ask unanimous consent to revise and extend my remarks.

[The prepared statement of Mr. Dingell follows:]

**Statement of
The Honorable John D. Dingell
Subcommittee on Health Hearing on
“Breast Cancer Screening Recommendations”**

December 2, 2009

Mr. Chairman, thank you for holding this important hearing today on an issue that has captured the attention of so many American women. Some predict that one in eight women will have invasive breast cancer at some point in her lifetime. This is a disease that affects so many and I am sure that all Members of this Committee have a loved one that has fought breast cancer. Therefore, it should be no surprise that there has been much interest in the recent U.S. Preventive Services Task Force (USPSTF) recommendations on breast cancer screening. There has been much concern with the way the recommendations were communicated to the American people and there has been some disagreement with the conclusions of the task force. However, we must consider these recommendations in the proper context and not lose sight of the fact that there is strong agreement—across the government, scientific community, advocacy groups, and health professionals—that screening saves lives and is most effective when decisions related to screening are made between the patient and their doctor.

The USPSTF, an outside independent panel of doctors and scientists, has a history of respect. They are not a political body, but one that focuses on science. They provide an incredibly valuable service to patients and physicians across the country and it is their unbiased assessments that allow for educated, patient-centered discussions about the type of screening, treatment and care individuals should receive. Without evidence-based guidelines, these types of decisions would be difficult to say the least.

Based on the evidence to date, the USPSTF now advises that women between the ages of 40 and 49 should decide on an individual basis whether or not to get periodic mammograms, a change from their 2002 population-wide recommendation that women should get routine screening. Other new recommendations include biannual instead of annual mammograms for women age 50 to 74; a statement of insufficient evidence for the need for mammograms for women over 75; and new advice against teaching of breast self-examinations.

These recommendations were based on scientific studies, not political agendas or cost cutting measures. Some of the panelists today disagree about the final recommendations, but we can all agree is that the evidence to date is inconclusive about the effectiveness of traditional mammogram screenings, especially for women in the age group of 40 to 49. Furthermore, we can all agree that the decisions for these types of diagnostic screenings should be made between individuals and their doctors.

I want to remind all of my colleagues that our purpose today is not to politicize or attack the USPSTF. Instead, we are here to understand the recommendations, and the science that guided the decision making of the task force.

Finally, some of my colleagues have tried and will try to twist and mislead the public about the task force recommendations as a means to kill health care reform and advance their own political agendas. As the lead author of the H.R. 3962, comprehensive health reform legislation that passed the House last month, let me assure you of the facts:

- Health care reform will not prevent women from getting mammograms or lead to rationed care. In fact, the Secretary of Health and Human Services Kathleen Sebelius has stated unequivocally that the task force is an outside body that makes recommendations and not federal policy. She said, “the task force has presented some new evidence for consideration, but our policies remain unchanged.” Under H.R. 3962, millions more men and women across the country will have access to regular screenings and preventive measures that will help everyone stay healthier, longer; and
- Health care reform will improve the important patient doctor relationship and decision making abilities. In fact, these types of evidence-based recommendations enhance patient-centered care. The more doctors and patients know about the effectiveness of screenings, treatments and services, the more people are able to have personalized care that meets their individual needs. This means, that the decision to get a mammogram remains in the hands of individual women, not an insurance company.

Thank you again, and I look forward to hearing from our witnesses.

Mr. PALLONE. So ordered. Thank you, Mr. Chairman.
Our ranking member, the gentleman from Texas, Mr. Barton.

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

Mr. BARTON. Thank you, Chairman Pallone, for holding this hearing.

I listened with great affection and with great interest to my good friend from Michigan, former Chairman and current Chairman Emeritus Dingell's opening statement. I think it goes without saying the personal esteem and professional respect that I have for him. Having said that, there are no fairy tales being told on this side of the aisle this morning. Here is the bill that passed the House. In this bill on page 1,762, the U.S. Preventive Services Task Force is given the authority, and I quote "to determine the frequency, the population to be served and the procedure or technology to be used for breast cancer screenings covered under the Indian Health Service." Section 303 of the legislation states, and I quote, "The commissioner shall specify the benefits to be made available under the exchange participating health plans." In plain English, Mr. Chairman, what this means is, the new health choices commissioner will determine what preventive services including mammography are covered under the health insurance that is in this bill.

Now, we also know that the U.S. Preventive Services Task Force is an outside independent counsel of doctors and scientists who make recommendations. They do not set federal policy and they don't determine what services are to be covered by the bill but their recommendations are going to be seriously listened to.

Now, I have an aunt who passed away in her early 50s as a consequence of breast cancer. I have a sister who was diagnosed with breast cancer in her 30s, luckily received proper treatment, had a mastectomy and so far in the last 10 years is cancer-free. I have a wife, beautiful wife who is under the age of 50 and she has annual mammograms every year. I have a good friend who was just diagnosed with breast cancer who is in her mid 40s. Again, she's undergoing treatment. Hopefully she is going to have a good outcome.

To have a task force make the recommendation that has been made and to have in this bill the authority that is given to various unelected bureaucrats to make health care decisions including coverage and frequency in my opinion is wrong. Now, on a bipartisan basis, this subcommittee and the full committee repeatedly has passed bills increasing and supporting the early detection of breast cancer, the prevention, the research. I mean, we do it almost every Congress. So we are starting down a path in my opinion of socialization of medicine in this country with the passage of this bill out of this committee, with its passage on the House floor, it is waiting approval in the Senate. This is an excellent time to hold this hearing. I appreciate the subcommittee chairman and the full chairman's personal attendance, but let us don't talk about fairy tales. Let us talk about the facts, the plain English of these bills. And if we continue to agree rhetorically, then we need to begin to make substantive changes in the legislation to prevent what we all say

we oppose. We don't want rationing of health care in America, we don't want to intervene between the doctor-patient relationship, we don't want young women or for that matter more mature women over the age of 74 developing breast cancer because they are not allowed a mammogram. My good friend to my right, Mr. Rogers of Michigan, had an amendment that was passed at committee that explicitly prevented the rationing of care and it mysteriously disappeared in the bill that got reported out of the Rules Committee. In the dark of the night some staffer on the Majority side or maybe a Member, I don't know, decided that the will of the committee didn't mean anything. It disappeared. Maybe we need to put that back in. I don't know.

So I have great respect for this committee. I have great respect for the leadership on the committee. But let us not talk about fairy tales when we can read these bills. Now, I am not saying the bill is a fairy tale but I will say the bill is not reflective of the policy that members on both sides of the aisle say they support.

With that, Mr. Chairman, I yield back.

[The prepared statement of Mr. Barton follows:]

STATEMENT OF THE HONORABLE JOE BARTON
RANKING MEMBER, COMMITTEE ON ENERGY & COMMERCE

SUBCOMMITTEE ON HEALTH HEARING
"BREAST CANCER SCREENING RECOMMENDATIONS"
DECEMBER 2, 2009

Thank you, Mr. Chairman, for having this hearing on the important topic of breast cancer screening. As we all know, breast cancer presents an extraordinary challenge to our health care delivery system because it is both lethal and the most common cancer among women in the United States. The good news is that breast cancer death rates have declined since 1990, an achievement that was largely due to early detection programs and a unified public education message that clinical breast examinations should begin in your 20s and annual mammography should begin when you turn 40.

My own sister, Jan, developed breast cancer before age 50, so I was alarmed when I heard that the U.S. Preventive Services Task Force released new guidelines that actually recommended *against* routine screening mammography for women aged 40-49. I was also disturbed to hear that the Task Force now only recommends screening mammography for women aged 50-74 on a biennial basis and for women over the age of 74, the Task Force no longer recommends any mammography screening at all. These

recommendations appear to me and to many others to represent a significant step backward in our efforts to combat this deadly disease.

I suppose we could ignore the existence of these recommendations and simply rely on doctors and patients to decide for themselves what's best on a case-by-case basis. We could do that, all right, except that while the Task Force's ideas have been challenged, they have quietly survived as a policy proposal. Where? Right in the middle of the the Democrats' health reform bill that recently passed the House.

In the House version of Democrats' health reform, the U.S. Preventative Services Task Force and its successor organization are cited over one dozen times and given disturbing new authority over coverage decisions regarding breast cancer screening. For example, on page 1762 of the Democratic health reform bill, the U.S. Preventative Services Task Force is given the authority to determine the "frequency," "the population to be served," and "the procedure or technology to be used" for breast cancer screenings covered under the Indian Health Service.

Additionally, Section 303 of the legislation states that “the Commissioner shall specify the benefits to be made available under Exchange participating health plans.” In plain English that means the new Health Choices Commissioner will determine what preventive services, including mammography, are covered under your health insurance based on what the Task Force says is right. And we already know what they think is right.

As we all know, Mr. Chairman, the Administration has been double-talking on this issue ever since the Task Force’s recommendations were made public. At the same time the Task Force was turning up inside the Democrats’ health reform bill, Secretary Sebelius was telling us on November 19th that “the U.S. Preventive Task Force is an outside independent panel of doctors and scientists who make recommendations. They do not set federal policy and they don’t determine what services are covered by the federal government.” Now we know that she was mistaken, because under the Democrats’ bill, the Task Force will set government policy and will determine what is covered.

Mr. Chairman, it was my hope that we could have had Secretary Sebelius appear before us today to explain where the Administration stands. Is it for or against these new, controversial recommendations, and what does the secretary have to tell us about the additional responsibilities called for under the health reform legislation passed by the House?

As my colleagues will recall, when Secretary Sebelius testified in front of us on June 24th, she agreed to come back before this Committee after she and her staff had time to read the Majority's health reform bill. Mr. Chairman, I would hope that you would take the Secretary up on her offer to testify about this legislation so we can get the Administration's perspective on questions the American people have been asking.

In closing, I want to thank our witnesses appearing before us today and the Breast Cancer community for their commitment and endless dedication to finding a cure. It is my hope that this hearing will have a positive effect on that effort, and with that, I yield back the balance of my time.

Mr. PALLONE. Thank you.
Next is the gentleman from Texas, Mr. Green.

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

Mr. GREEN. Thank you, Mr. Chairman, and I appreciate the opportunity you have in so quickly dealing with this.

First of all, I want to thank the chairman emeritus for his offer, Chairman Dingell willing to conduct a class on remedial health care comprehension, and my only question is, is it going to be mandatory or permissive. And hearing my colleagues on the other side talk about unelected bureaucrats, unelected insurance companies do this every day right now, and I will give you an example. When I moved to be a Member of Congress, my wife had been getting annual mammograms and yet our new insurance in Congress refused that after the first year, and she was a survivor. Her mom was a 40-year survivor of breast cancer and she so fit the exception, and it took me as a Member of Congress—I can't practice law, but believe me, I will file suit against our carrier if they continue not to pay for those mammograms. You have to fight for the care that you want. And to say that the House bill that passed would set up this unelected group to do it, it all rests on our shoulders and I think that decision ought to be made by elected officials.

Now, this group will take recommendations from everyone but ultimately it is going to be our decision and we will continue to provide legislation to have minimum benefits, and the statement I have, in 2002 the task force changed their breast cancer screening to a grade B to recommend mammograms every 1 to 2 years for women 40 to 75. That was only 7 years ago. And yet now the task force is making a change. Two weeks ago they revised it and made a grade C, and that's the issue I think that my colleagues are talking about, that women at the age of 40 would not be automatic but should not be denied. And again, it does go back to the doctor and the patient's decision. And I have in fact doctors on both sides. I have doctors tell me all the time that they have battles with insurance companies saying we need to do this and the insurance company won't allow it, and they are the ones that are practicing medicine and that is a battle that has to be fought every day no matter what happens if we pass a national health care bill. But to use this opportunity to pick at the national health care bill I think is interesting because the task force will be given the opportunity to clarify their statements and I am glad we have the testimony here today.

The adverse reactions to the poor wording of the task force recommendations obviously have not gone unnoticed by our committee and the members of the committee. In fact, I have been contacted by a number of constituents in my district including M.D. Anderson Cancer Center in Houston about the recommendations. They were very public. They are opposed to the task force recommendations. They will continue to recommend it along with many, many other groups. And luckily the State of Texas has a mandate that all private insurers must cover annual breast cancer screenings beginning at the age of 40 but these new screening recommendations will cause some access problems for women.

The topic is also especially sensitive because the reform bill 3962 states that the U.S. Preventive Services Task Force recommendations A and B are mandated benefits and the bill also includes report language saying A and B recommendations are a floor for benefits, not a ceiling. The A and B are a floor. So the task force recommendation will be considered that but the decision could be made still no matter what the task force says. So that is what we are here today to talk about. I have concerns about jeopardizing access to preventive screenings for women, especially since I represent a majority Latino district that is medically underserved, and I worked for years in Congress to expand the coverage of mammograms in our community for primary and preventive care services. I like the fact that the task force is an independent commission and is designed to keep politics out of medical recommendations because I can be an expert for 30 seconds on anything but I do depend on the experts to be able to make those decisions.

Again, I look forward to the testimony, Mr. Chairman, and I ask unanimous consent that my full statement be placed into the record.

[The information was unavailable at the time of printing.]

Mr. PALLONE. Without objection, so ordered. Thank you, Mr. Green.

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

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

Mrs. MYRICK. Thank you, Mr. Chairman. Thank you for holding the hearing today.

I understand that scientifically and statistically this report information is not new, and I know that mammography is not perfect by any stretch of the imagination, but I want to talk to this whole report from the preventive side because to me it is sending the wrong message to women. It is saying you don't have to be vigilant, you don't have to take care of yourself, you don't have to do preventive care, and the reason that concerns me is, I am a 10-year breast cancer survivor. I am one of those who persevered literally to find, you know, my own cancer because I knew something was wrong with my body and I had good doctors who helped me. But because of that, I am here today, and we all know that earlier detection means longer survival. I mean, that is a no brainer. So many women really say to me I don't want to get a mammogram, it hurts, you know, or whatever, I just don't want to do it. I heard that over and over again ever since I started to get active on this issue. And then a lot of women have told me I don't want to know, you know, I really don't want to know if I have cancer. Well, my point whole in this is, you know, you better find out sooner rather than later because of what I said before.

So I am very concerned that we are saying hey, you don't have to take care of yourself. Women look for an excuse not to do this anyway and not to do self-exams, and especially, you know, younger women today. There are so many younger women in my area that are in their 20s and 30s getting breast cancer, they have their own support group and that never used to happen. So when we

talk about what we need to do, I hope that we will very seriously consider, you know—and I am glad the panel is going to be here to explain why they did what they did. But I know that some of the groups are going to continue to recommend they do the same thing and with digital mammography now, things have changed, especially with younger women.

So, Mr. Chairman, I appreciate this opportunity very much and just look forward to hearing the recommendations from the panel.

Mr. PALLONE. Thank you.

The gentlewoman from Wisconsin, Ms. Baldwin.

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

Ms. BALDWIN. Thank you, Mr. Chairman. I appreciate your calling this hearing of the Health Subcommittee to discuss what is both a deeply personal and deeply political issue for myself and as you have heard many of our colleagues in this room.

The U.S. Preventive Services Task Force was authorized by Congress to deliver recommendations regarding the efficacy of clinical preventive services. Ideally, these recommendations will be used to inform primary medical care. On November 16, the task force delivered new recommendations regarding breast cancer screenings incorporating the most extensive scientific evidence available. Among their more controversial findings were the grade C recommendation for mammography in women over 40, which means that because the science does not point to any significant harm or tremendous benefit, that the provision of the services should be a decision between an individual and her doctor. An independent, rigorous examination of the science behind clinical preventive services is an essential part of delivering effective health care. The task force was doing its job. And as they may admit today, they could have done much more around such a sensitive topic by educating and explaining their recommendations to women across the country. They could have engaged community and advocacy groups to be messengers of this information rather than combatants. Moving forward with additional recommendations in sensitive areas, I would encourage them to do just that.

I came away from this report and the surrounding controversy with two additional thoughts that I would like to quickly share. First, we clearly need better screening and diagnostic tools. Mammography is not a precise enough tool. We need advancements in technology that can help us understand what conditions require further tests, what requires treatment and how we can best help women live long and healthy lives. Some of these advancements in technology are being developed in my home State of Wisconsin, tools to help us identify types of issue with more precision, improving the efficacy of an X-ray screening for breast cancer.

My second point is that we urgently and desperately need health care reform. We must ensure that every woman and every American has access to a regular source of care. If the best approach is to discuss the option of mammography or other screening with your doctor, you have to have a doctor. The villain here is the lack of coverage and access to care. Otherwise women who are shut out of

the health care system whether by stigma or lack of resources or even abusive and discriminatory insurance industry practices, these women have the potential of dying of breast cancer or other conditions before we even have a chance to intervene.

Again, Mr. Chairman, thank you for allowing us this venue to discuss and clarify this critical topic. It has bearing not only on the health of women but the health of all Americans.

Mr. PALLONE. Thank you.

The gentlewoman from Colorado, Ms. DeGette.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you very much, Mr. Chairman. I will submit my full statement for the record.

I just want to say that as Mr. Sarbanes said, we have got to look at science here and we have got to look at the recommendations based on science which, you know, sometimes I feel revolutionary in Congress saying that, but that is what we need to look at. All of this excitement on the other side of the aisle about how these recommendations are going to be implemented, first of all, Mr. Green said, it is not a ceiling, it is just a floor, but secondly, even if they were implemented, most of them probably we wouldn't object to. The recommendations say, number one, the decision to initiate regular screening mammography in women age 40 to 49 years should be an individual one accounting for patient context and values rather than a population-wide recommendation for routine screening. That makes sense to me. Number two, biannual screening mammography for women age 50 to 74 years. Number three, insufficient evidence to assess the additional benefits and harms of screening in women over 75 years or old, and then the others.

So really, if you actually look at the recommendations, they probably do make some sense from a scientific standpoint but I have got to say, it is no wonder why the women of America are unbelievably confused as to what these recommendations are saying because what they are saying is, most women need to talk to their care provider and they need to figure out for themselves based on their health and their family history what is appropriate for them. It is not a one-size-fits-all testing. That makes sense to me. But if you look at the 24-hour news cycle, that is not what is being said to people. They are scared, they are confused. And when you add the misinformation that we hear from some of my friends on the other side, they are triply confused and scared because they think now when we have a health care plan that applies to everybody, suddenly they are going to be told that they can't have tests that they need, and that is simply not the case.

So, Mr. Chairman, that is why I came down and sat through all the opening statements and am looking forward to the testimony because I think we really need to clear it up. What is it that we are saying should be done with mammography and testing for women and what is it that women need to be talking to their physicians about. Ultimately it is going to be the decision of the physician and the woman what they need and they need to figure that

out and then they need to feel secure that they are getting the level of testing that they need. Thank you, Mr. Chairman.

Mr. PALLONE. I thank the gentlewoman.

Next is the gentleman from Ohio, Mr. Space.

**OPENING STATEMENT OF HON. ZACHARY T. SPACE, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO**

Mr. SPACE. Thank you, Mr. Chairman, for taking the time to hold the hearing on this very important issue.

Cancer is a terrifying specter for all Americans and almost all of us have had a loved one or a friend who has been affected by it. It certainly is a disease that strikes fear in the heart of all of us, and I want to preface my remarks by saying that I have heard some things from the other side of the aisle that have made a lot of sense, and I specifically point to Congresswoman Myrick's comments, and I find them very consistent with those just provided by my colleague from Colorado, Congresswoman DeGette. But we have heard some things from the other side of the aisle today that I think cause us or certainly cause me considerable concern. I think that it is wrong to use that fear that we all share of cancer to intimidate the people of this country into fear of comprehensive legislation that as some of our witnesses will testify today is good for people with cancer.

In following up with some of the remarks made by Chairman Dingell, there are some things this bill does not do that need to be clarified. These task force recommendations will not lead to rationing care. That is simply not true. You know, I think it is tactics like these that weaken the faith of the American people not in any one particular party but in the institution of Congress. Nothing in this legislation prohibits insurers from covering mammograms. In fact, the legislation gives the Secretary leeway to add to the minimum benefits package as needed. I think it is disingenuous to on the one hand defend the status quo which sees the insurance industry every day making decisions about the lives of their insureds based on strictly financial considerations and then on the other hand condemn a system because you speculate that these kinds of recommendations will lead to the rationing of care.

Second, what this bill does do is, it provides the benefit of insurance to millions of Americans that don't have it and then following on what Dr. Christensen mentioned earlier, it is not just those Americans that don't have insurance that would benefit from this bill when it comes to preventive care and access to mammograms, it is those who have insurance but can't afford the copayments, specifically those who are indigent or middle-class Americans. That makes a difference for them. This bill makes preventive care a basic and fundamental right for every American. That means again that my constituents, the 65,000 of them that have no access to coverage right now and tens of thousands more who can't afford copays will now have access to things like mammograms when they wouldn't have otherwise had that.

These are questions that we all should be asking: what is the net benefit of this legislation to our constituents. Rather than jumping to irrational conclusions, adding confusion to the public and politicizing an issue which should transcend politics, we should be ask-

ing these rational questions, again as my colleague from Maryland indicates, based on reason and science.

With that, Mr. Chairman, I thank you once again for calling this hearing and yield back.

Mr. PALLONE. Thank you.

The gentlewoman from Ohio, Ms. Sutton.

**OPENING STATEMENT OF HON. BETTY SUTTON, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO**

Ms. SUTTON. Thank you, Mr. Chairman, for holding this extremely important hearing on the recommendations from the U.S. Preventive Services Task Force on mammograms for women in their 40s.

As we have all heard and has been discussed here, the task force is no longer recommending routine mammograms for women in their 40s, and as someone who cares deeply about women's health, I like others was surprised by this change. Breast cancer is, to say the least, a terrible disease. It is the leading cause of death for women between ages 20 and 59. We all know people who have been touched by breast cancer, people that we love and care about, and we all know people who have benefited from early detection.

So this is such an important hearing and I look forward to hearing the discussion of the panel, and what the recommendations basically are is that a woman should talk to her doctor and make decisions accordingly for their care but many women as has been pointed out don't have doctors and many women don't have access to health care and women who should get mammograms either under the old recommendations or the new recommendations do not get the mammogram. In 2007, only 70 percent of the women in the country who should have been screened for breast cancer were screened for breast cancer, and part of the reason women, whether they are 40 or they are 60, are not screened is because they do not have insurance and because they don't have insurance they don't have access to the care that they need when they need it including preventive care.

So let us be clear, that providing access to health insurance means providing access to preventive care which means saving lives. So what is important is that patients and doctors are able to consult and access the care that that patient needs when that patient needs it and that the patients and doctors together will decide the best course of care whether that includes a mammogram but in order to do that, people have to have access to doctors. Women of all ages under the health care bill that has been passed by this House will have improved access to coverage. That should not be lost and it certainly should not discussions otherwise representations otherwise should not be used as we debate and discuss this very important issue to derail efforts to give women access to the health care that they need in this country. I don't think that that serves women well. I don't think that serves our country well, and frankly, I find it outrageous, and I yield back.

Mr. PALLONE. Thank you.

The gentleman from Iowa, Mr. Braley.

**OPENING STATEMENT OF HON. BRUCE L. BRALEY, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF IOWA**

Mr. BRALEY. Thank you, Mr. Chairman, and thank you for holding this important hearing.

I also want to commend my colleague, the gentlewoman from North Carolina, for her eloquent and thoughtful statement on a very important topic, and while I disagreed with what some of my colleague from Georgia said, I have great respect for his real-world experience on women's health issues and appreciate the concern he brought to this hearing.

But I also want to talk about the comments that were made by the chairman emeritus and others on this committee. If people don't believe that rationing takes place right now in our private insurance system every day and every State in every Congressional district, they are sorely misguided. It does happen every day under the current system, which is failing to meet the needs of the American people. I will give you a good example of a friend of mine who was diagnosed with prostate cancer and conferred with his physician on treatment options and agreed that proton beam therapy was the best choice of treatment for him, and he went to his private insurance company, which also is the Medicare administrator in my State of Iowa, and his treatment was denied on the basis that it was experimental. Well, guess what? Under the Medicare plan that that same private insurance company administered, it was considered non-experimental, and even though he was eligible for Medicare because of his age he was still covered by a private plan through his employer and was denied coverage for the same treatment he would have gotten if he had been a member of Medicare. That is what is wrong with our broken health care delivery system and that is why comparative effectiveness research is such a critical part of a rational discussion about health care policy-making.

In an earlier hearing in this same subcommittee, I talked about a hearing that took place in this very room years ago when a researcher advocating high-dose chemotherapy with bone marrow transplant for metastatic breast cancer patients was the only path to cure for those women, even though it had not been tested by rigorous academic research. Then years after that, we came to the realization that many women were actually harmed and died because of being subjected to that treatment.

And that is why, by the way, it is so important that the plain language amendment that I put in the health care bill be implemented in people dealing with health care issues. I think that in its position paper, the U.S. Preventive Services Task Force highlights why that is so important. They indicate on one page of their statement that the problem was a matter of communications because they did not say what the task force meant to say that the communication of the mammography screening recommendations was poor. Well, I agree with that, and all you have to look at is the next two sentences to find out why. This is what two of the sentences say, "The we said is that screening starting at age 40 should not be automatic nor should it be denied." That doesn't make sense. The next sentence says, "What we are saying is that a decision to

have a mammogram for women in their 40s should be based on a discussion between a women, her doctor.”

If you don't communicate for your intended audience in language that they can comprehend easily, these barriers of communication between highly technical scientific and medical information will be a problem but the debate we are having is a healthy debate and what the most effective use and treatment for breast cancer patients is and that is what we need to focus on going forward, and I yield back my time.

Mr. PALLONE. I thank the gentleman.

Next is the gentleman from Utah, Mr. Matheson.

Mr. MATHESON. Thank you, Mr. Chairman. I will be brief because I am looking forward to hearing from our two panels on this topic.

In my State of Utah, the incidence of breast cancer is lower than most States, however, our mortality rate is high because women in Utah are diagnosed in cancer's later stages. As a witness on our panel notes in his testimony, the recent recommendations provided by the U.S. Preventive Services Task Force November 16th have sparked concern and disagreement among providers, patients, families as well as sparked a public discourse that has led to further confusion and anxiety. As we can see from the testimony before this committee, there is not consensus on screening protocols but there does seem to be consensus that any screening and treatment discussion is an individual one between a provider and a patient.

So I hope today's hearing can provide concrete information on the evidence-based decision-making processes of the task force but I am also interested to hear from the cancer community and medical providers on their next steps for outreach and patient education on the benefits and limitations of mammography screening.

Thank you, Mr. Chairman. I yield back my time.

Mr. PALLONE. Thank you.

I believe that concludes the opening statements by members of the subcommittee, so we will now turn to our witnesses, and if our first panel would come forward, I would appreciate it. Thank you.

We have two witnesses both from the U.S. Preventive Services Task Force. To my left is Dr. Ned Calonge, who is chair of the U.S. Preventive Services Task Force, and next to him is Dr. Diana Petitti, who is vice chair of the U.S. Preventive Services Task Force. Now, I will just mention as I think you know that we have 5-minute opening statements from you. They become part of the record, and each of you may in the discretion of the committee submit additional statements in writing for inclusion in the record, and I would now recognize first Dr. Calonge.

STATEMENTS OF NED CALONGE, M.D., M.P.H., CHAIR, U.S. PREVENTIVE SERVICES TASK FORCE; AND DIANA B. PETITTI, M.D., M.P.H., VICE CHAIR, U.S. PREVENTIVE SERVICES TASK FORCE

STATEMENT OF NED CALONGE

Dr. CALONGE. Good morning, Mr. Chairman and distinguished members of the committee. On behalf of our fellow task force mem-

bers, we thank you for the opportunity to discuss the task force and our work.

Our recently published recommendations on breast cancer screening have drawn a remarkable amount of attention. We recognize the communication of what the recommendations say was poor and the timing of the release was unfortunate. We wish to explain the process and timeline for creating these recommendations and to clarify what we intended to say to clinicians and women.

The health care clinician scientists on the task force fully understand, most through personal experience, the impact of breast cancer on the lives of women and their families. Our job, though, is to rigorously review scientific evidence. Politics play no part in our processes. Costs were never considered in our considerations. We voted on these recommendations long before the last Presidential election. The timing of the release of the findings last month was determined not by us but both the publication schedule of the medical research journal which peer reviewed our work.

The current task force was created by Congressional mandate as an independent body with the mission of reviewing the scientific evidence for clinical preventive services and developing evidence-based recommendations for the health care community. Our primary audience for recommendations remains primary care clinicians. The task force has 16 volunteer termed members representing a diverse array of expertise in primary care and preventive health-related disciplines including adult, child preventive and behavioral medicine, women's health, nursing and research methods. The AHRQ director appoints members from the chair's recommendations developed from a public nomination process. Given the scope of topics covered, subspecialists who consult on or care for those identified through screening by primary care clinicians may not necessarily be recruited as members but instead are consulted to review and comment on our work at critical points in the process.

Our current portfolio includes a broad array of 105 clinical preventive services that are listed on our website. We strive to update topics every 5 years, which is what prompted the new breast cancer recommendations. To address a topic, designated task force work group members and scientists at an evidence-based practice center collaboratively develop an analytic framework and pertinent key questions. A structured, systematic review of evidence for each key question is conducted and a draft evidence report is created with working group consultation. Based on the evidence review and explicit methodology, the work group drafts a recommendation statement and at an in-person meeting the evidence and the draft statement are presented and discussed and the task force votes on the recommendation.

There is careful attention to conflicts of interest such that members with potential conflicts are recused from discussion and vote or otherwise restricted in participation. Representatives of 24 partner organizations including all primary care specialties, key federal agencies and other key stakeholders specified in our written testimony and on our website are invited to participate in the discussion. At three key points in the process, work products are sent for review and comment by the partner organizations by subspecialty

expert consults from the relevant disease area such as oncologists and by other stakeholders such as subspecialty professional organizations and advocacy groups. These products include the analytic framework and key questions, the draft systematic evidence review and the draft recommendation statement as voted on. All comments are considered in creating the final products. Final recommendation statements and evidence reviews are published in peer-reviewed medical journals.

Recommendations are expressed as letter grades based on two factors only: the magnitude of net benefit or balance of benefits and harms of providing the service and the scientific certainty about whether the service works. Cost and cost-effectiveness are not addressed in our deliberations and making a recommendation. Over the past several years we have discussed whether cost should ever influence a recommendation and we have repeatedly said no.

For A and B recommendations, they are sufficient net health benefits such as that primary care clinicians are recommended to provide these services for all appropriate patients. If there is no net benefit or there is net harm, we assign a D recommendation indicating to not provide the service. If gaps in the evidence prevent net benefit from being determined, we assign an I statement reflecting insufficient evidence, indicating that more research is needed.

Finally, a C recommendation is assigned when there is a small net benefit. For C recommendations, we recommend the patient be informed about the potential benefits and harms and then be supported in making his or her own informed choice about being tested. The specific C language that we recommend against routine provision was intended for consideration by primary care clinicians, but unfortunately as played out in unintended ways in the public interpretation of the breast cancer recommendation.

Congress through Public Law section 915 mandates that AHRQ convene the task force to address our mission. The role of AHRQ in the process is to support our activities and processes of AHRQ staff and the director of AHRQ do not vote or otherwise influence our decisions.

I will have to admit to the committee that breast cancer is of particular concern to me. I lost both my mother-in-law to breast cancer and my sister is currently undergoing therapy. I fully understand this issue and have to rely on the science as we provide our recommendations.

With that, I would like to turn testimony over to Dr. Petitti to testify specifically about the breast cancer screening recommendation.

[The prepared statement of Drs. Calonge and Petitti follows:]

Testimony by
Ned Calonge, MD, MPH
Chair, United States Preventive Services Task Force
Diana Petitti, MD, MPH
Vice-Chair, United States Preventive Services Task Force

Before

The Committee on Energy and Commerce
Health Subcommittee
United States House of Representatives
Wednesday, December 2, 2009, 10 AM
2123 Rayburn House Office Building

Good morning, Mr. Chairman and distinguished members of the Committee. I am Dr. Ned Calonge, Chair of the United States Preventive Medicine Task Force. This is Dr. Diana Petitti, Vice-Chair of the Task Force. We speak today on behalf of the members of the United States Preventive Services Task Force in thanking you and members of the Subcommittee for the opportunity to explain to the members of this Committee who the Task Force is, to describe how the Task Force goes about doing its work, and to explain the relationship of the Task Force to the Agency for Healthcare Research and Quality and to other federal government entities.

Two and a half weeks ago, the Task Force published, in the *Annals of Internal Medicine*, a set of recommendations about breast cancer preventive services that have drawn a remarkable amount of media attention. The members of the Task Force particularly welcome the opportunity to today explain to members of the Committee the history of how the breast cancer recommendations came about and the timeline for their release, to describe the kinds of evidence that were used to make the recommendations, and to clarify what the recommendations said and what actions the Task Force intended for clinicians and women to take based on recommendations.

The men and women who serve on the Task Force are physicians and academics and scientists who have dedicated their lives to studying medical evidence. We are the husbands or daughters, sons or siblings of people who have suffered with breast cancer. Many of us have lost patients and loved ones to this disease. I myself have lost a mother-in-law, and my sister is in the middle of treatment. We are well familiar with the ruthless horror of cancer, and the role that detection and treatment plays. We certainly know that mammography saves lives.

However, our job as the Task Force is to rigorously review scientific evidence. Politics play no part in our processes. Cost and cost-effectiveness were never considered in our discussions. We voted on these breast cancer screening recommendations in June of 2008 – long before the last presidential election and any serious discussion of national health reform. The timing of the release of the findings last month was determined by the publication schedule of the medical research journal, the *Annals of Internal Medicine*, which peer-reviewed the research.

Overview of the USPSTF

The mission of the Task Force is to evaluate the benefits of individual preventive services based on age, gender, and risk factors for disease; to make evidence-based recommendations to primary care clinicians about which preventive services should be incorporated routinely into primary medical care and for which populations; and identify a research agenda for clinical preventive care. Recommendations issued by the Task Force are intended for use by clinicians in the primary care setting. The Task Force recommendation statements present health care providers with information about the evidence behind each

recommendation, allowing clinicians to make informed decisions about implementation into their own practices.

History of the USPSTF

The Task Force was established in 1984 by the Public Health Service, based on similar work by the Royal Canadian Task Force on the Periodic Health Exam. Then, as now, the members met as volunteers. The Task Force conducted evidence reviews and decided on recommendations to be made to primary care clinicians based on these reviews. These pioneering efforts resulted in the publication in 1989 of the first Guide to Clinical Preventive Services, which was broadly announced with the tag line, "Talk more, test less", and was widely distributed to primary care physicians. A second Task Force was assembled and, using similarly methods, released the second edition of the Guide in 1996. After this, the third Task Force, with a rotating membership and a new approach of continuous reviews and recommendation releases was created, and the Task Force was codified by Congressional mandate as an independent body with the mission of reviewing the scientific evidence for clinical preventive services and developing evidence-based recommendations for the health care community.

Since 2002, the Task Force has issued its recommendations via publication in peer-reviewed journals and has a relationship with the *Annals of Internal Medicine* that permits the editors of the Annals of Internal Medicine to publish its recommendations and report about the evidence that support the recommendations.

Members of the USPSTF

Since 2001 the Task Force has been a standing Task Force of 16 members including a Chair and Vice-Chair. Members are invited to serve for a 4-year term, with a possible 1-2 year extension. The 16 members represent an array of experts in primary care and preventive health-related disciplines including internal medicine, family medicine, behavioral medicine, pediatrics, obstetrics/gynecology, preventive medicine and nursing as well as and experts in medical research methods. As the recommendations are intended for use by primary care clinicians, who are the health care providers who actually implement the broad array of screening and other preventive services recommended by the Task Force, the subspecialists who consult on or care for those identified with specific diseases are not recruited by the Task Force but instead are asked to review and comment on the Task Force's work at critical points in our processes.

The Chair of the Task Force is selected by the out-going Chair from among current members of the Task Force. The criteria for selection as Chair are experience in running meetings and a willingness to commit a substantial amount of time to representing the Task Force in public forums and to overseeing the work done by the Task Force. The Vice-Chair is selected by the Chair from among current members of the Task Force after consulting with other members of the Task Force with medical officers at AHRQ.

New members of the Task Force are selected each year to replace those who have completed their appointment terms. Every year, a notice is placed in the Federal Register soliciting nominations for new members. This notice is circulated to all 24 Task Force Partner organizations (Partner organizations are described below) and distributed via AHRQ's prevention listserv, received by more than 22,000 individuals and organizations. Anyone can submit a nomination; self nominations also are accepted. Individuals nominated but not appointed in previous years, as well as those newly nominated, are considered in the annual selection process.

Nominated individuals are selected for the Task Force on the basis of specific qualifications and the current needs of the Task Force for particular areas of expertise. Strongest consideration is given to individuals who are recognized nationally or internationally for scientific leadership within their fields of expertise. Applicants must have no substantial conflicts of interest that would impair the scientific integrity of the work of the Task Force, including financial, intellectual, or other conflicts. The AHRQ

Director appoints new members upon the recommendations developed by the Task Force Chairs.

In order to qualify for nomination to the Task Force, an applicant must demonstrate the following:

- Knowledge and experience in the critical evaluation of research published in peer reviewed literature and in the methods of evidence review.
- Understanding and experience in the application of synthesized evidence to clinical decision-making and/or policy.
- Expertise in disease prevention and health promotion.
- Ability to work collaboratively with peers.
- Clinical expertise in the primary health care of children and/or adults, and/or expertise in counseling and behavioral interventions for primary care patients. Members are also selected based on other relevant expertise such as medical decision-making, clinical epidemiology, behavioral medicine, and health economics.

Topics

Description of Portfolio of Topics

The Task Force develops recommendations on a broad array of clinical preventive services, which the Task Force calls its “portfolio” of topics. As of November 24, 2009, there were 105 topics in the Task Force active portfolio of topics. These 105 topics are listed on the USPSTF website, <http://www.ahrq.gov/CLINIC/uspstfix.htm>.

Selection of New Topics

New topic nominations are solicited from the field every other year via a notice in the Federal Register. Topic nominations are also provided by Task Force partners who are drawn from the fields of primary care, public health, health promotion, policy, and quality improvement. Task Force members themselves may also submit topics for consideration.

All nominations for new topics are reviewed by the Topic Prioritization Subcommittee of the Task Force. The members of this Subcommittee evaluate each topic and prioritize them for inclusion in the Task Force portfolio based on the following criteria: public health importance which includes the burden of suffering, the potential of the preventive service to reduce the burden and the potential for the Task Force to impact clinical care. The latter considers such factors as whether there is clinical controversy or uncertainty, whether current practice does not reflect current evidence, or whether there is inappropriate timing in delivery of services. The Task Force prioritizes topics for which there is a known gap in performance and there is the potential to significantly improve clinical practice. The recommendations of the Topic Prioritization Subcommittee for addition of new topics to the Task Force portfolio are reviewed and voted on by the entire Task Force.

Topic Updates

The Task Force makes every effort to update all topics in the portfolio at regular intervals, striving to keep evidence reviews and recommendations less than five years old. The Task Force also may retire or inactivate some recommendations made in previous years rather than update the evidence review and issue new recommendations. The Task Force inactivates topics that are: 1) No longer relevant to clinical practice due to changes in technology, new understanding of disease etiology/natural history, or evolving natural history of the disease; 2) Not relevant to primary care setting, because the service is not implemented in a primary care setting or not referable by a primary care provider; 3) has low public health burden; 4) is otherwise deemed out of scope for the Task Force.

How the USPSTF Does Its Work

The Task Force does its work in face-to-face meetings, by conference call and by email. The Task Force has three standing Subcommittees, the Methods Subcommittee, the Topic Prioritization Subcommittee, and the Implementation Subcommittee, which meet via conference calls, most often held monthly.

Ad hoc committees, called Work Groups, are designated to address special prevention topics when necessary. A Chair for each ad hoc Work Group is designated by the Chair in consultation with the Vice-Chair. On the November 29, 2009, there are two designated ad hoc Work Groups, the Child Health Work Group and the Geriatrics Work Group. Ad hoc Work Groups meet by conference call.

In-person meetings of the entire Task Force membership are held three times a year for one and a half days in March, July and November. The meetings occur in meeting rooms at the Agency for Healthcare Research and Quality. Scientists from Evidence-based Practice Centers (EPCs) working on topics considered at the meeting attend. The meetings are also attended by AHRQ staff who work as medical officers with the Task Force and representatives of Partner organizations. Preventive medicine residents taking rotations at AHRQ are permitted to attend with the permission of the Chair. Other special guests from partner organizations are permitted to attend with permission of the Chair.

Partner organizations include a list of organizations that have an interest in the work of the Task Force in terms of the recommendations produced. These organizations send a representative to attend and participate in meetings, and the organizations are also consulted for review and comment on the work products of the Task Force at key points along the recommendation creation process. Primary care partners include the American Academies of Family Physicians, Nurse Practitioners, Pediatrics, Physician Assistants; the American Colleges of Physicians, Obstetricians and Gynecologists, and Preventive Medicine, the American Osteopathic Association and the National Association of Pediatric Nurse Practitioners. Policy, population and quality improvement partners include America's Health Insurance Plans, the National Committee for Quality Assurance, and new to the Partner group as of our July 2009 meeting, AARP. Federal partners include the Centers for Disease Control and Prevention, the Center for Medicaid and Medicare Services, the US Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, the Veteran's Health Administration, the Department of Defense/Military Health System, the Office of Disease Prevention and Health Promotion, and the Office of the Surgeon General.

Conflict of Interest Policies and Procedures

Policies and procedures designed to assure that recommendations are free of financial and other conflicts of interest are described in detail in the Task Force Procedure Manual, which is publicly available. Prior to each meeting, Task Force members are required to disclose in writing information about conflicts and potential conflicts—including financial, intellectual, and other conflicts—that may interfere with their abilities to discuss and/or vote objectively on a specific topic. A committee comprised of AHRQ staff and the Task Force Chair and Vice Chair review each member's disclosures and issues a recommendation on the member's eligibility to participate on a specific topic(s) in one of the following categories:

- A. No action.
No disclosure or recusal necessary.
- B. Information disclosure only.
Member may participate as topic lead, and may discuss and vote on the topic.
- C. Recusal from participation as lead of topic workgroup; information disclosure.
Member may discuss and vote on the topic.
- D. Recusal from all participation; information disclosure.
Member may not participate as topic lead, and may not discuss or vote on the topic. Member will leave the meeting room for all discussion and voting. Publicly released recommendations will denote the member's recusal from participation and voting on this topic.

Topic to Recommendation and Release of Recommendation

A topic selected as a new topic or scheduled for update moves from this point to recommendation and recommendation release according to the following steps.

A topic Work Group comprising three Task Force members is designated. One member of the Work Group is designated as the “lead.” It is the responsibility of the lead to attend every conference call for the topic, chair calls about the topic and to be the primary liaison with other members of the Work Group, with the assigned AHRQ medical officer and the Evidence-based Practice Center.

For each topic, key questions are developed and a systematic review of the evidence for each key question is conducted. These systematic reviews are done by scientists in the Evidence-based Practice Centers who work under contract to AHRQ.

After a topic has been selected, the members of the Work Group and the scientists at the Evidence-based Practice Center collaboratively develop the analytic framework and craft key questions pertinent to evaluating the topic. The analytic framework and key questions are sent out to the Task Force Partners organizations as well as to identified subspecialty experts in the disease topic and other stakeholders, such as subspecialty professional societies, for review and comment. This peer review is used in refining the analytic framework and key questions as deemed appropriate in consultation with the Work Group and the Evidence-based Practice Center scientists.

The Evidence-based Practice Center then conducts a systematic review of evidence for each key question using methods described in detail in the Task Force Procedure Manual. A draft systematic evidence report (SER) is prepared by the Evidence-based Practice Center, discussed with the Task Force Work Group and edited with their direction, then again, this work product is distributed to the Task Force Partner organizations and other identified expert stakeholders, including subspecialists, for review and comment. This peer review comment is summarized and addressed and a final draft of the Evidence Review is completed.

At this point, the members of the Work Group and the Evidence-based Practice Center review the draft Evidence Review. Members of the Work Group then work with an AHRQ medical officer to prepare a draft recommendation statement reflecting their synthesis of the evidence and using the explicit Task Force methods and grades and evidence. The topic is scheduled for an in-person Task Force meeting for discussion of the evidence and the draft recommendation statement and a vote on the recommendation.

The Evidence Review is distributed to all members of the Task Force to be reviewed prior to the meeting. At the meeting at when the vote is scheduled, the Evidence-based Practice Center summarizes the evidence related to each key question. A Task Force member of the Work Group presents the draft recommendation statement to the Task Force along with the rationale for the recommendation.

After a full discussion of the evidence and the proposed recommendation, which can include input from both federal and non-federal partners, the Task Force members vote on the proposed recommendation or, if deemed appropriate after the discussion, an alternative recommendation. A quorum is required for a vote. A vote is passed if a majority of the total membership, or nine members, vote yes. In practice, however, when votes appear to be very close, an effort is made to craft recommendation language that is acceptable to all of the members and many, though not all, recommendations eventually pass based on a unanimous vote.

After drafting the specific recommendation statement, the statement is once again sent out for Partner and expert stakeholder review and comment, these comments are considered and used to craft the final statement, and the recommendation statement and Evidence Review are submitted for publication. Thus,

there are three key opportunities in the process for experts in the disease area to review and provide input for consideration by the Task Force in making a recommendation.

Methods for Identifying and Assessing Evidence and Making Recommendations

The Task Force makes its recommendations based on “rules of evidence” that are described in a 99 page Procedure Manual publicly available at the USPSTF website. Additionally, the Task Force has published descriptions of the most salient processes and methods in the *Annals of Internal Medicine*. Publications in the *Annals of Internal Medicine* that describe the processes and methods that the USPSTF in effect now (November 29, 2009) are available on the USPSTF website. These methods were in used when the TF made its recommendations about breast cancer preventive services.

Task Force recommendations are based on consideration of the health benefits and the health harms of providing the preventive service and on the scientific certainty about whether the preventive service “works.” Cost and cost-effectiveness of specific prevention services are not addressed by the Task Force in its deliberations. The Task Force only considers scientific evidence of health benefits and health harms. The Task Force has specifically discussed whether cost should influence a recommendation and has repeatedly voted to leave costs out of all deliberations of whether to provide or not provide a preventive service.

The evidence from the Evidence Review is graded for each key question and for the body of evidence as a whole as “convincing”, “adequate” or “insufficient”. Using at least adequate evidence, the Task Force then considers only two factors in assigning a letter grade along with its template recommendation language. One factor is the magnitude of net health benefit, or the balance between benefits and harms as indicated by the SER, and this is graded as “substantial”, “moderate” or “small”. The other is the certainty of the net benefit, or the level of confidence that Task Force has that the recommendation will not change based on future research, and this is graded as “high”, “moderate” or “low”. “A” recommendations require a high certainty of substantial net benefit and “B” recommendations require at least a moderate certainty of at least a moderate net benefit. Primary care clinicians are recommended to implement the provision of A and B services for most of their appropriate average risk patients as well as for high risk patients where the Task Force has made an “A” or “B” recommendation. A “D” recommendation requires at least a moderate certainty that the service provides no benefit, or leads to harms in excess of benefits, and primary care clinicians are recommended to not provide these services. Low certainty always leads to a conclusion of insufficient evidence to make a recommendation, which is indicated by making an “I” statement, an indication that more research is needed to fill in the gaps in evidence in order to support an evidence-based recommendation. Finally, a “C” recommendation is given when there is at least moderate certainty of a small net benefit.

The C Recommendation/Small Net Benefit

In the 1980s, the USPSTF assigned a C grade in situations where the Task Force concluded that there was “insufficient evidence to make a recommendation.” In these situations, the first 1989 edition of the Guide to Clinical Preventive Services qualified the C grade recommendations with language that implied certain actions even in the absence of evidence (“there is insufficient evidence to recommend for or against x, but recommendations for/against the service can be made on other grounds” or that “a prudent person” might undertake to provide the service even in the absence of evidence.

In the 1990s, this practice came under criticism by those who sought greater purity and consistency and who felt that the “other grounds” and “clinical prudence” were not evidence-based arguments. The Task Force created a neutral C recommendation, stating only that the risks and benefits were closely matched and therefore, there was not a recommendation for or against providing the service. It also created the new I or insufficient evidence category, to distinguish between a true lack of evidence (I) and the existence of evidence that net benefit was small (C).

In the period from the late 1990's to 2006-2007, the Task Force came under increasing criticism for failing to give practical guidance about what to do when net benefit was small. Clinicians commonly complained (and reported in focus groups) that the C recommendation gave insufficient guidance for use in the exam room. Clinicians stated that people wanted to know what to do and found the C grade recommendations unhelpful, and most often chose to not offer the service at all. Based on this input, the Task Force concluded that in situations where the net benefit of the preventive service was small (that is a C grade recommendation), the patient should be informed about the potential benefits, harms, and on balance a small overall benefit and then make his or her own informed choice about being tested. In essence, in recommending to the primary care clinician that testing should not be "routine", the Task Force was promoting this informed patient decision-making. Clinicians could be comfortable in recommending the A and B recommendations without much thought, but when faced with a C recommendation, they should talk with their patients and support an informed decision. The Task Force elected to adopt language to associate with a C grade recommendation---"the Task Force recommends against ROUTINE"--that, while intended for consideration for primary care clinicians, has played out in unintended ways in the context of its breast cancer recommendation as interpreted by the public.

Relationship of USPSTF to AHRQ

Congress (through Public Law Section 915) mandates that the Agency for Healthcare Research and Quality convene the Task Force to conduct scientific evidence reviews and make evidence-based recommendations for primary care. The role of AHRQ in the process is to support the Task Force in specific activities:

1. AHRQ provides for the face-to-face meetings and conference calls for Task Force members.
2. AHRQ manages the contracts for the Evidence-based Practice Centers to do the Systematic Evidence Reviews under Task Force direction.
3. AHRQ Medical officers provide administrative support to the Task Force and its standing, ad hoc and topic workgroups, and work with Task Force members on evidence reviews for the re-affirmation of topics where the Task Force believes the recommendation is unlikely to change. While present for Task Force meetings and discussions, no medical officer has a vote nor otherwise influences the decisions of the Task Force. Similarly, the Director of AHRQ has no role in or influence on the recommendations of the Task Force, and unlike the medical officers, does not attend during Task Force deliberations.

Breast Cancer Preventive Services

History of Task Force Recommendations on Screening Mammography

The Task Force first addressed screening mammography as a topic in 1989. At that time, the Task Force recommended screening women age 50-75 every 1-2 years based on randomized trial evidence that screening reduced mortality due to breast cancer in women first screened at this age. With regard to screening younger women, the Task Force stated that "it may be prudent to begin mammography at an earlier age for women at high risk of breast cancer."

In its 1996 Guide, the Task Force recommendation was in favor of screening women 50-69 every 1-2 years. Mammography screening for women age 40-49 was given a C grade. At that time, a C grade recommendation meant insufficient evidence to make a recommendation for or against screening and was linked with the following statement that the Task Force stated that it "recognized that there may be other grounds on which to base a recommendation for or against an intervention when scientific evidence is unavailable."

In 2002, the Task Force recommended screening women 40-69 every 1-2 years stating that that the benefits were smaller and took longer to emerge for women who were first screened in the 40's.

Recommendation in 2009

On November 16, 2009, the Task Force issued its updated recommendations for breast cancer preventive services in the form of a publication in the *Annals of Internal Medicine*. Based on its evidence review and using its defined “rules of evidence” the Task Force recommendation about screening women age 50-74 was given a “B” grade. The recommendation about screening women 40-49 was given a “C” grade.

The language used to link these grades with advice to clinicians that was used by the Task Force was its standard language. This language has been described in the Task Force Methods manual and in publications.

The Task Force acknowledges that the standard language used to describe its recommendations about breast cancer screening for women age 40-49 did not say what the Task Force meant to say. The Task Force communication of the mammography screening recommendation for women 40-49 was poor. The Task Force makes a commitment to making changes in the way that it communicates its conclusion that will assure that this kind of miscommunication does not occur in the future.

The Task Force appreciates the opportunity to clarify that it recommends the following:

“Women age 50-74 should have mammography every other year. The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient’s values regarding specific benefits and harms.”

The we said is that screening starting at age 40 should not be automatic. Nor should it be denied.

What we are saying is that the decision to have a mammogram for women in their 40s should be based on a discussion between a woman her doctor.

Many doctors and many women, perhaps even most women, will decide to have mammography screening starting at age 40. The Task Force supports those decisions.

Timing for Undertaking the Update of Breast Cancer and Timeline

The Task Force issued recommendations about breast cancer preventive services in 2002. In late 2006, discussion of a plan for updating the 2002 recommendation in 2007 with the hope that the update might be issued within 1 year of the 5 year target for updating topics. Because the Task Force undertook updates of a large number of recommendation updates from 2002 at the same time, it was recognized that the 5-year timeline might not be able to be addressed. The alternative--reaffirming the recommendation without conducting an update of the evidence--was not considered by the Task Force because its own rules of evidence require an evidence update.

Process for Breast Cancer Recommendation

The Task Force process for undertaking to make a recommendation is described in detail in the 99-page Methods Manual that the Task Force makes available at its website. The steps have been described in general terms earlier in this testimony. The breast cancer recommendation topic was initiated as other topics and the steps taken progressed as for other topics up to the November 17, 2007 Task Force meeting. When the breast cancer recommendation statements came up for a vote at the November 17, 2007 meeting of the Task Force, unusually, the members of the Task Force could not come to agreement about what to recommend. The following table shows the timeline of progress of the breast cancer recommendation update to the point that the Task Force was unable to agree on what to recommend.

Task/Activity	Date
Breast cancer topic due for reconsideration/new topic	Late 2006- January, 2007
3 member Work Group comprising Task Force members designated by Chair	Late 2006- January, 2007
Evidence Based Practice Center (EPC) selected to conduct systematic review and contract negotiated	Late 2006-January, 2007
Work Group holds conference call with EPC scientists to discuss analytic framework and key questions	January, 2007
Draft of analytic framework and key questions prepared by EPC scientists	February, 2007
Work Group and EPC scientists hold conference call to finalize analytic framework and key questions	February, 2007
EPC scientists conduct evidence review and prepare draft of evidence report	February-October, 2007
EPC systematic evidence review is sent to Partners for peer review	Early October, 2007
EPC evidence review distributed to Work Group	October, 2007
Work Group and EPC scientists hold conference call at which EPC summarizes evidence for each key question	October, 2007
Work Group drafts recommendation statement	October, 2007
Work Group holds conference call(s) to review and finalize draft recommendation statement	October, 2007
Evidence report (minus full Outcomes Table) distributed to full Task Force 2 weeks prior to meeting	October, 2007
Meeting to vote on RS <ul style="list-style-type: none"> • Full Outcomes Table distributed to Work Group and other Task Force members at start of meeting • EPC presents summary of evidence report • Draft recommendation presented by Work Group member • Task Force members discuss recommendation statement • Task Force member vote on recommendations but are unable to obtain a majority vote for any presented or modified set of recommendations • Task Force members request EPC and Work Group to obtain more evidence on age-specific benefits and harms 	November, 2007
TOPIC SENT BACK TO WORK GROUP	

The members of Task Force were not able to come to agreement on a breast cancer screening recommendation based on the initial evidence report because of disagreement about what to say about the balance of benefits and harms for starting to screen in the 40's compared with the 50's. Thus, the discussion by the members of the Task Force centered on the very issues that have moved this topic to the spotlight in the recent weeks---what to say about a starting age or screening. The Task Force was also unable to agree on what to recommend about screening mammography for women age 75 or more years. The issue of what to recommend about screening for women age 75 or more years was a major issue for the Task Force as a focus of its current work has been on providing better evidence-based advice on preventive services for older adults.

Additionally, since 2002, the Task Force has been attempting to provide clinicians with evidence-based advice on starting and stopping age and on screening interval for all of the topics in its portfolio. The need for more specific advice on stopping and starting age and on service interval is a recurring request from primary care practitioners.

It is in this context that the Task Force sought information that would permit a better weighing of benefits and harms.

To accomplish this aim, the Task Force asked the EPC scientists to obtain information on the age-specific harms and potential harms of mammography. The Task Force commissioned a decision modeling study to evaluate the trade-offs of various starting and stopping ages and screening intervals as information to inform its recommendations on screening mammography.

The Task Force considered this evidence at its July 14-15, 2009 meeting. The Task Force decided to make six separate recommendations about breast cancer preventive services---three related to film mammography screening (screening in women age 50-75, age 40-49, and 75+) and one about teaching breast self-examination, one about digital and MRI mammography and MRI for screening, and one about clinical breast examination.

Evidence Considered in Making Final Recommendations

In making its final recommendations, the Task Force considered evidence identified in a systematic review of the evidence for six key questions done by the Evidence-based Practice Center (EPC) that had done a review of the breast cancer topic for the Task Force at the time of its 2002 update; the results of an analysis of data from the Breast Cancer Screening Consortium, and the results of a modeling study commissioned by the Task Force and conducted by the Cancer Intervention and Surveillance Modeling Network (CISNET).

The systematic evidence review addressed six key questions related to breast cancer preventive services. It identified evidence about the effectiveness of mammography based on published reports of randomized, controlled screening trials with specifically updated information from new and more recent mammography trials among women aged 40 to 49 and 70 years and older. It identified evidence on the effectiveness of teaching breast self-examination, the comparative effectiveness of digital and magnetic resonance imaging compared with film mammography, and evidence about the effectiveness of clinical breast examination, based on updated information from randomized trials, comparative studies, and descriptive studies. The systematic evidence review also identified data on the harms and potential harms of breast cancer screening, including false-positive test results, overdiagnosis and treatments for cancers that would never have progressed and low level radiation. Evidence was gathered from multiple sources, including systematic reviews, meta-analyses, and recently published literature.

To assess the follow-up testing and other outcomes of mammography screening, the EPC scientists were

also asked by the Task Force to include data from an analysis of the Breast Cancer Surveillance Consortium (BCSC) from 2000 to 2005. Finally, the Task Force asked the Breast Cancer Modeling Group of the Cancer Intervention and Surveillance Modeling Network (CISNET) to provide data from comparative decision models that evaluated the trade-offs of various screening strategies with regard to starting and stopping ages and intervals for screening mammography.

The evidence report prepared by EPC scientists and considered by the Task Force included 45 pages of text; with references, tables, figures and appendices, it was 120 pages. This complete evidence reports is publicly available at the Task Force website. The report from the CISNET modeling group was 44 pages long and it is also publicly available.

Benefits of Screening Mammography

The Task Force concluded from the evidence that screening mammography for women 40-74 has a benefit in reducing death due to breast cancer. The Task Force focused on reduction in death due to breast cancer because this is the benefit of breast cancer screening that has been the focus of randomized trials. The Task Force recognizes that there may be other benefits of screening, such as earlier diagnosis that permits less invasive and toxic therapies, for which evidence is lacking.

Harms of Screening Mammography

Preventive services are provided to asymptomatic individuals for the sole purpose of preventing or delaying morbidity, preventing or delaying functional decline, and/or postponing death by decreasing the chances of death due a specific cause. The promise of service delivery for prevention is net benefit. Net benefit is the benefit of the service in achieving its aim—to prevent or delay morbidity or functional decline or to postpone death—minus its harms.

The benefits of screening mammography have been easy to communicate. These benefits are the identification by mammography of something that turns out to be cancer, the treatment of that cancer, and the effect of the treatment of that cancer in prolonging life by preventing death due to breast cancer.

The harms and potential harms of mammography screening have been difficult to communicate.

The easily understandable and commonly used definition of harm is a physical injury that is direct and immediate. Some women report a small amount of pain or discomfort when undergoing a screening mammogram. Pain and discomfort are easily understood as harms of screening mammography based on the commonly used definition of harm. These harms are very, very small.

The Task Force considers as harms not just the physical harms of the screening test and it construes harms more broadly than physical harms. For mammography screening, false positive tests are viewed as a potential harm of screening. It is not, of course, the false positive test itself that carries the potential for harm. Rather, it is the consequences of the positive test. These include the additional imaging and other tests done to follow-up on a false positive, biopsies done for lesions that turn out not to be cancer, and the inconvenience of medical appointments due to false-positive screening tests.

There has been disagreement about the seriousness of false positive tests as a harm or potential harm of screening mammography. The mention of anxiety and psychologic distress as a harm of a false positive test has, in particular, been ridiculed.

To understand the consequences of a false positive test within the framework of harm that considers anxiety and distress, it is necessary to consider how women enter screening and what happens or might happen to a woman who has a positive screening mammogram.

No matter how hard the concept of screening is explained before a healthy woman is sent to have a screening mammogram, a positive mammography screening test means cancer until cancer is proven not to exist. For some women who have a positive mammogram, the time between a positive mammography screening test and a statement--"there is no cancer"--is mercifully short. For other women, the follow-up of a positive mammography screening test involves more than one additional imaging test, perhaps a clinical breast examination along with a test, a trip to a surgeon.....over a period of time that is not always short and over a period of time that is unpredictable and is not within the control of the woman who has had the positive test. Some women eventually need a biopsy in order to be certain that there is no cancer.

Cancer is a terrifying prospect. Breast cancer carries special emotional weight because the consequences of a breast cancer diagnosis have, in the past, been not only the prospect of death due to breast cancer but the prospect of mutilating surgery. Anxiety and psychological distress in women who have had a positive screening test is documented. The Task Force wants only that screening mammography be done with full knowledge of the potential harms, the frequency of these harms and what is gained by being screened at an earlier compared with a later age.

For screening mammography, there are other harms that are difficult to quantify because so little information about them is available. Some women screened in their 40's are diagnosed with cancer that could be treated just as well if diagnosed in their 50's and some had cancers that would never progress. These women may have been unnecessarily exposed to the harms of treatment, including surgery, chemotherapy and radiation, years earlier than necessary.

More research and more attention to this topic is a pressing need.

A final harm is exposure of the breast to radiation and the risks of radiation. With modern mammography equipment the radiation exposure for any single examination is small. But over time and over examinations, which include the examinations done to follow-up of false positive tests, radiation exposure increases.

Net Benefit

The concept of net benefit--benefits minus harms--is central to the Task Force approach. The Task Force maps evidence to an evidence grade recommendation based on evidence certainty and the magnitude of the net benefit in categories---"substantial," "moderate" and "small." There is no single number that the Task Force uses to place a recommendation in a category. Based on its assessment of the balance of benefits and harms,

Timeline

A great deal had been read in to the timing of the release of the Task Force recommendations following its final vote. These recommendations were released in unfortunate and entirely accidental temporal juxtaposition with major events in the health care reform debate. The following is a detailed timeline that shows the events from the vote of the Task Force about breast cancer on July 15, 2008 (also discussed on July 14, 2008) and the release of the recommendations on November 16, 2009 through publication in the Annals of Internal Medicine.

Task/Activity	Date
Task Force leads work with modeling group to commission modeling study	December- January, 2008
Off-line work in progress <ul style="list-style-type: none"> • Modeling study being done by CISNET 	February – Early May, 2008

<ul style="list-style-type: none"> • BCSC analysis being done by EPC scientists • Revised Outcomes Table being prepared by EPC scientists 	
Work Group holds conference calls to hear presentations by EPC and CISNET scientists	Mid May, 2008
Work Group holds conference calls to review and finalize NEW draft Recommendation Statement	July 1 and July 9, 2008
Revised Evidence Report and Modeling Study Report distributed to full Task Force 2 weeks prior to meeting	July, 2008
Meeting to vote on new recommendation statement <ul style="list-style-type: none"> • EPC scientists present revised evidence report incorporating analysis of BCSC data and revised Outcomes Table • Modeling scientists present modeling results • Draft recommendation presented by Work Group member • Task Force members discuss Recommendation Statement • Task Force member vote on recommendations 	July 14-15, 2008
Work Group finalizes rationale, clinical considerations, and discussion before sending out to Partners for review and comment	January to April, 2009
Recommendation statement document sent to Partners for review and comment	April, 2009
Target month for publication in Annals of Internal Medicine known	August, 2009
Work Group reviews Partner comments Changes are made to the Recommendation Statement in response to Partner comments	September, 2009
Manuscript of Recommendation Statement submitted for publication (Annals of Internal Medicine)	September, 2009
Galley proofs from Annals received and returned	Late September, 2009
Exact date of publication of breast cancer recommendations known to AHRQ and to Task Force Chair and Vice-Chair	November, 2009
Publication in Annals of Internal Medicine	November 16, 2009

Between July 15, 2008 and the recommendation release through publication on November 16, 2009, the Chair and the Vice-Chair of the Task Force were regularly updated on the progress of the breast cancer recommendation. Every effort was made by the members of the Task Force and by those working with the members to assure that the recommendations moved as quickly as possible. There was no interference of any AHRQ employee or government official in the movement of these recommendations through the process.

The process was too long. The long time between the vote and the release of the recommendations is the basis for a quality review of processes and the development of an explicit plan to make certain that future topics

do not encounter delays this long.

Again, the Task Force did not in any way attempt to accelerate or delay these recommendations. The fact is the Task Force members were, depending on the commentator, either naively out of touch or woefully out of touch, with the events in Congress that have now swept up these recommendations.

Expert Review of Breast Cancer Recommendations

The EPC Evidence Report on Breast Cancer Preventive Services, the Task Force Recommendation Statement (including clinical considerations, rationale, and discussion), and the supporting document describing the CISNET modeling study were sent for review to Partner organizations as part of the regular process of review that the Task Force requires as part of its methods. The Task Force asks partner organizations to select reviewers based on their expertise in the topic field as scientists.

The specific names of reviewers of the breast cancer prevention recommendation statement are listed in Appendix B6 of the evidence report for the Breast Cancer Prevention topic. These expert reviewers included one oncologist, an expert in modeling, two radiologists, one breast surgeon, and three physician/epidemiologists. Individuals representing the views of the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Family Physicians weighed in. The American Cancer Society provided the Task Force with a statement of its recommendations on breast preventive services. physician/epidemiologists. Additional reviewers chosen by the Annals of Internal Medicine are anonymous.

Comments of the reviewers identified by the partner organizations were collated and each was addressed individually and each comment or suggestion was reviewed and accepted or changed by the Task Force leads. The comments of specific reviewers were technical and relatively minor. The American College of Obstetricians and Gynecologists expressed concern that the wording of the language for the Task Force C recommendation would be misunderstood by clinicians, patients, policy makers, and insurers.

The Task Force recognizes now the wisdom of the ACOG advice. The communication of the meaning of a recommendation give a "C" grade was poor. Our message was misunderstood.

The Task Force stands behind the evidence and the conclusions based on the evidence.

Mammography at age 40 should not be automatic. The Task Force recommends that women in their 40's decide on an age to begin screening that is based on a conversation with their doctor.

The Task Force commits to improving how it communicates information with particular attention to situations where there are benefits and there are harms and the net benefit is small.

Role of Cost in Making Breast Cancer Recommendations

Cost and cost-effectiveness did not play a role in the Task Force recommendations about breast cancer screening.

Mr. PALLONE. I am sorry. I just wanted to thank Dr. Calonge and now ask Dr. Petitti to begin.

STATEMENT OF DIANE B. PETITTI

Dr. PETITTI. I am Diana Petitti. I am the vice chair of the U.S. Preventive Services Task Force. I am a physician and an epidemiologist. I have spent my entire 32-year career as a scientist working on issues of women's health. I published on the topic of mammography screening. I served as vice chair of the National Cancer Policy Board and I have expert in evidence synthesis, systematic review and meta-analysis. I participated in this process from the very beginning. I would not sign off on any recommendation that I did not believe reflected the best possible use of evidence for the benefit of women.

I appreciate the opportunity to clarify for members of this subcommittee the task force recommendations and the evidence and weighing of the evidence that led to these recommendations. In specific, the task force recommends the following: women age 50 through 74 should have mammography every other year. The decision to start regular, biannual screening mammography before the age of 50 should be an individual one and take the patient context into account including the patient's values regarding specific benefits and harms. That is, the task force is saying that screening starting at 40 should not be automatic nor should it be denied. Many doctors and many women, perhaps even most women, will decide to have mammography screening starting at age 40. The task force supports those decisions.

The task force acknowledges that the language used to describe its C grade recommendation about breast cancer screening for women 40 to 49 did not say what the task force meant to say. The task force communication was poor. The task force is committed, really committed to improving its communication.

The task force first addressed the screening mammography topic in 1989. At that time the task force recommended screening women 50 through 75 every 1 to 2 years. With regard to screening younger women, the task force stated it may be prudent to begin screening at an earlier age for women at high risk of breast cancer. In its 1996 guide, the task force recommendation was in favor of screening women 50 to 59 every 1 to 2 years. Mammography screening for women 40 to 49 was given a C grade. At that time the C grade recommendation meant insufficient evidence. In 2002, the task force recommended screening women 40 to 69 every 1 to 2 years, stating that the benefits were smaller and took longer to emerge for women who were first screened in their 50s.

On November 16th, as this committee knows, the task force issued its updated recommendations on breast cancer services. I wish for us to clarify that the timing of issuance of these recommendations. In late 2006, discussion of a plan for updating recommendations began. The breast cancer topic came up for review at the regularly scheduled time. Work on the topic started in 2007. When the recommendation statements came up for a vote in November 2007, the members could not come to agreement about what to recommend because agreement about what to say about the balance of benefits and harms. In this context, the task force

asked for additional evidence from its evidence-based practice center. The task force considered this evidence at its July 14-15 meeting.

In making its final recommendation, the task force considered evidence identified in a systematic review of evidence for six key questions, the results of an analysis from the breast cancer screening consortiums and the results of a study commissioned by the task force and conducted by the cancer intervention and surveillance modeling network. The systematic review identified almost 3,000 studies, and 550 of these were used to make the recommendation. The final recommendations were made based on a weighing of the benefits and harms of screening mammography. The task force concluded from the evidence that screening mammography for women 40 to 64 has a benefit in reducing death due to breast cancer. The benefit is larger in older women than in younger women, and I would like to speak specifically to the issue of harms in this net benefit equation.

Preventive services are provided to asymptomatic individuals for the sole purpose of preventing or delaying morbidity, delaying functional decline or postponing death. The promise of service delivery is net benefit, benefit minus harms. The benefits of mammography have been easy to communicate. The harms and potential harms have been difficult to communicate. The easily identifiable and commonly used definition of harm is physical injury. These physical injury direct harms are very, very small but the task force considers the harms of a screening test not just physical harms but psychological harms.

A great deal of the controversy has centered on the task force use of consideration of anxiety and psychological distress as a harm of a false positive test. In particular, the psychological distress has been ridiculed. To understand the consequences of false positive tests, it is necessary to consider how women enter the screening cycle, what happens and what might happen to a woman who has a positive test. No matter how hard the concept of screening is explained, a positive mammogram screening test means cancer until cancer is proven not to exist. For some women who have a positive test, the time between a positive test and a statement there is no cancer is mercifully short. For other women, the follow-up involves more than one additional test, perhaps a clinical breast examination along with a test, a trip to a surgeon over a period of time that is not always short and over a period of time it is unpredictable and not within the control of the woman. Some women eventually need a biopsy. Cancer is a terrifying prospect. It carries special emotional weight because of the consequences of the diagnosis have in the past involve not only death but the prospect of mutilating surgery. Anxiety and psychological distress in women who have had positive screening tests is amply documented in the evidence. The task force wants only that screening mammograms be done with full knowledge of these potential harms, the frequencies of these harms and what is to be gained by being screened at an earlier compared with a later age. False positive tests are more frequent in younger than in older women.

Other harms of mammography include ones that are less well documented. Some women are diagnosed in their 40s with cancer

that could have been treated just as well if diagnosed later. These women may have unnecessarily been exposed to the harms of treatment including surgery, chemotherapy—

Mr. PALLONE. Doctor, I didn't want to stop because it is so important, but you are 2 minutes over, so keep going but—

Dr. PETITTI. I am going to say that—my final statement. Mammography starting at 40 should not be automatic. The task force recommends that women in their 40s decide on an age to begin screening that is based on a conversation with their doctor and is individual, and I apologize for going over.

Mr. PALLONE. I am going to apologize for trying to stop you because it is so important that you clarify a lot of these things, and I appreciate that.

Our procedure now is that we have questions from the members of the panel—I mean from the Members of Congress, and I will start with myself.

Let me say that you have actually clarified some of the questions I was going to ask very well but I still want to kind of review this if I could in my own mind, and if I say anything you disagree with, tell me, but I do want to ask you some questions as well. There are a lot of myths out there that have been spread both today and certainly in the last few weeks since you came out with your recommendations, and the way I understand it, the current task force uses these A, B, C ratings. These are the same kind of ratings that would be used under the different task force that is in the legislation, the larger health care reform legislation that we passed. In other words, you are the U.S. Preventive Services Task Force. The new task force in the bill that we pass has a different name, Clinical Preventive Services, but the A, B and the C ratings are the same or similar.

But right now these A, B and C ratings have no force. They are just recommendations. And what some of my colleagues have said is that these insurance companies now don't have to cover A, B or C, they don't have to cover anything, and in fact what we are getting is that a lot of insurance companies right now don't prefer to cover any screenings because if you do a screening and they have to pay for treatment, it costs them money, which they try to avoid. And so what I see right now is that in some cases, States have required certain screening like my own State, but on the other hand we heard the gentleman from Utah talk about Utah where my understanding is, they don't require any screenings.

So the point I am trying to make is that the big advantage of the health care reform bill that we pass is that H.R. 3962 will for the first time create minimum standards for requiring preventive benefits. So private insurers would be required under that bill to cover services with a grade A or B recommendation. Right now they don't have to cover anything. What we're doing in the bill is basically saying that at a minimum if you or your successor task force says that this is an A or B, it has to be required, which it is not now. The other thing that we do in the bill is that we say that the Secretary could require a C rating also be covered under both a public option or private insurance plans. In fact, my understanding is that the new task force—I mean the Secretary under the bill could even require a C rating under the basic benefit pack-

age. Now, that is contrary to what some of my colleagues have been saying on the other side of the aisle, and my whole point here is to say that the truth is that if enacted into law, H.R. 3962 would result in a lot of people who are not getting mammograms, Pap smears, colonoscopies, a lot of people don't get that at all now because insurance companies basically don't have to do it unless the State requires it. Now under this bill, they would have to do anything that you rate as an A or B and the Secretary could even require the C either in the public option or in the private plan under the basic benefit package.

Now, I mention this because the bottom line is that women's ability to continue to obtain mammograms increases in these House and Senate bills that are being passed, and when I look at the Republican bill on the other side, it sets no floor whatsoever. There would be no minimum required benefits for insurance to provide under the Republican bill. Essentially it would just like the status quo that we have now. So I listen to the debate that we have had today and the bottom line is that the bill that we passed in this House provides a lot more coverage, has a lot more guarantees. The status quo doesn't provide any guarantees at the federal level nor would the Republican alternative that we have been given on the other side.

Now, my question is, again, you mention that when you recommend a C, it says that it has a small net benefit and women are supposed to make their own decisions so you made it quite clear today that even if it is a C, there is some net benefit and the Secretary could decide under the new bill to say okay, that is going to be required as well. So you are not in any way with the C recommendation saying that this screening is not a good thing. In fact, you are actually saying there is a net benefit but you would like individual women to make that decision with their doctor because it is only a small net benefit. Is that accurate?

Dr. PETITTI. Mr. Chairman, I am going to speak to the science.

Mr. PALLONE. Absolutely.

Dr. PETITTI. And the science is that a C recommendation does mean a small net benefit, and we map that C recommendation through advice that women make the decision with their doctors about whether or not to undergo screening. I think this committee is dealing with incredibly complicated issues about health reform and coverage but the task force is not a coverage and health care reform and policy committee; we are scientists.

Mr. PALLONE. But the bottom line is—and I will end with this—is that even when you recommend a C you are saying there is a small net benefit, so again, let us not talk about today but let us talk about if the bill that we passed in this committee becomes law. Even then, you know, the Secretary could say okay, there is a small net benefit and so we do want to require this as a basic benefit, or, you know, you basically leave it up to the insurance companies to decide the way they do today. But, you know, the misinformation out there I think is that even under the bill that we passed, for once there is going to be a requirement that some of these screenings occur. If you rate it as an A, it has to be done. If you rate it as a B, it has to be done. If you rate it as a C, the Secretary can say it has to be done. Right now there is nothing,

nothing at all, and the Republicans in their alternative would continue the status quo that says you don't have to cover anything, and I just appreciate it because I think you have helped me clarify.

I yield now to the gentleman from Illinois, Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman, because what we need in this country is a continued debate on the failed health care bill that we passed on the Floor of the House. That is what we really need to do and that is what we are doing today, and we are using obviously what happened through your process to make the claim, the short-term concern of a public option, which many of my colleagues on the other side have said is the gateway to a one-payer system. So when the government controls all the health care decisions in this country, they will eventually default to control costs through rationed care.

Now, the process, the scientific process that you have just admitted to said there is a small net benefit. When there is decreased revenue available, the default will be based upon 3962 just what you say on your website. Your website recommends against routine screening mammography in women age 40 to 49. Do you think that this statement would be perceived by women younger than 50 that they should not get a mammogram on your website?

Dr. PETITTI. We have communicated very poorly about the C recommendation. It is clear that many women, many physicians and certainly the media interpreted that language as if we were recommending against women in their 40s ever having a mammogram. That was not our intention.

Mr. SHIMKUS. I understand, but we are concerned of commissions. We are concerned of bureaucracy. We are concerned of rationed care. We are concerned about bureaucrats saying there is no real net benefit, and then—yeah, it is right. It is exactly what we are concerned about and that is why we are having this debate. In the bill, and Chairman Pallone pretty adequately talked about the differences—we know that services with a rating of A and B must be included in essential benefit package. In this case with the highest rating of C, women would not receive—currently if this was law, as is today, women in the C category would not receive this as a covered benefit under 3962, and that is part of our concern and this does segue into the full health care debate. The commissioner on part of the bill, and I don't have the whole 2,000 pages, I just pulled out excerpts. The commissioner shall specify the benefits to be made available under exchange participating health benefits plans during each year, and then you can go further on. Basic, enhanced and premium, and then the premium plus, A, approved by the commissioner, and then you can go to the C section, which is again highlighted, and we continue to have preventive services including those services recommended with a grade A or B by the task force on clinical preventive services.

So this is again for a lot of us an important debate. Do any of you know an individual who has been diagnosed for cancer between the ages of 40 and 49 personally?

Dr. PETITTI. Oh, I know many individuals who have been diagnosed with cancer—

Mr. SHIMKUS. Dr. Calonge?

Dr. PETITTI [continuing]. Between the ages of 40 and 49.

Dr. CALONGE. Yes.

Mr. SHIMKUS. And then the other question, what about over the age of 74? Anyone who has been diagnosed with—

Dr. PETITTI. Yes.

Mr. SHIMKUS. Because although we are focusing on 40 to 49, in your report over 74 has the I category, and we don't even know if it is. So what are we saying to those over the age of 74?

Dr. PETITTI. I speak to the evidence and to the mapping of the evidence to the task force recommendations.

Mr. SHIMKUS. And I appreciate that, and I only got 38 seconds and I am going to be punctual on my time. Part of this concern with H.R. 3962 is as we said, the public option, the gateway to a one-payer system, eventually rationed care, and then a decision based upon the financial ability of the country to fund care across the spectrum but also our seniors in our country, and again, this incomplete aspect for 74, it speaks to the concern that if you are elderly in this country and we get to a one-payer system, there will be decisions made not based upon health care but on cost, and I yield back my time.

Mr. PALLONE. Thank you.

Chairman Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman.

The health care bill that the Republicans are complaining about is not law yet your agency, the Preventive Task Force, is an operation. Is it set up under law?

Dr. CALONGE. Yes.

Mr. WAXMAN. And your job isn't to make recommendations to insurance companies, is it?

Dr. CALONGE. That is correct.

Mr. WAXMAN. Your job is to make recommendations on preventive services so that the latest science and information about the science is communicated to clinical practitioners. Isn't that your job?

Dr. CALONGE. That is correct.

Mr. WAXMAN. And this is very useful information. Now, we are focused on the breast cancer issue, but that is not the only area where you have made recommendations. Isn't that true?

Dr. CALONGE. That is correct.

Mr. WAXMAN. How many other areas has the task force made recommendations in the last couple of years, let us say?

Dr. CALONGE. Well, our current portfolio is 105 total and we take up around 15 new or updated topics annually.

Mr. WAXMAN. You have recommended that teenagers be screened for mental illness?

Dr. CALONGE. Yes, that was a new recommendation this year, Congressman, that we just came out with, so this is new services that have not been recommended prior.

Mr. WAXMAN. And there was a breast feeding behavioral intervention recommendation?

Dr. CALONGE. That is correct.

Mr. WAXMAN. And you have had a recommendation that aspirin for the prevention of cardiovascular disease be a way to prevent the disease. Is that right?

Dr. CALONGE. That is correct.

Mr. WAXMAN. So you have had a whole range. You say how many, 103?

Dr. CALONGE. A hundred and five total.

Mr. WAXMAN. A hundred and five total. I am assuming that none of the others have been as controversial as this particular one.

Dr. CALONGE. That is correct.

Mr. WAXMAN. So we have a controversial issue because it challenges the accepted notion about the frequency of breast cancer screening and we are going to hear a lot more about that from the next panel. But I want to have us look at the challenges being raised by some of the Republicans, which I think is all political. They are acting as if your recommendations based on bringing the scientists who have the expertise which are directed at clinical people will be used to ration care. That is their argument: we are going to ration care. And then they say well, that is because there is going to be a health care bill that will provide a requirement for minimum benefits. Now, there will be minimum benefits in that it should have access to hospitals, it should have access to doctors, have access to pharmaceuticals. Your area is in the preventive area and nothing could be more important to me than having the latest science on how to prevent diseases, because if we can prevent illnesses, we won't have to treat them later. Your task force will continue in operation. You will convene the scientists who are experts in different areas of prevention.

Now, I guess the question, I am not raising this to you but the question is, how will your recommendations affect the minimum benefits that will be required for health care insurers? Health care insurers could be a public insurance, if that survives in this legislation process. It certainly would be private insurance. Right now private insurance doesn't have to abide by your recommendations. Isn't that true?

Dr. CALONGE. That is correct.

Mr. WAXMAN. And some of them cover these preventive services and some of them don't. Isn't that true?

Dr. CALONGE. That is correct as well.

Mr. WAXMAN. It is their decision. But if we are going to provide subsidies for people to get insurance and we are going to try to get a market where insurance companies compete against each other based on price and quality, we ought to make sure that all of them provide at least a minimum set of benefits. One of the star issues for Republicans is to have a lot of insurance plans that don't provide any minimum benefit at all. They can be cheaper if they don't provide minimum benefits. Well, I find that troubling. But let us say we are going to have minimum benefits and you make a recommendation. Is your recommendation under the proposed bill automatically going to be in effect for all insurance? Do you know whether that to be the case?

Dr. CALONGE. Congressman, I am not well—

Mr. WAXMAN. You are not an expert on the bill.

Dr. CALONGE. That is correct.

Mr. WAXMAN. But let me explain what the bill will do. The new bill will take your recommendations. They will go to the Secretary. The Secretary will review them. The Secretary will have a notice of rule and comment and a public process and then decide whether

that is a minimum benefit. Now, a minimum benefit is a minimum benefit. It is not a maximum benefit. So if there is a recommendation as you proposed on breast cancer screening, that will be not a requirement of insurance to do no more than that, it will be a recommendation that will require insurance companies to do that as a floor, not a ceiling. I just wanted to set this out because I think some people watching this hearing may get confused when they hear stories about bureaucrats or rationing care or the health care bill being a gateway to single payer. We expect a bill with competition and people to make choices between insurance plans but we don't want the choices between insurance plans to be those that cover breast cancer screening and those who don't, but those are at least a minimum of preventive services that we can hope will prevent diseases and need for paying for care for those diseases.

Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Chairman Waxman.

Next is the gentleman from Texas, Mr. Burgess.

Dr. BURGESS. Thank you, Mr. Chairman.

Let me ask you a question. I have got the clinical guidelines, and I guess this is a reprint from the Annals of Internal Medicine, the last page of which is an appendix which lists the members of the U.S. Preventive Services Task Force, and a number of individuals are listed there. Their specialties are not. Is anyone on the list there a board-certified OB/GYN?

Dr. PETITTI. Yes, there are two board-certified OB/GYNs on the task force, and that is a usual—we usually have two.

Dr. BURGESS. Which are those two that are on the list that I have in front of me?

Dr. PETITTI. Kimberly Gregory and Wanda Nicholson.

Dr. BURGESS. And they both participated in this decision?

Dr. PETITTI. Kimberly Gregory was on the task force when this decision was voted; Wanda was not. There was another OB/GYN on the task force when this topic was voted. That was George Siwaya, who is a professor of OB/GYN at University of California-San Francisco.

Dr. BURGESS. Were these unanimous votes?

Dr. PETITTI. No, the votes were not unanimous.

Dr. BURGESS. Do we know how the individuals voted?

Dr. PETITTI. I can't recall. That is in the record, and we could make that information available to the committee if that is important.

Dr. BURGESS. I would like to see it. I don't know if the committee will deem it as important, but I would certainly appreciate the opportunity to see it.

Now, is there a radiologist in this group?

Dr. PETITTI. No, there is no radiologist in this group.

Dr. BURGESS. Is that a problem?

Dr. PETITTI. The expertise of this panel has been called into question. The experts are individuals who have experience in screening science and prevention. Radiologists were consulted and reviewed the documents and the recommendations and provided input.

Dr. BURGESS. On this task force, the majority of these individuals were primary care doctors. Was there a general surgeon on the task force?

Dr. PETITTI. Well, again, the experts are experts in primary care and prevention, and yes, there were, and I would have to count them, four primary care physicians on the task force currently and four at the time that these were voted.

Dr. BURGESS. But was there a general surgeon who specializes in—

Dr. PETITTI. No, there was no—

Dr. BURGESS [continuing]. Needle localization and breast biopsy?

Dr. PETITTI. No, there wasn't. They were consulted.

Dr. BURGESS. They were consulted. All right. And I apologize for being in and out but we are doing nine simultaneous hearings today and the financial services makeover requires some attention and thought as well. On the issue, though of talking about—you said you factored in the psychological events surrounding a call-back on a positive mammogram. You factored in the psychological cost, if you will, to the patient in that exchange. Do I understand that correctly?

Dr. PETITTI. Well, the issue was a qualitative assessment. Anxiety, psychological distress, inconvenience are all considered to be harms and potential harms, and again, it is a part of the net benefit equation.

Dr. BURGESS. When I was in school back in the 1970s, I realize it was a long time ago, but mammographic screening was not, at least in the area that I went to school, that was not something that was done. You sent someone for a mammogram, it was kind of a big deal because you felt something, but it wasn't done as just part of a routine screening. In fact, I don't think, as I recall looking back, it was probably the mid-1980s when that became a standardized screening test, and in fact in Texas, I don't know whether this is true nationwide but in Texas I know women can self-refer for mammography. When that all happened, that psychological cost was one of the arguments that was used by people who felt that routine screening would not be a good idea. So how is it that we have come to the point now where we rejected it back in the 1980s but now in 2009 this is a factor again that is worthy of our consideration?

Dr. PETITTI. Again, this is not determinative. It is information that we want women to know about. We want them to know how common it is. Again, the false positive rate is much lower as women get older and that is part of the net risk benefit equation. We would not want women to be afraid of having mammography. This is again one piece of information that women and their physicians should discuss when decided when to start screening.

Dr. BURGESS. And does that same rationale apply to self-examination?

Dr. PETITTI. The task force recommended against clinicians teaching women breast self-examination. They did not recommend that women not pay attention to their bodies, that they ignore lumps or that they ignore problems that might come up when they find a lump. Again, the task force recommendation was against doctors teaching women breast self-examination.

Dr. BURGESS. Well, how are women supposed to get that knowledge? If they can't just get it by intuition, someone along the line has got to provide them some guidelines on proper time to do the exam and how to do it and what to be concerned about and what not to be concerned about. As I recall, and I may be wrong on this but I don't ever recall coding and being compensated for teaching breast self-exams so it is not a—I mean, I wasn't a cost center for you. I wasn't a cost driver. My only inference from that could be that you are worried that people will find things that then lead to procedures and we are better off if we don't ask, don't tell.

Dr. PETITTI. Again, the evidence—there have been two very well-conducted randomized clinical trials in which women were taught how to do breast self-examination and both of those trials found no overall benefit in terms of reducing mortality from breast cancer. Again, we go to the evidence.

Dr. BURGESS. Well, and I will say anecdotally—

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

Dr. BURGESS [continuing]. As I said in my opening statement, it does strike me—

Mr. PALLONE. Mr. Burgess, you are 2 minutes over.

Dr. BURGESS. It does strike me that the amount of disease—

Mr. PALLONE. Mr. Burgess.

Dr. BURGESS [continuing]. The amount of disease that was brought to my attention by the patient herself, and again—

Mr. PALLONE. Dr. Burgess, your time has expired.

Dr. BURGESS. I will just be interested in what some of the other clinicians tell us when they get their chance to testify. Thank you, Chairman.

Mr. PALLONE. Dr. Burgess, you are almost 3 minutes over and we are about to vote.

I think we have time for one more set of questions and then we are going to vote. We have five votes. We will take one more set of questions and then we will adjourn and come back after the five votes. Next is—Chairman Dingell, did you want to proceed now?

Mr. DINGELL. I think I can proceed rather quickly, Mr. Chairman. Yes, please.

I would like to welcome you both to the committee and tell you how helpful it is to have you here. From the things I have heard said on the other side of the aisle about you folks at the agency, I was afraid you would appear with horns, tail, fangs and in a red suit breathing fire demanding that we immediately terminate all health benefits for the unfortunate, sick, weak, poor and especially with regard to mammograms and Pap smears. So I am very much comforted and I want to welcome you to the committee this morning.

I just have really one question that I think is important. I find it curious that the task force has repeatedly over the years voted to leave costs out of its deliberations on whether to provide or not approved preventive service. Why?

Dr. CALONGE. Thank you, Congressman. I think this is a key question. The task force believes its major charge from Congress and responsibility to primary care clinicians and patients is that we set the evidence-based stake in the ground immune from how

much it costs to achieve the benefits associated with a given effective preventive service. So—

Mr. DINGELL. So your short answer is, that you are recommending the needed services, the needed tests, the needed treatments as opposed to looking at the cost. Is that it?

Dr. CALONGE. That is correct.

Mr. DINGELL. Okay. Now, to assist my colleagues on the other side of the aisle, and I do this out of great affection and respect and charity, you address this question in your statement and you say here, and I will read this for the benefit of my colleagues on the other side, you say, "Task force recommendations are based on consideration of the health benefits and health harms of providing the preventive service and on the scientific certainty of whether the preventive service works. Cost effectiveness of specific prevention services are not addressed by the task force in its deliberation." Then you say this: "The task force only—" and that is underlined "considers scientific evidence of health benefits and health harms. The task force has specifically discussed whether cost should influence a recommendation and has repeatedly voted to leave costs out of deliberations on whether or not to provide a preventive service." Is that right?

Dr. CALONGE. That is correct.

Mr. DINGELL. Now, when your recommendations are made, are they used to put a ceiling on benefits or are they used to describe a minimum level of benefits that people should get?

Dr. CALONGE. Congressman, I must admit that it is outside of the scope of our recommendations how they are used by other entities.

Mr. DINGELL. Okay. Now, your recommendations are not expected to be substituted for the need of the patient or the concerns and expertise of the doctor, and they are not intended to intrude into the doctor-patient relationship. Am I correct in that interpretation or am I wrong?

Dr. CALONGE. That is correct. In fact, if you read our statement that is published in the annals, it says, "The task force recognizes the clinical or policy decisions involve more considerations than this body of evidence alone. Clinicians should understand the evidence and individualized decision-making to the specific patient or situation." This actually precedes all recommendations. It is a recommendation statement that we expect clinicians to do what they are trained to do in order to address the needs of the individual patient for his or her best interest.

Mr. DINGELL. Now, you do permit as the task force goes about its business to have different agencies and persons of concern present in the deliberations. Is that not so?

Dr. CALONGE. That is correct.

Mr. DINGELL. And your deliberations are public?

Dr. CALONGE. At this point, the deliberations of a task force vote are by invitation only.

Mr. DINGELL. By invitation, but you don't gag the people who come in to listen. They can go out and say what is going on and they also are permitted to make comments to you on the task force. Is that not so?

Dr. CALONGE. We actually invite comments from our partners to help us do our job better and to take into consideration different viewpoints and different issues.

Mr. DINGELL. And you allow citizen input?

Dr. CALONGE. The task force is currently moving towards increased private-citizen input with the resource we have available to consider and identify those. We have prior to this time done more with input through specific groups that we invite to comment because we think they are important stakeholders. This is an issue that the task force believes that in the interests of enhanced transparency and responsibility to the American public and the patients whose physicians may consider our recommendation needs to be improved.

Mr. DINGELL. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Chairman Dingell.

We have five votes, I would say about an hour, but when they are done we will come back and reconvene. The committee stands in recess.

[Recess.]

Mr. PALLONE. Thank you both for being here. We now go to a Republican member, Mr. Gingrey.

Dr. GINGREY. Mr. Chairman, thank you, and I thank the witnesses.

My first question kind of pertains to what Dr. Burgess, Dr. Petitti, was asking you a little bit earlier about how many OB/GYNs there currently are on the task force. I wanted to specifically ask you though how many GYN oncologists serve as members of the task force when the recommendations were promulgated—GYN cancer specialists.

Dr. PETITTI. There are no GYN cancer specialists on the U.S. Preventive Services Task Force.

Dr. GINGREY. Well, let me read to you from testimony that we are going to hear from the second panel, in fact, the president of the National Breast Cancer Coalition, Fran Visco, Attorney Fran Visco, where she states in her testimony, “We want to note that the attacks against the makeup of the task force are misplaced. Screening is an issue of primary care. It is a health intervention for a healthy population. The experts in this area, those with the scientific training and objectivity to do the necessary analyses are primary care health professionals and methodologists such as epidemiologists and biostatisticians, not radiologists or medical oncologists.” And I am quoting directly from her statement, which we will hear later. What is your opinion on that?

Dr. PETITTI. The task force expertise in this area was sufficient to weight the evidence that led to its recommendations. The recommendations are made by the task force with the input of a variety of other specialty groups. They are not made in a vacuum. In this case, they were submitted to, I can’t remember the number of partner organizations but it was at least 10. Each of these partner organizations sent them out to experts. Those experts provided written opinions.

Dr. GINGREY. And some of those experts then would be cancer specialists?

Dr. PETITTI. Yes.

Dr. GINGREY. Female-cancer specialists?

Dr. PETITTI. There was—

Dr. GINGREY. So by that response, I guess you would take exception to the comments by Ms. Visco, but we will hear from her later.

Let me ask you another question. On your website—and either you or Dr. Calonge—on the USPSTF website, it clearly states that the United States Preventive Services Task Force recommends against routine screening mammography in women age 40 to 49 years. Do you think that this statement could be perceived by women younger than 50 that they should not get a mammogram?

Dr. PETITTI. We need to immediately figure out how to get that statement off the website. I think it could be misconstrued. It has been misconstrued and we need to fix our website.

Dr. GINGREY. Dr. Petitti, I thank you for that response, and I hope that you will do that. I think it is very important. I agree with you.

I want to ask you, Dr. Calonge, are you aware that the Senate version of health care reform, specifically section 4004, I think it is on page 1,150, that requires the Secretary of HHS to create a national prevention awareness campaign based on all of your task force recommendations, both those that you favor, the A's and B's, and those you recommend against, the C's and D's? Do you think that this national awareness campaign could be perceived by women younger than 50 that they should not get a mammogram or perform a breast self-examination?

Dr. CALONGE. I wonder, Congressman, if it would be okay if you restate your question, because the first part of it and the second part I didn't—

Dr. GINGREY. Well, what I am saying is, in the Senate bill, if it becomes law, if that prevails, the Senate language in the conference report, it becomes law, and it specifically says, and I named the page and section, that the Secretary would require the creation of a national prevention awareness campaign, television ads, TV spots based on all the task force recommendations both those that you in favor of and those you recommend against. Don't you think or do you think this national awareness campaign could be perceived by women younger than 50 that they should not get a mammogram nor should they perform breast self-examination?

Dr. CALONGE. Thank you for the clarification, Congressman. So I can't speak specifically to the bill or to the policy. I will speak to the communication of the recommendation which we believe needs to focus on the decision to start regular biannual screening before the age of 50 should be an individual one and take patient context into account including the patient's values regarding specific benefits and harms, and so that message which I realize is preceded by the "recommends against" statement is one we feel communication needs to be improved and that clear message of what the task force intended needs to lead that, not follow.

Dr. GINGREY. Thank you, Doctor.

Mr. Chairman, if you will bear with me just for maybe 15 seconds, I had one other point I wanted to make. The United States Preventive Services Task Force concludes that the current evidence is insufficient to assess the additional benefits and harms of clinical breast examination beyond screening mammography in women

40 years or older. That is saying that you don't recommend that the clinician, a physician, primary care physician, OB/GYN specialist, should routinely do a breast examination as part of a complete physical in her or her patients, that that has no value?

Dr. PETITTI. The evidence does not provide support for a clinical doing a clinical breast examination.

Dr. GINGREY. Well, I thank you for that response and your honesty.

Mr. Chairman, I know I have gone beyond my time. I appreciate your patience. I think that is terrible and something needs to be done about that.

Mr. PALLONE. Next is our vice chair, the gentlewoman from California, Ms. Capps.

Mrs. CAPPS. Thank you, Mr. Chairman.

I just want to say thank you to both of you for being here, for your excellent testimony and being among the few on Capitol Hill who apologize occasionally, and it is not a habit that we do very well so the fact that you—I wouldn't call it an apology as much as acknowledging the communication glitches that occurred perhaps, and for me, I think it was a lot of was timing, but I don't take it as a negative thing. I think we are seen as a very positive overall experience happening in our country, not to minimize the confusion that many women experience, but I think we can use it as a teachable moment. Let us put it that way. The timing of the release of the report and the debate on health care reform has been seized by many who want to detract really from the health care legislation to use your testimony in widely misconstrued ways, and I want to take a minute of my time to mention one very important distinction but it is also an important point of what the health care reform bill is, which actually will be augmenting a lot of the preventive work that you are doing because women will be able to have occasion to understand more about cancer prevention in its wider forms and their behaviors and their body changes, which are all essential. But the essential benefits package in the exchange consists of 11 benefit categories including inpatient hospital services as examples, outpatient services, maternity care, prescription drugs as well as preventive services. But with regard to preventive services, the bill says that the recommended items and services with a grade of A or B from U.S. Preventive Services Task Force shall be covered as part of the essential benefits package, a rightful designation of the importance of your studies and your recommendations, but not a conclusive piece of it, and they said this be something which we highly recommend that there be no cost sharing for this grade A and B of your recommendations. The benefits advisory committee, part of the health reform, will be able to recommend through its public standard-setting process that additional preventive services such as mammograms for women under 40 or between 40 and 49 be covered without cost sharing. I mean, there is an additional recommendation that can come as part of the bcc bill. The Secretary may also approve such coverage. The essential thing here is that the benefits package, the essential benefits package is a floor, not a ceiling, and that really is important. I want the record to state that very clearly. Once the exchange goes into effect and there is real competition between private insurance plans, they

may wish to offer more-attractive packages to win more, you know, coverage so it may be understood more fully as we go along this. I just wanted to make sure that is in the record.

But I wanted to give you even more opportunity, both of you or one of you, to talk about what the future could hold. You see, I think this is an opportunity, a “wow” moment, as one of the advocate groups put it, and I want to commend all of the breast cancer advocacy groups who have brought us to a level in this country where when a set of recommendations like yours comes out, that there is a more intelligent audience receiving it, able to understand it and able to use it and to advocate even more in a wide range of ways which I think is very healthy for our country to be a part of. I am only giving you about a minute but I would like you to elaborate further on ways that your task force can communicate in the future in ways that maybe we can access and use more efficiently.

Dr. PETITTI. Well, what I thought would happen with these recommendations is that it would move the discussion more towards the notion of individualized decision making and risk stratification. What I thought is, it might initiate a dialog where we decided to work harder at finding out who really is at higher risk so we could make more tailored recommendations for screening, and among those groups that we really have ignored are African American women who—

Mrs. CAPPS. Absolutely.

Dr. PETITTI [continuing]. Are younger and women of Ashkenazi Jewish background, some of whom have a very high risk based strictly on their membership in this group. Again, what I thought would happen would be a move towards individualized, tailored, risk-stratified decision making and not this sort of rehashing of a bunch of old data.

Mrs. CAPPS. Dr. Calonge, would you like to add anything to that? And I know I am squeezing a few more seconds. I think this is really important.

Dr. CALONGE. I want to echo the issue about individualized decision making. We hear a lot about personalized medicine and I think the basis of personalized medicine can be and should be individual based decision making, and it is really what we were hoping the language for the younger age group would start engendering, this issue about, you know, we as consumers of health care should kind of understand that every test we have and every treatment we have has both inherent risks and benefits and we should make our decisions based on understanding those and then what is important to us.

Mrs. CAPPS. And that underscores the value of the work that you do in this topic and in every other topic and the importance of having educated in the area of health a population that can seize the material as well as primary care providers and others doctors, you know, use your information every single day to make the kind of informed decisions that they and their patients need to have before them. So I hope this can be the beginning.

I again want to thank our chairman. This is the kind of setting, this hearing setting that is so important for us to take advantage of and use your expertise and your research and have this kind of

debate, if you will, but discussion. So I thank you again for being here.

Mr. PALLONE. Thank you.

Mr. ROGERS.

Mr. ROGERS. Thank you for being here, and I have some quick yes or no questions if I may just to get through it. Were you familiar with the references to your task force in the bill as it was introduced in July?

Dr. PETITTI. No.

Mr. ROGERS. So you knew nothing about the over a dozen references to your task force in this bill?

Dr. PETITTI. You know, I hate to say, but I was busy preparing a course in biostatistics, and the answer is honestly no.

Mr. ROGERS. And is that consistent through the whole task force or any of its representatives or administration thereof?

Dr. CALONGE. I hesitate to have the two of us represent the opinions of all the task force.

Mr. ROGERS. But it wasn't part of your discussions?

Dr. CALONGE. In July? Absolutely not.

Mr. ROGERS. Are you aware that in this particular bill, and I think maybe our Health Committee chairman was mistaken and I think the chairman emeritus was mistaken. This is not necessarily a new committee. They may create a new name but in the bill—and I will just read right from the bill. "The preventive services task force convened under section 915A of the Public Health Service Act and the Task Force on Community Preventive Services, and then in quotation marks "as such section task forces were in existence the day before the day of the enactment of this Act shall be transferred to the Task Force on Clinical Preventive Services and the Task Force on Community Preventive Services, respectively, established under these sections," And then it goes on to say that whatever your recommendations were prior to that enactment are in effect. Are you aware of that, sir or ma'am?

Dr. PETITTI. Well, certainly——

Mr. ROGERS. Yes or no. I am sorry.

Dr. PETITTI. Yes, I am now aware of it.

Mr. ROGERS. But were you aware of that during your deliberations?

Dr. PETITTI. No.

Mr. ROGERS. Would that have changed your deliberations at all?

Dr. PETITTI. I can't speculate on what might have happened.

Mr. ROGERS. Interesting. So what you are saying is that according to the law of which this committee wants to enact you have now taken ages 40 to 49 and made them a category C which means they will not be paid for under this committee. That is interesting.

Now, let me ask you this. You say you didn't consider cost. Is every appendix that is attached to your task force recommendation, is that something that would have been reviewed by the individuals who made the determination? Is that something of value? That is why you attached it as an appendix, I imagine?

Dr. PETITTI. Yes, all the material and evidence is germane to the——

Mr. ROGERS. Thank you very much. Are you familiar with appendix C1 where the question is, what is the cost effectiveness of

screening, that assigns a dollar value by quality of years of life? Are you familiar with this? This clearly is a cost-effectiveness portion of your study. Clearly you cannot in good conscience tell this committee you didn't consider cost. You just told me that every piece of information according to your study is considered. This is a dollar value per quality of life and it is done on mammography screenings.

Dr. PETITTI. The committee—

Mr. ROGERS. Will you remove this from your task force study as well as your recommendation that said—

Dr. PETITTI. I am sorry but I am trying to see what you are pointing at, and I—

Mr. ROGERS. It is appendix C1 of your own task force recommendation that clearly, clearly considers cost just by your own testimony, and again, you can see why women of America and those of us who are very concerned about bureaucracies interacting between health care. On your website again you say that you recommend against routine screening. You say that you are going to take that off. That is great. You say that gee, we didn't consider cost but on your own report it says you considered costs. You can see why after we are creating 118 brand-new commissions just like yours all of your authority will now be enacted into law according to their own bill by the reference I have just read. I mean, it is pretty serious.

And let me ask you another question. As a part of this, it says, and I am going to read this again from the bill because I think some of my members on the other side maybe either haven't read the bill or maybe misunderstand their own language, but even under the—this is the Indian health care section, section 206, I would encourage you to read it, under mammography and other cancer screening, "The Secretary shall ensure that screening provided for under this paragraph complies," meaning you have got to do it "with the recommendations of the task force with respect to, A, frequency, B, the population to be served, and C, the procedure or technology to be used," all of which is referenced in your report. Imagine that when this passes your report now becomes a matter of law according to their own language in this bill right here. Would that change your consideration as a scientist knowing by your own testimony it did not pass unanimously? You say science and evidence but clearly people equally learned as both of you believe that that was the wrong answer? Is this something you should reconsider?

Mr. PALLONE. Mr. Rogers—

Mr. ROGERS. I would like an answer to my question.

Mr. PALLONE. No, I know, but I am going to ask you to go beyond that. I mean, you used your 5 minutes. Take what time is necessary to respond because I am not sure you even know what the questions are, but please take your time.

Dr. PETITTI. I was going to say that.

Mr. ROGER. I got my yes and no's.

Dr. PETITTI. There were a number of different questions and I am not sure which one to respond to. What I would like to say, and I want to say it again on the record, that when we voted for the recommendations for mammography screening A, B and C, we

voted them without regard to cost or cost-effectiveness analysis. I can say honestly, absolutely, the word “cost” was not in the room. It was not mentioned. It was not uttered and it did not in any way determine—

Mr. ROGERS. But it was part of your study, was it not? Was it not part of your study? You just told me that everything that was in your study was considered. Appendix C1 considers cost. How could you—

Mr. PALLONE. Mr. Rogers’ time is up, but you can respond and say what you want but we have got to move on.

Mr. ROGERS. I have more questions, Mr. Chairman, if you would like.

Dr. PETITTI. I have nothing more to say.

Mr. PALLONE. Mr. Rogers, I am just trying to make sure she is able to respond, but I think we should move on because we are a minute over now and she doesn’t want to say anything else.

Mr. ROGERS. Well, Mr. Chairman, my only caution here is that—and I—

Mr. PALLONE. I understand what you are—

Mr. ROGERS. No, I do believe the intention of the other side is real. I do believe that. But the language of the bill of which I believe that most Members of Congress have not read—

Mr. PALLONE. But she has repeatedly said that the bill—she didn’t even know what was in the bill and their deliberations were done under the previous Administration before President Obama was even President of the United States, so—

Mr. ROGERS. But, Mr. Chairman, the point here is that she did say that cost wasn’t part of their voting but it certainly was part of their report. That is very important knowledge for all of us to know when we raise questions about adding—when you—

Mr. PALLONE. You made your statement. She responded to it. Let us move on. I can’t help but repeat that their deliberations, as I said, even preceded the current Administration. But whatever, let us move on.

Next on the Democratic side is the gentlewoman from the Virgin Islands, Ms. Christensen.

Mrs. CHRISTENSEN. Thank you for your presentations and your answers thus far. I want to go back to the issue of African American women. Some years ago, many of us worked to ensure that mammograms be recommended and covered for women of African descent under age 40, and given that even though we may have a lower breast cancer incidence, we are more than likely to be diagnosed at later stages and have a higher mortality rate, and even in younger women, we find that younger African American women are more likely to be diagnosed with breast cancer. So in the recommendations, why wouldn’t the task force single out this particular group and maybe give them a different recommendation rather than lumping all women between 40 and 49 or younger under C or I?

Dr. PETITTI. You make an excellent point, and I think again what I expected to happen with these recommendations is that we would begin to focus on how to make more stratified and nuanced recommendations that would identify those groups who are unrecog-

nized as being at higher risk of consequences of breast cancer when diagnosed at a young age.

Mrs. CHRISTENSEN. So even though the bill says in the Indian Health Service that your recommendations would be applied, you might look at the Native American population as a group and decide maybe a different grade for different age groups in that particular age group and make that recommendation. Might that not happen?

Dr. PETITTI. Yes. I think that the accompanying editorial to our recommendations pointed the direction that we thought we would be going, you know, not in Congress trying to defend them but moving to the point where we have more individualized risk, and I would say that based on my understanding of the science, which I follow very closely, that breast cancer in young African American women is a topic which is not widely appreciated as being one which perhaps needs a different kind of recommendation. Again, we need to do better at the risk stratification and individualized risk. I can't say the task force will immediately be able to go back and—

Mrs. CHRISTENSEN. I understand, but you recognize it, and this is not the final answer?

Dr. PETITTI. This is definitely not the final answer. I think people would have wished that we would have not even ever opened this topic again after 2002.

Mrs. CHRISTENSEN. Especially not right now.

Dr. PETITTI. That was an accident.

Mrs. CHRISTENSEN. But given what occurred in response to the article and the press taking it up and how it has been interpreted, have you looked at other ways of presenting recommendations that might be controversial? I have never really liked the fact that the press really gets these advance notices and they start to tell us what is coming up in the medical journal because they don't really understand it.

Dr. PETITTI. Well, we communicated very poorly. We should have spent more time talking with our stakeholder groups. We should have had a formal communication plan both to consumers and physicians.

Mrs. CHRISTENSEN. I agree. Can you explain how the overdiagnosis—it is a bit confusing but can you explain how overdiagnosis occurs when DCIS or early-stage lesions, especially in younger individuals is diagnosed and treated? Because my understanding on the DCIS is that it is likely a precursor to invasive cancer, so is the task force that it might be better to not diagnose it or if you think it is there to leave it alone and not do further investigation or remove it? Because I would think—anxiety is one of the issues that you raised. I would think it would be more anxiety provoking to think that I had a CA in situ or early-stage cancer and sit and wait on it rather than to have it biopsied and removed.

Dr. PETITTI. Well, here we are definitely getting way out of my range of expertise. This is a topic which I would want to have addressed by a medical oncologist and those who are now working so hard to try to understand better how we separate and differentiate those tumors that are going to progress rapidly and those tumors

that aren't going to progress, but this is outside my area of expertise.

Mrs. CHRISTENSEN. Well, speaking to surgical oncologists actually yesterday, they feel that DCIS is many times a precursor to invasive cancer and I am surprised that it is listed as one of those things that maybe we are overdiagnosing or overtreating, but I think my time is up, so thank you for your answers.

Mr. PALLONE. The gentleman from Arizona, Mr. Shadegg.

Mr. SHADEGG. I thank you, Mr. Chairman.

First, I have to express some sympathy for you. You have stepped into a controversy which has been made much larger as a result of the overall health care reform that is going forward, and I think that to a certain degree you have been sucked into a much larger battle than your own efforts to try to make recommendations would have otherwise merited.

As I understand your recommendation, you base it on science and you say look, here is what we have concluded based on that science, it shouldn't be automatic, it ought to be something you think through and here is our recommendations. That makes a lot of sense to me. I presume from that you believe that it should be a decision between the patient and her doctor and that, for example, if a particular patient had a history of cancer or breast cancer, then you might get screening at a younger age, or in some of the categories where you didn't feel it should be automatic but under those circumstances it should occur. Is that correct?

Dr. PETITTI. Yes, that is correct.

Mr. SHADEGG. Okay. You would then agree with me that if the government were to prohibit an insurance plan from providing coverage for someone who after consulting with their doctor or looking at their family history thought she needed it, that would make that at least not an insurable event, correct?

Dr. PETITTI. I am not here to get involved in the coverage and health care reform coverage issue.

Mr. SHADEGG. Fair enough. I will just then state for the record that in my view, the government should never prohibit someone and the government should never be able to prohibit someone from offering mammogram coverage or as an insurance company or a public plan nor should it be able to prohibit an individual woman or her family from deciding they want to purchase mammogram coverage, and I am deeply troubled that this bill, which seems to be the larger context into which your work has been reported, does precisely that.

I do want to say that it is important, Mr. Chairman, that facts be abided by and unfortunately, in a piece of legislation this size, it is subject to interpretation and it is subject to quick review without people being very precise in their language. I want to make it very clear, I mean no personal offense by this by there have been things stated in this room today that are flat untrue. For example, the chairman said that if a C option—you have your A and your B and now a C—is determined by the Secretary to be covered, it is to be covered. That is in fact flat not true. The only way a C option can be covered under the language of this bill is for two things to happen. First, the Health Benefits Advisory Committee has to say contrary to what the bill says we think it should be covered,

and then the Secretary has to say it. So it not a single decision by the Secretary.

Second, and I am sorry he is not here but the chairman of the full committee came and made an adamant argument, which has been repeated several times here today, that the bill prescribes minimum benefits and therefore to say that coverage of mammograms is not prohibited is untrue, that all the bill does is prescribe minimums. That also is flat not true. If you go to page 169 of the bill passed by the Congress, you will discover, as I mentioned earlier, that there are four levels of plans. There is a basic plan, an enhanced plan, a premium plan and a premium plus plan. The basic plan can only cover A's and B's, the things you recommend be an A or a B. It could cover a C if the two exceptions I just pointed out were to occur. But the basic plan absent those things happening does not cover anything but A's and B's, but more important than that, the definition of enhanced plan and the definition of premium plan both prohibit any additional benefits. They say you can have an enhanced plan and you can have lower cost sharing. You can have a premium plan and it can have lower cost sharing but it can only cover the basic services. So all three of the first levels of plans are prohibited from covering any service other than an A or a B. Only until you get the definition of a premium plus plan, and I would point the chairman of the full committee to page 169, lines 20 through 25, does it say a premium plus plan is a premium plan that also provides additional benefits. That is the only plan that can provide a benefit beyond the basic plan, and therefore the first three levels of plans are prohibited from covering mammograms by law whether they are offered by the government or offered by a private insurance company. Whether they are in the public plan or in a private plan, they are prohibited, and that may not be the intent. As the ranking member, Mr. Barton, made very clear, we need to deal not with what the—we need to deal with what the bill says and if it does not reflect our intent, and I would hope in this case it doesn't, because I don't think the government ought to be in the business of telling people you cannot buy coverage for mammograms. Then we need to fix the language of the bill or at least talk truthfully about it, and the chairman of the full committee was wrong when he said that this sets only minimums. There are words at the beginning of the bill which refer to minimums but the words of the bill specifically say it can only cover those items with the exception of when both the Secretary and the Health Benefits Advisory Committee decide to cover a C, and I appreciate the opportunity to put that into the record. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. I don't want to keep belaboring the point but the reason I responded to your statement and said that there were situations where the Secretary, and now you are saying advisory commission could add it to a basic benefit package was because when you made your opening statement you suggested that it couldn't be done that way, that they couldn't include it. So I don't want to belabor the point. I don't disagree with you but you are disagreeing with yourself because you initially said that they couldn't add it as a basic benefit, and now you are saying they can.

Mr. SHADEGG. If the gentleman would yield?

Mr. PALLONE. Sure.

Mr. SHADEGG. I actually didn't say they couldn't add it. I didn't discuss whether they could add it. I said that the basic plan cannot offer it, and it cannot offer it absent extraordinary circumstances, which are two other things.

Mr. PALLONE. See, I think—

Mr. SHADEGG. And I think what we are—

Mr. PALLONE. I think the problem is, we are saying the same thing but I am not going to get into it. I don't think there is any difference between what you said and what I said.

Mr. SHADEGG. Let us agree on that, but let us agree to fix it so that the bill doesn't say that someone cannot choose to buy a plan—for that matter, let us allow people who get a public plan to get mammogram coverage.

Mr. PALLONE. I am not going to continue to belabor it because I think that we are not necessarily disagreeing on whether it could or could not be included.

The next person is the gentlewoman from Florida, Ms. Castor.

Ms. CASTOR. Thank you, Mr. Chairman, and thank you very much for your testimony today. I believe the larger issue is the lack of access to any screening or health service for millions of American women of all ages, and I would like you to comment upon the implications of your latest recommendations on the millions of women who are not being screened at all. What do you say to them no matter their age?

Dr. PETITTI. You know, again, the task force can't fix these problems. I am here as a member of the task force speaking to mammography guidelines and speaking to the evidence we used to make them. There are clearly huge issues facing this country about health care and health insurance and health policy but I am not an expert in that area.

Dr. CALONGE. If I could just add to the point that it is clear that the provision of mammography and screening for breast cancer extends life, and so that is the service that we recommend, and I think everyone in the room knows that and needs to keep in mind that if the idea is to maximize health and extend life, then the services that are recommended should be considered for provision.

Ms. CASTOR. I mean, your recommendations talk about how, for example, the age 40 to 49, how it is important for women and their doctors to have a personalized plan with their trusted physician but there are many, many women out there who don't have a trusted physician, they don't have—they are not receiving their check-ups. Certainly you all have something to say to women all across America no matter their age on being as proactive as they can in taking personal responsibility, finding—you must have something to say on higher risk groups to help us communicate in a better way. You have already acknowledged that you did not do the job in communication but here is your chance today to bring all of your expertise and to provide a message to women on the importance of taking personal responsibility and getting their screenings. They may not have access to care but there are wonderful nonprofit groups where they provide some services in communities. Can you at least go that far and provide a proactive message to women in

this country on the importance of taking care of themselves and seeking out these screenings?

Dr. PETITTI. Well, again, I feel uncomfortable in being asked to put on a personal hat rather than my task force hat. I would be remiss if I didn't encourage women to be interested in their health, to take care of themselves, but I am here as a member of task force to speak to the mammography guideline recommendations and not to go beyond my expertise. I have friends who have no insurance. My daughter is uninsured. I know women who are uninsured who can't get surgeries they need. But that is not my role here. My role here is to speak to the mammography guidelines.

Ms. CASTOR. You are familiar with the huge disparities in screening, diagnosis and treatment among various income levels and if you are African American, you are a Latina, correct?

Dr. PETITTI. There are disparities in health care throughout all services.

Ms. CASTOR. If you could go back or will you go back and review your recommendations along the lines of higher risk groups, what we know in disparities of screening, diagnosis and treatment? Don't you think you could have done a better job in fleshing out some of those recommendations?

Dr. PETITTI. I think on many levels we know we could do a better job and among them is communication. We need to—we have tried for a number of years to make our recommendations more risk stratified. For breast cancer, this has been perhaps a little more difficult than for some other topics like osteoporosis, but again, what I thought would happen with these recommendations is we would start having exactly this kind of discussion: how do we find women who are extremely high risk, how do we communicate with them effectively, how do we make screening mammography something that is more individualized and tailored.

Ms. CASTOR. Thank you.

Dr. CALONGE. I would only add to that a plea for consideration of research of preventive services in the specific populations who are underrepresented in screening and other prevention studies. We often fail in this area, and I will inform the committee that we had a discussion about health disparities associated with nearly every recommendation vote, and the frustration on our part is the lack of evidence of efficacy in a specific trial aimed at high-risk populations. So I think this is a consideration of the task force, and as we are evidence based, this is a real plea on our part for researchers and funders of research to consider adequate studies that include disparate groups for where we are concerned there may be differences and require different recommendations.

Ms. CASTOR. Thank you.

Mr. PALLONE. Is the gentlewoman complete? All right. Thanks. The gentlewoman from Tennessee, Ms. Blackburn.

Mrs. BLACKBURN. Thank you, Mr. Chairman. I guess you are not used to women speaking a little more quickly and being a bit more succinct and so maybe that is why we have time left many times.

I want to thank you all for your patience and your endurance today and I really want to thank you for being here. This is an issue that is of tremendous concern to us, and as we look at what your findings were and as we look at the language of the bills that

are before us, I think what we want to make certain we do is, if there is offending language in the bill, we want to get it out, and of course we want to make certain that we have a clear understanding of what you brought forward and of your intent, and I am going to try to be succinct on this because I do know you are ready to move on and we have another panel. Dr. Burgess asked that you submit the vote from your committee as you arrived at your finding and your guidance that you made public, and as you submit that vote, who voted and how, one thing I would like for you to do for the record is also submit to us your science or evidence upon which you based these recommendations, what was reviewed, what studies, what findings, what groups. If we can have that as a part of the record so that we can look at it, I think that would be very instructive to us as we decide how to best move forward. So I would like to ask you all to do that.

I would also like to know what period of time, how long did you spend on this? How long was this up for discussion and under review? What was the thought process and the matrix that you worked from to come to this decision? Let us see a little bit about what you went through and how you went through it and how you worked, what your process is, how you arrived at those decisions. I do honestly believe that will be helpful to us with an understanding. I will have to say I agree with some of my colleagues, you have probably stepped into a bit of a quagmire that you did not expect as you released these findings, and I would like to ask you, were you all aware of how the H.R. 3962, how it would affect you, how your task force would be drawn into that bill, that the language of 3962 actually pulls you in, renames you and then gives credence to these findings through statute?

Dr. PETITTI. Well, as unbelievable as it may seem to those who are so caught up in Washington, I was writing my biostatistics lecture and have been actually woefully and naively oblivious of what has been going on in the health care reform arena. Certainly from the point of view of specific statutory language in now what I know is a 2,000-page bill, you know, I knew nothing, and quite honestly when I found out that these recommendations were being released the week of the vote, the big vote, I was sort of stunned and then also terrified, and I think my being terrified was actually exactly the right reaction.

Mrs. BLACKBURN. Dr. Calonge.

Dr. CALONGE. I would like to add again speaking specifically to the timeline for the consideration of this recommendation that it was completed prior to any sense that the role of the task force might change under upcoming health care reform. I will say that earlier this year we became aware of language in the House bill regarding the recommendations of the task force. However, this recommendation was considered and voted on with our explicit scientific methods well before that.

Mrs. BLACKBURN. I appreciate that, and I do thank you all for your sensitivity to this. I think the linkage that exists with the language of changing your title and then giving credence in the force of law basically to the priority assignments that you would make is of concern to us and to our constituents. I thank you all. And

I am only going to yield back 18 seconds but I yield it back, Mr. Chairman.

Mr. PALLONE. Thank you.

Oh, I am sorry. The gentleman from Ohio, Mr. Space.

Mr. SPACE. Thank you, Mr. Chairman.

Just so I understand this correctly, the task force has been charged with developing a scientifically determined floor for preventive services in this bill. Is that your understanding of your role?

Dr. PETITTI. You know, I am realizing that I really don't understand the bill. I shouldn't speak to the bill. I have learned a lot about the bill here.

Mr. SPACE. Well, the bill itself does in fact vest that kind of power with the task force to develop a scientifically determined floor, in other words, a minimum threshold under the basic coverage. Those recommendations then follow to the benefits advisory committee. Your recommendations will establish a floor under which the benefits advisory committee cannot go. They can go higher, however. Once the benefits advisory committee—and by the way, the benefits advisory committee consists of private medical doctors, patients, employers, insurance experts, a dentist and representatives of relevant government agencies. It is chaired by the surgeon general. Once it issues its recommendations, the Secretary—those recommendations then are the floor. The Secretary then has the discretion to increase or enhance the coverage available in the basic essential benefits package. Once that has been established, private insurers have the additional option of offering more coverage. So the suggestion that because your task force has issued the recommendations that it has, no insurance policies will cover mammograms for women in these categories, even the suggestion that the essential benefits package as established by this bill will not cover them is preposterous. There is no truth in it.

I do have a specific question I would like to ask you regarding some confusion that your findings have created back home in my district. There was a recent letter to the editor that was very widely distributed regarding your findings that have created some confusion, and I'd ask that you try to clear this up for us. The author of this letter writes, this is a quote, "What is most troubling about the federal panel's recommendations is that they are based mainly on cost saving." She also expresses concern that the recommendations are "cost-saving measures." Can you tell us today in no uncertain terms what the role of cost of mammograms played in your investigation and findings?

Dr. PETITTI. This is an easy question. Cost played no role in our recommendations. Again, and I said it publicly in other settings and I will say it again here, I think I have said it three times here, cost was not a consideration in the voting of our recommendations.

Mr. SPACE. Thank you. And finally, the author of that same letter pointed out that the task force contains "no cancer specialists." This is obviously a point that would be disconcerting to many. Is it true that no member of the preventive task force have any experience in working with cancer?

Dr. PETITTI. That is incorrect. Members of the task force consist of myself. I was the vice chair of the National Cancer Policy Board.

One member is a member of the National Cancer Institute Board of Scientific Counselors. Another member, current member is a professor of—he is the associate director of population sciences for the Dartmouth Hitchcock Comprehensive Cancer Center and an endowed chair of oncology. Again, the members of the task force have the expertise that permits them to make the kinds of recommendations they make within the arena of screening and preventive services.

Mr. SPACE. Thank you, Doctor.

I yield back my time.

Mr. PALLONE. Thank you.

The gentleman from Texas, Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman, and I will be as quick as I can.

I want to welcome our doctors. I guess having served on this subcommittee for 12 years now and the release from the USPSTF probably got more coverage than anything our subcommittee has done except the health care bill, and there was a lot of misinformation about it. But in your testimony you say that the individuals representing the views of the American College of Obstetricians and Gynecologists and the American Academy of Family Physicians weighed in on your recommendations and the obstetricians and gynecologists expressed concerns with the wording of the recommendations. Do you believe in the future it would be a good idea for the task force to actually have individual organizations such as these as actual reviewers instead of commenters?

Dr. PETITTI. Well, I want to clarify that they were official reviewers. First of all, as I pointed out, there were two members of the American College of Obstetrics and Gynecology on the panel. The ACOG reviewers were official reviewers. They made a number of comments. One of their comments which was the most substantive comment in retrospect was about their anticipation of misperception of our C recommendation, and they were right. And we should have listened more carefully to them and I am sure we will listen more carefully in the future.

Mr. GREEN. And I think there was information I guess on the self-exam, and from your testimony earlier was that, you know, physicians need to be able to provide the expertise so women can do the self-exam, that it is not perfect. If there a question, then they ought to talk to their physician and that is where it goes from there. So that is why I don't understand the fear of the self-exam.

My last question is, a major concern I have is the lack of transparency of the process within the USPSTF for deciding whether or not to change or create new screening recommendations, and depending on what happens with the health care bill, your initial decision could make a big difference. How could the task force be more open to outside input and feedback and what changes would you make in the future after what you have learned from this experience?

Dr. CALONGE. Thank you for this question. The task force understands the criticisms regarding transparency. As our profile has been increased during the discussion of health care reform, we believe it is incumbent upon us to increase our transparency in such a way that people understand as the previous Congresswoman

asked how we get to the decisions that we get to. The task force is already working on new transparency approaches including allowing Internet-based public comment on different work products. We think that is a good step. We are cautiously trying to expand into areas of transparency to include potentially public commentary during meetings and other approaches that we believe meet the intent and the requirement for transparency so that the decisions are made in such a way that we are not spending time in front of the public trying to help people understand the processes. So we understand this criticism. We actually started working on enhancing transparency about a year and a half ago and I will only tell the Congressman that our slow working has to do with understanding the resource impact of becoming more transparent but we absolutely believe we need to do it and we are working towards that end.

Mr. GREEN. Thank you.

Thank you. Mr. Chairman.

Mr. PALLONE. Thank you, and I think that concludes our questions, but let me just thank both of you really. I think that you did a tremendous job today of clearing up a lot of misunderstandings, and as someone who has been in politics I guess I could say my entire life, I think it is kind of refreshing to find out that, you know, you really were very independent and not at all aware of what we were doing. I think we gives ourselves too much importance. We all think we are all so important, that everybody is paying so much attention to everything we do. It is kind of refreshing to know that you were not. Thank you.

I will ask the next panel to come forward. Let me welcome our second panel and introduce the panel beginning on my left is Dr. Otis Webb Brawley, who is chief medical officer for the American Cancer Society, and next is Jennifer Luray, who is president of the Susan G. Komen for the Cure Advocacy Alliance, and then we have Dr. Donna Sweet, who is a member of the American College of Physicians' Clinical Assessment Efficacy Subcommittee, and finally, Fran Visco, who is president of the National Breast Cancer Coalition. I know some of you have been here before and thank you for being here. I won't repeat that we ask you each to keep your comments if you can to 5 minutes. They become part of the record. And if you want to, you can submit additional written comments later.

Let us start with Dr. Brawley. Thank you.

STATEMENTS OF OTIS WEBB BRAWLEY, M.D., CHIEF MEDICAL OFFICER, AMERICAN CANCER SOCIETY; JENNIFER LURAY, PRESIDENT, SUSAN G. KOMEN FOR THE CURE ADVOCACY ALLIANCE; DONNA SWEET, M.D., M.A.C.P., MEMBER, AMERICAN COLLEGE OF PHYSICIANS' CLINICAL ASSESSMENT EFFICACY SUBCOMMITTEE; AND FRAN VISCO, PRESIDENT, NATIONAL BREAST CANCER COALITION

STATEMENT OF OTIS WEBB BRAWLEY

Dr. BRAWLEY. Good afternoon, Mr. Chairman and distinguished members of the committee. I am Otis Brawley, the chief medical officer of the American Cancer Society. On behalf of the 11 million patients and survivors in America today, the Society thanks you for

your continued leadership in the fight against your cancer and your commitment to enacting comprehensive health care reform legislation this year. I appreciate the opportunity to testify today about the important role mammograms play in combating breast cancer deaths.

As a medical oncologist who actually treats breast cancer patients, I have treated hundreds of breast cancer patients in my career. Indeed, I have observed firsthand the heartbreak this disease has on women and their families. Over the years I have also witnessed the advances we have made in breast cancer early detection and treatment, advances that led to fewer women suffering and ultimately dying from this dreaded disease. I can't help but note that in our current system our society prohibits a large number of women, 30 to 40 percent of those who should be getting mammograms, from actually getting mammograms. I also have to note that in my own research published and cited before this committee before has shown that uninsured women of the same stage have poorer survival compared to insured women of the same stage. That is to say that even when early detected, insurance is a prognostic factor in breast cancer.

Mr. Chairman, as you know, the Society in recent weeks has publicly disagreed with the recommendations of the U.S. Preventive Services Task Force with respect to mammography. Let me say right now that I have tremendous respect for the task force. As an academic physician, I look forward to virtually everything that the task force has published over the last 20 years regarding cancer. I also want to say that reasonable experts can look at the science and disagree. There is useful screening that should be done and useless screening that actually can be harmful, and that is something that the task force I think should be looking at in an objective fashion and actually has generally done a very good job of doing.

With respect to mammography, the scientific evidence supporting its value in reducing deaths from breast cancer is quite strong. In looking at the evidence, the Society along with other medical groups believes that screening mammography offers an identifiable and important survival benefit to women in the age group 40 to 49 and indeed women age 40 and above. More specifically, the Society believes that the reduction in mortality and less-invasive treatments associated with early detection of breast cancer using mammography continues to warrant a recommendation of annual screening for all women beginning at the age of 40. We do agree with the task force that women should be informed of the potential risks as well as the potential benefits of the procedure.

The data and literature examined by the task force in the lead-up to its November announcement on mammography is essentially the same data reviewed by an expert panel of breast cancer researchers, clinicians and epidemiologists convened by the American Cancer Society in 2003. However, in that earlier review the Society's panel considered the additional findings of a population-based study of modern mammography which showed much stronger benefits from screening compared with the more limited data examined by the task force. Translated, we actually think there is a greater benefit to the mammography screening that does the task force.

In addition, since that time, a number of advancements have emerged that have shown to increase the effectiveness of mammography for women age 40 to 49. There have been improvements in the quality of mammograms resulting from the Mammography Quality Standards Act, or MQSA. There has been a shift to using digital mammograms over film mammograms, which research indicates may be more effective in screening younger women with denser breasts. The introduction of new technologies such as magnetic resonance imaging has also proven to be a particularly effective tool in high-risk women.

Let me very clear on the next point. We understand and acknowledge that mammography screening is not a perfect test. Indeed, it is an imperfect test but we also believe that this imperfect test is the only good test other than awareness of one's breasts to help save lives at this time. We can and we must invest in research to find better tools for detecting and treating breast cancer. Women deserve a better test than mammography. Indeed, one of the great problems right now is, there is a certain complacency or satisfaction with the use of mammography in women of all ages. We need a better test. The essential fact right now is, mammography is one of the two ways that we can use to save lives.

I have to note that there has been a lot of talk about breast self-exam, and as a medical oncologist and epidemiologist who is involved in screening and reads the screening literature and a doctor who treats, let me say that we have been talking past ourselves when we talk about breast self-exam today. Breast self-exam has shown in the medical literature and as spoken against by the task force is a woman doing a specific regimen and exam once a month. It actually would take about 20 to 30 minutes for a woman to do. What most of us including the American Cancer Society have done is moved away from that regimented breast self-exam, which was advocated 20 to 30 years ago, toward something which is a little bit different, which is women being aware of their breasts and essentially being aware of their breasts and looking for differences in their breasts on an almost daily basis. This is called breast awareness. Most women indeed find their breast cancer through breast awareness, not breast self-exam. There are two randomized clinical trials that show that breast awareness and breast self-exam are equivalent in terms of mortality reduction but breast self-exam actually increases the number of unnecessary biopsies done versus breast awareness, so I prefer to advocate breast awareness.

I will note also that approximately 30 to 40 percent of American women age 40 and up are currently not getting regular mammograms. In the United States, about half of all women diagnosed with breast cancer actually are diagnosed through this breast awareness and not through mammography. For many of the women who cannot get mammography, this is the only way that they can actually have any type of early detection.

In summing up, we know we can do better and with your help, Mr. Chairman, we are heading in the right direction. The Affordable Health Care for America Act, recently passed by the House, will improve health care and it provides a significant investment in cancer prevention and early detection by requiring first dollar coverage for prevention in both public and private plans with little

or no cost to patients. The Society and its affiliate, the American Cancer Society—

Mr. PALLONE. Doctor, I think you are concluding but I know you are 2½ minutes over.

Dr. BRAWLEY. I am sorry. We strong support the changes you have made in the legislation that will help the task force improve the transparency and inclusiveness of its operations.

Let me just stop at that point and say thank you for asking me to appear here.

[The prepared statement of Dr. Brawley follows:]



Statement by
Otis W. Brawley, MD
Chief Medical Officer
American Cancer Society

Before

The Committee on Energy and Commerce
Subcommittee on Health
United States House of Representatives

Wednesday, December 2, 2009, 10:00 a.m.
2123 Rayburn House Office Building

Good morning, Mr. Chairman, Mr. Ranking Member, and distinguished members of the Committee. I am Dr. Otis Brawley, Chief Medical Officer of the American Cancer Society (the Society). On behalf of the millions of cancer patients and survivors in America today, the Society thanks you for your continued leadership in the fight against cancer and your commitment to enacting comprehensive health care reform this year. I appreciate the opportunity to testify today about mammograms and their important role in the fight against breast cancer.

Introduction

Apart from skin cancer, cancer of the breast is the most common malignancy in women.¹ While breast cancer ranks second after lung cancer for the most common cancer death, it causes more lost years of potential life than any other cancer.² For a woman of average risk, she has a 1 in 8 chance of developing breast cancer and a 3 percent chance of dying from the disease.³ Fortunately, breast cancer mortality has been declining significantly in the United States since screening mammography has become the standard of care for most women. The steady drop in the breast cancer death rate means that this year alone, about 15,000 breast cancer deaths were

¹ American Cancer Society. Cancer Facts and Figures 2009.

² Green BB, Taplin SH. Breast cancer screening controversies. *J Am Board Fam Pract.* 2003 May-Jun;16(3):233-41.

³ American Cancer Society. Breast Cancer Facts and Figures 2009-2010.

avoided that would have occurred had rates not begun to drop due in part to greater access to mammography.³

On November 16th, 2009, the U.S. Preventive Services Task Force (USPSTF) announced that it would no longer recommend routine mammograms for women between the ages of 40 and 49, a group that accounts for about 1 out of 6 breast cancers.⁴ The USPSTF recommendation has caused a heated public discourse on the benefits, risks and harms of mammograms and breast cancer screening.

Unfortunately, where we might have had an opportunity to further refine our messages about the benefits and limitations of screening, we have had yet another episode of messy and confusing public discourse about an issue that is a leading health concern of women. An unfortunate consequence may be that fewer women will be getting screened, and for those who are unlucky and develop breast cancer, those cancers won't be caught early but rather when they are big enough to feel. That's a step backward we should all be unwilling to take.

In my testimony, I will outline the scientific evidence that supports annual screening for all women age 40 and over. I will also highlight areas of agreement, most notably that all women should have access to this and other evidence-based cancer screenings; mammography remains the best widely-available early detection method for breast cancer available today that has been scientifically proven to reduce deaths from breast cancer; and not enough women in the United States currently get this life-saving test.

American Cancer Society's Review of the Evidence

Mammography is possibly the most intensely scrutinized and debated medical procedure of our time. To help understand the history and the science behind early detection of breast cancer, I will first outline the scope of evidence as analyzed by the nation's leading breast cancer experts who were part of the Society's breast cancer screening guidelines process.

⁴ Screening for Breast Cancer, Topic Page, November 2009. U.S. Preventive Services Task Force. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/clinic/uspstf/uspstfbrca.htm>

Our scientific and medical experts monitor the emerging literature on an ongoing basis to ensure that the Society's guidelines reflect the most current scientific evidence. As such, the Society's guidelines are reviewed and updated regularly. The members of the guidelines committee include breast cancer experts, cancer epidemiologists, gynecologists, primary care physicians, oncologists and radiologists having diverse, extensive research and/or clinical backgrounds in breast cancer screening. The Society's breast cancer screening guidelines were last systematically reviewed and evaluated in 2003 for average-risk women⁵ and in 2007 for high-risk women⁶. Our most current recommendations⁷ for breast cancer screening are as follows:

- Yearly mammograms are recommended starting at age 40 and continuing for as long as a woman is in good health.
- Clinical breast exam (CBE) should be part of a periodic health exam, about every 3 years for women in their 20s and 30s and every year for women 40 and over.
- Women should know how their breasts normally feel and report any breast change promptly to their health care providers. Breast self-exam (BSE) is an option for women starting in their 20s.
- Women at high risk (greater than 20% lifetime risk) should get an MRI and a mammogram every year. Women at moderately increased risk (15% to 20% lifetime risk) should talk with their doctors about the benefits and limitations of adding MRI screening to their yearly mammogram. Yearly MRI screening is not recommended for women whose lifetime risk of breast cancer is less than 15%.

The Society is not changing its guidelines for breast cancer screening as a result of the USPSTF new recommendations.

⁵ Smith RA, Saslow D, Sawyer KA, et al. American Cancer Society guidelines for breast cancer screening: update 2003. *CA Cancer J Clin.* 2003;53:141-169.

⁶ Saslow D, Boetes C, Burke W, et al. American Cancer Society guidelines for breast screening with MRI as an adjunct to mammography. *CA Cancer J Clin.* 2007;57:75-89.

⁷ Smith RA, Cokkinides V, Brawley OW. Cancer screening in the United States, 2009: a review of current American Cancer Society guidelines and issues in cancer screening. *CA Cancer J Clin.* 2009;59:27-41.

Mammograms for Women Age 40-49

The primary evidence⁵ supporting the recommendation for periodic screening for breast cancer with mammography derives from nine randomized clinical trials (RCTs). These RCTs were the same trials used in the USPSTF analysis. Two of the trials took place in North America, two in the United Kingdom, one in Scotland, and four in Sweden. These RCTs were the same trials used in the USPSTF analysis. The Society also included in its analysis several recent population-based studies of modern mammography which show much stronger benefits from screening as compared to the more limited data examined by USPSTF. The Society found that while variation exists in the observed mortality reductions, a meta-analysis of all the studies' results showed a 24 percent mortality reduction associated with screening. Furthermore, although the trials vary somewhat in their design, the results are uniformly consistent with respect to the relationships between the stage shift at diagnosis and a reduction in mortality.

Modern population studies have shown much greater mortality reductions for women ages 40-49 and 50-69 than are estimated with USPSTF's meta-analyses of all randomized trial data. These mortality reductions also are very similar due to the fact that modern screening programs tailor the screening interval to screen younger women at a shorter interval. Let me cite just one example. In a report published in 2003 in the *Lancet*, an international team of researchers compared deaths from breast cancer diagnosed in the 20 years before screening was introduced in two large Swedish counties with those with those from breast cancer diagnosed in the 20 years after the introduction of screening.⁸ This was a study involving over 200,000 women. In the analysis, data were stratified into age-groups invited for screening (40-49, and 40-69) and not invited (20-39 years), and by whether or not the women had actually received a screening mammogram in the post screening epoch. After adjustment for age, self-selection bias, and changes in breast-cancer incidence in the 40-69 years age-group, breast-cancer mortality was reduced in women who were screened by 44%, but only 16% in women who were not screened. In the 40-49 age group, there was a 48% reduction in deaths in the women who were screened, but only 19% fewer deaths in women who were not screened. While this study was not a

⁵ Tabar L, Yen MF, Vitak B, Chen HH, Smith RA, Duffy SW. Mammography service screening and mortality in breast cancer patients: 20-year follow-up before and after introduction of screening. *Lancet*. 2003 Apr 26;361(9367):1405-10.

randomized trial, it applies statistical adjustments derived from what was learned in the trials, represents 40 years of data from a health system with impeccable record keeping and very high rates of adherence to screening in the mammography program. It shows that modern mammography screening is achieving mortality reductions as good as or better than those observed in the individual trials that showed the strongest benefits. Unfortunately, this study was not included for consideration by the USPSTF.

While we commend the USPSTF for their legacy of evidence-based guidelines for preventive health, we do have some fundamental concerns about the conclusions that were drawn in this update of breast cancer screening guidelines based on the evidence it considered. Unlike the USPSTF, the Society believes that achieving even a 15 percent reduction in mortality (and we believe this estimate of benefit is artificially low), associated stage-shifts, and improvements in quality of life due to less invasive treatment warrant a recommendation of annual screening in the 40-49 population. The Society, along with numerous other medical groups, believes that the available evidence supports the conclusion that screening mammography offers an identifiable and important survival benefit to women in this age group.

Furthermore, since the studies included in the USPSTF analysis were published, we have seen a number of advancements that have increased the effectiveness of mammograms in the 40-49 population. For example, we have seen improvements in the quality of mammograms resulting from passage of the Mammography Quality Standards Act (MQSA); a shift to using digital mammograms over film mammograms, which research shows may be more sensitive in younger women and women with denser breasts; and finally, new technology has been introduced, including breast Magnetic Resonance Imaging (MRI) that has proven to be an effective screening tool in high-risk women.

While we believe the efficacy of mammography has been demonstrated, we also acknowledge that it is not a perfect test. As such, we must strive to improve these tests and address issues of adverse consequences for women who undergo screening. For example, women often must undergo additional studies for suspicious lesions. Some women have biopsies that ultimately do not show breast cancer. We know that mammography screening comes with limitations, and the

Society is committed to finding better tests. In the meantime, it is equally important to acknowledge that beginning in 1990, breast cancer deaths declined 2.3 percent annually for all women and 3.3 percent per year for women aged 40-50 years. That may not seem like much from year to year, but when you consider the total over 19 years, the impact translates to a 20 percent drop in mortality for women less than 50. This is particularly significant when taking into consideration that the death rate was absolutely stable for the preceding six decades. There is no dispute that screening mammograms and better treatments are responsible for that success. Based on our review of the USPSTF analysis, we see no reason to change a strategy that has proven effective in reducing the death rates for breast cancer in all recommended age groups, including those women ages 40-49.

Screening Intervals

The goal of screening is to reduce the incidence rate of advanced disease. Therefore, the routine screening interval should be set to help ensure adherence that is likely to result in the detection of the majority of cancers while still localized. Data from randomized clinical trials (RCTs) and inferential evidence have provided persuasive evidence that women likely will benefit more from annual screening compared with screening at two-year intervals. Both the Society and the USPSTF reached this conclusion in 2002. Further, data from the RCTs have shown that progressively shorter screening intervals result in detection of tumors at smaller sizes and a decrease in mortality rates. The American College of Radiology estimates that providing mammography only every other year in women 50-74 would miss 19 to 33 percent of cancers that could be detected by annual screening.⁹ As a result, the breast cancer experts involved with review of the Society's guidelines concluded that "given the prognostic value of smaller tumors, and the findings that annual screening results in more favorable tumor characteristics in both pre- and postmenopausal women, annual screening may offer advantages over biennial screening for all women."⁵

⁹ American College of Radiology. Joint Statement from the American College of Radiology and Society of Breast Imaging. USPSTF Mammography Recommendations Should Be Specifically Excluded From Health Care Reform Legislation.

Breast Self Examination (BSE)

Breast self-examination (BSE) is a monthly step-by-step approach that involves women examining her breasts in a systematic pattern while in front of a mirror, lying on her back, and/or in a shower. Part of the controversy on the net impact of BSE is that the actual definition and what is involved for effective BSE is not clear. BSE is different than breast awareness, which is where women are knowledgeable about how their breasts normally look and feel and are able to recognize any changes. The Society's guideline recommends that: "Women should know how their breasts normally feel and report any breast change promptly to their health care providers." BSE, a formal monthly-exam of the breast, is still viewed as an option for women starting in their 20s. However, the Society wants to be clear that the current evidence based on two new randomized trials have shown that breast awareness alone has the same mortality reduction as monthly BSE.⁵

Even when provided with the evidence, some women feel very comfortable doing BSE regularly and may benefit from the routine examination of the breast. Other women are more comfortable simply feeling their breasts in a less systematic approach, such as while showering or getting dressed or doing an occasional thorough exam. Sometimes, women are so concerned about "doing it right" that they become stressed over the technique. Doing BSE regularly is only one way for women to know how their breasts normally look and feel and to notice any changes. It is okay for women to choose not to do BSE or not to do it on a regular schedule such as once every month. We must work harder to get a responsible message out to all women that checking their breasts in a way they feel comfortable with is absolutely vital for protecting their breast health. Furthermore, it is critical if a woman feels or sees a change in her breast, she should be able to access a health care provider to undergo further evaluation.

Improving Breast Cancer Screening and the Messages about it

The real travesty today is that approximately 30 to 40 percent of American women aged 40 and over fail to have regular screening mammograms.¹⁰ The inability of millions of women to access proven life-saving services such as mammograms is a failure of our health care system. We also

¹⁰ American Cancer Society. Cancer Prevention and Early Detection Facts and Figures 2009.

know that lack of adequate health insurance coverage can be deadly. Only one in four women without health insurance had a regular mammogram in the past year.¹¹ Furthermore, a recent study by the Society found that uninsured breast cancer patients are more likely to be diagnosed at a later stage and have lower survival rates than women who are privately insured.¹² Without access to these tools, far too many women are at risk of being diagnosed at later stages of the disease after the cancer has spread, when treatment is more difficult, more expensive, and less likely to save lives.

Mammography screening is not perfect. Women deserve a better test, but in the meantime, we must stop sending messages that a screening and early detection test is of little or no value. We need to encourage women to get this test because it has shown to save lives.

Throughout the country, women are forced to choose between health care and more routine things, such as paying for food, housing, utilities or even the health of their kids and spouses, especially in hard economic times. The American Cancer Society Cancer Action Network (ACS CAN), the nonprofit, nonpartisan advocacy affiliate of the Society, conducted a national survey in April 2009 to understand how Americans are dealing with health care costs in the current economic environment and found that 1 in 5 women said that they or a family member in their home put off getting a cancer screening test in the past year. Furthermore, nearly one-third of Americans with household incomes less than \$35,000 said they put off potentially lifesaving screenings such as mammograms.¹³

We should be particularly concerned about how these guidelines will influence the perceptions of medically underserved women, such as minority women and those who lack health insurance. Evidence shows that African Americans and Ashkenazi Jewish women get breast cancer at an earlier age, and may have a greater benefit from starting screening sooner. We all have a duty to ensure that progress made in breast cancer does not get reversed as a result of these new recommendations or confusion about what they mean. It is our collective job to strive to do

¹¹ *Ibid.*

¹² Halpern MT, Ward EM, Pavluck AL, Schrag NM, Bian J, Chen AY. Association of insurance status and ethnicity with cancer stage at diagnosis for 12 cancer sites: a retrospective analysis. *Lancet Oncol.* 2008;9(3):222-31

¹³ The American Cancer Society Cancer Action Network (ACS CAN). The Need for Health Care Reform through the Eyes of Cancer Patients: A National Poll. <http://acescan.org/pdf/healthcare/reports/healthcare-cancerpoll.pdf>

better in providing clear and understandable information about the benefits of evidence-based prevention and early detection, particularly for populations most in need to help decrease disparities in health care and improve health outcomes.

The Implications for Health Care Reform

On behalf of the Society and ACS CAN, we applaud you for your work on HR 3962, the Affordable Health Care for America Act, which has the potential to take our country's fight against cancer to a new level.

The legislation presents an exceptional opportunity to advance the Society's mission of reducing suffering and death related to cancer and the potential to transform our nation's health care system in a fundamental way that begins the process of making adequate and affordable health care accessible to all Americans.

The House bill takes a number of steps to improve health care for cancer patients and their families by refocusing the system to emphasize prevention, ending the practice of denying coverage because of pre-existing conditions, limiting the cost burden on families by providing care that covers more and costs less and emphasizing patients' quality of life.

The Society and ACS CAN believe more than 60 percent of all cancer deaths could be avoided through more effective use of existing scientific knowledge. The House bill proposes a significant investment in cancer prevention and early detection by requiring coverage for preventive programs in both public and private plans at little or no cost to patients. HR 3962 also calls for an investment of \$34 billion over five years in a new Public Health Investment Fund for community health centers, primary care training and prevention and wellness research.

We thank you and the members of Congress who have worked so hard to pass meaningful health care reform and we are strongly supportive of the changes which you made to the operation of USPSTF in the legislation. These changes are particularly important given that the legislation stipulates that both public and private insurance entities would be required to cover all preventive services receiving an "A" or "B" rating from USPSTF. However, we remain concerned that due

to USPSTF's November 16th recommendation, coverage for mammography services for certain women could be reduced or eliminated. ACS CAN strongly believes that an essential benefits package cover more than what receives a USPSTF grade of 'A' or 'B', and USPSTF recommendations should constitute a floor, not a ceiling, for coverage. We support the committee's report language to the House-passed reform bill that advises the Secretary to consider the USPSTF guidelines a floor for prevention benefits, and strongly urge that this provision be included in the final conference statutory language.

For the record, ACS CAN has been advocating for the following changes to the function and composition of the USPSTF:

- Membership -- USPSTF membership should include experts in clinical and community medicine, specialists in the technology under consideration, health delivery, public health, and health data, as well as patient representation and representatives experienced in minority health and health disparities.
- Transparency -- USPSTF meetings should be open to the public, and the methodologies used to establish priorities should be made available to the public through forums and drafts that are subject to public review and comment before being made final.
- Representation -- USPSTF advisory panels should include a cross-section of interests, including patient representatives, experts in health care delivery and health care providers.
- Outside sources -- The Secretary of Health and Human Services should be empowered to recognize other sources and interpretations of scientific evidence in determining recommendations for preventive services.

Accordingly, the Society and ACS CAN commend the members of the House, especially on this Committee, for including provisions in HR 3962 that will ensure that USPSTF will be transformed and the process for making these recommendations will incorporate the perspectives and interpretations of outside individuals and groups. These constructive changes will lead to a more transparent and inclusive process for the task force to perform its important work. We look forward to working with you and members of the Senate to ensure that all Americans have

access to credible information and coverage that allows them to make meaningful decisions on what preventive services are the most-effective and best choice for them.

Conclusion

We all value the lives of American women and want to eradicate this deadly disease. This year alone in the United States, over 192,370 women will be diagnosed with breast cancer and approximately 40,170 women will die from the disease.³ The USPSTF, with its new recommendations, is telling women that mammography saves lives -- just not enough of them to recommend that all women over 40 get screened. The Society disagrees with the USPSTF new recommendation and urges all women age 40 and older to get a mammogram every year. We will continue to provide information designed to inform the public about the benefits and limitations of mammography screening. We are confident that, armed with information, women and their health care providers will continue to see mammography as the best current strategy to reduce death from this disease.

We have made so much progress in the last 30 years. The decline in breast cancer deaths adds up to more than 130,000 grandmothers, mothers, wives, sisters and daughters who were alive, perhaps to celebrate another birthday, and even to go on to live a full, rich life. Let's make sure we do not reverse the course of our progress. Thank you again for the opportunity to testify before this committee today, we look forward to working with you to help ensure that we continue to make progress in the war against cancer.

Mr. PALLONE. Thank you.
Ms. Luray.

STATEMENT OF JENNIFER LURAY

Ms. LURAY. Thank you, Mr. Chairman, Mr. Ranking Member and members of the committee. Thank you for the opportunity to testify about the recommendations of the U.S. Preventive Services Task Force. My name is Jennifer Luray and I am president of the Susan G. Komen for the Cure Advocacy Alliance, and on behalf of the patients, survivors, scientists, clinicians and advocates of the Komen family, we thank you for holding this hearing, and I also want to thank the previous task force witnesses for their honesty in discussing how this was communicated to the public.

Let me begin by stating that breast cancer experts agree far more than they disagree. This is a point that we have stressed since the task force recommendations were first released. There is no debate that mammography reduces the risk of dying from breast cancer, only debate over the timing and frequency of mammography. We don't want women to react to this latest controversy as a reason not to get screened.

Komen in consultation with our scientific advisory board is not changing our screening recommendations at this time. We continue to recommend that women be aware of their breast health, understand their risks and continue to follow existing screening recommendations including mammography beginning at age 40 for women of average risk and earlier for women with known risks of breast cancer. As you can imagine, Komen affiliates have been inundated with concerns that the task force recommendations could lead to impediments to mammography. Many comments have come from breast cancer survivors who are diagnosed before the age of 50. This is a very typical one: "I was 46 years old when I went in for my annual mammogram. Like so many other women, there is no history of breast cancer in my family. I was stage II, and if not for the mammogram, I would have had much more advanced cancer."

We know that mammography is an imperfect tool, but instead of stepping away from it, we must close the technology gap and come up with better methods. That is why Komen is funding promising screening research. We must work together, government, private industry, doctors and patient advocates to deliver screening technology that is more predictive and personalized but less expensive. Next year, Komen will host a national technology summit and we asked NIH to help us prepare by reporting on investments that they have made in screening technology. But let us also redouble our efforts on behalf of the one-third of women, some 23 million American women, who are not being screened due to lack of access, education or awareness.

We partner closely with the CDC's National Breast and Cervical Cancer Early Detection Program to fund free clinics and mobile vans yet the GAO found that over half of eligible women for this program do not receive screening. That is a disturbing finding that underscores the need for access to affordable insurance to eliminate health disparities. And that is why Komen supports the valuable patient protections in H.R. 3962 that would increase access to af-

fordable health insurance, prevent insurance companies from denying coverage due to preexisting conditions, protect patients from high out-of-pocket costs and increase access to mammography screening.

In light of the new task force recommendations, however, we must ensure that women ages 40 to 49 will have access to the same coverage and cost-sharing benefits as women age 50 and older. Even a relatively small copayment reduces mammography rates. We do understand that H.R. 3962 will create a new entity which would not be bound by the task force's guidelines and that the bill does not exclude from the minimum benefits package services that are not rated A and B, i.e., we understand that the task force recommendations are a floor, not a ceiling. But our bottom line is that women in the 40 to 49 age group may after consulting with their doctor choose to forego a mammogram but those who do choose to have one must have access to it on the same terms as women age 50 and older. The Komen Advocacy Alliance is pleased that H.R. 3962 includes patient representatives as advisors to the task force on clinical preventive services. We believe that patient advocates can help to develop and deliver effective messages about prevention and screening.

We hope that these past few weeks of confusion will ultimately result in women taking more interest in their breast health, that many more underserved women will be screened and that an intensive effort to make breakthroughs in screening technology will begin anew. Thank you, Mr. Chairman.

[The prepared statement of Ms. Luray follows:]



**Committee on Energy & Commerce
U.S. House of Representatives
Subcommittee on Health**

“Breast Cancer Screening Recommendations”

Testimony of
Jennifer Luray
President

Susan G. Komen for the Cure® Advocacy Alliance

Wednesday, December 2, 2009

Mr. Chairman, Mr. Ranking Member, and Members of the Committee, thank you for the opportunity to testify today about the recent mammography screening recommendations of the U.S. Preventive Services Task Force (USPSTF). My name is Jennifer Luray, and I am President of the Susan G. Komen for the Cure® Advocacy Alliance and Vice President of Government Affairs and Public Policy of Susan G. Komen for the Cure®. On behalf of the breast cancer patients, survivors, families, friends, scientists, clinicians and advocates in the Komen family, thank you for holding this hearing.

More than 190,000 women will be diagnosed with breast cancer in the U.S. this year, and more than 40,000 will die.¹ In the last twenty years, there have been modest declines in the breast cancer mortality rate, attributed to increases in early detection and improvements in breast cancer treatment. When breast cancer is found before it spreads beyond the breast, the 5-year relative survival rate is 98 percent, but declines to 84 percent for regional disease and 23 percent when cancer has metastasized or spread to other parts of the body.²

In November, the USPSTF released the following new guidelines for screening mammography:

- For women ages 40-49, the guidelines for screening mammography changed from a B rating (recommended) to a C rating;
- For women ages 50-74, the guidelines for screening mammography remains a B (recommended), but the recommended frequency changed from “every 1-2 years” to biennial (every other year);
- For women ages 75 and over, the guidelines for screening mammography changed from a B (recommended) to an I (insufficient evidence);
- The guideline for teaching regular breast self-examination (BSE) changed from an I (insufficient evidence) to a D (not recommended); and
- A guideline was added, rating digital mammography and magnetic resonance imaging (MRI) over film mammography as an I (insufficient evidence).

These changes have again reignited the controversy over mammography screening, a debate that has raged for a number of years. It is important to remember the following:

¹ American Cancer Society, “Breast Cancer Facts & Figures, 2009-2010.” Available online at http://www.cancer.org/downloads/STT/F861009_final%209-08-09.pdf.

² *Ibid.*

- While there is some disagreement about when mammograms should begin and on what schedule, all agree — including the USPSTF — that mammograms save lives in women 40 to 49, as well as women over 50.
- Susan G. Komen for the Cure continues to recommend annual mammography beginning at age 40 for women of average risk and earlier for women with known risks for breast cancer. We are constantly evaluating our guidelines and would not change them without serious consideration.
- Our real focus, however, should be on the fact that one-third of the women who qualify for screening under today's guidelines are not being screened due to lack of access, education or awareness. That issue needs focus and attention: if we can make progress with screening in vulnerable populations, we could make more progress in the fight against breast cancer.

Komen's Response to USPSTF Recommendations

Susan G. Komen for the Cure®, the world's leading breast cancer advocacy organization, has carefully reviewed the data and new recommendations from the U.S. Preventive Services Task Force (USPSTF) concerning mammography screening.

Komen for the Cure wants to eliminate any impediments to regular mammography screening for women age 40 and older. While there is no question that mammograms save lives for women over 50 and women age 40 to 49, there is enough uncertainty about the age at which mammography should begin and the frequency of screening that we would not want to see a change in policy for screening mammography at this time. As with all screening tests, the decision to perform a mammogram must include an evaluation of the benefits and the risks of the screening tool, as well as a consideration of patient preference. Komen's current screening guidelines can be found at www.komen.org and will not be changed at this time.

The recent controversy about mammography should not suggest that there is debate about the most important issues. Most breast cancer experts agree far more than they disagree. For example, there is no debate that mammography reduces the risk of dying from breast cancer. As stated in the new USPSTF recommendations, extensive scientific evidence demonstrates that mammography reduces breast cancer mortality both among women age 50 and older, as well as among women age 40 to 49.

Because breast cancer false positive results are more common in women under 50, some argue for a different screening approach in women 40 to 49 than in those over 50. The USPSTF suggests that women 40 to 49 consider their individual risk of developing breast cancer before making a decision about screening mammography. They further suggest that those women at increased risk should strongly consider regular mammography screening. Women at lower risk, who wish to initiate screening in their 40s should recognize that the benefits of screening are less than in older women.

As to the timing of mammography, the USPSTF also suggests that screening every other year is likely to be as effective as annual screening, and that this approach would decrease false positives. Biennial screening is already practiced in many countries. Different organizations, based on a review of the same data, may recommend either yearly or every other year screening for women at average risk of breast cancer between the ages of 40 and 75. We believe that the timing of assessment is best left to a woman and her health care provider. It is our view, however, that the exact timing of assessments is less important than guaranteeing access to screening. We call upon third party payers to fund annual mammography if a woman and her health care provider opt for this approach. There are no studies that directly address the role of mammography in women over the age of 75. Thus, we recommend that older women, particularly those in excellent health, discuss the role of ongoing screening with their health care provider.

As a breast cancer community, we must all recognize that both breast cancer screening and breast cancer treatment are moving targets. As treatment continues to evolve in the years ahead, these changes may have an impact on the optimal approaches to screening as well. In the meantime, honest differences in opinion can and do exist, and such differences represent attempts on the part of individuals and/or organizations to provide the best possible care to women of all ages and to minimize mortality and suffering from breast cancer.

It is important to note that the USPSTF analysis is based on studies of conventional mammography, and some have noted that digital mammography may offer better results and may alter recommendations in the future.

We encourage women to be aware of their breast health, understand their risks, and continue to follow existing recommendations for routine screenings including mammography beginning at age 40. Additionally, women with unresolved questions about breast cancer screening should engage in discussion with their health care providers.

Public Reaction to the USPSTF Recommendations

Since the announcement of the new USPSTF guidelines, our offices have been inundated with worried and outraged women, expressing deep concern that this change could create impediments to mammography. Many comments have come from breast cancer survivors who were diagnosed before the age of 50.

Here is a sample of the reaction we have received:

"If a woman is diagnosed at a later age because she couldn't get a mammogram and the cancer got a head start, then time was lost in her chance to win the fight."

"I am a breast cancer thriver and a yearly visitor at my Komen Center in Peoria, Illinois, where they biopsied and diagnosed my breast cancer at age 44. I know far too many younger women who either died because they did not receive proper treatment and diagnosis early, or whose lives were saved due to early detection."

"I am shocked and saddened... They clearly have not spoken to the thousands of women who have fought breast cancer. I was 44 when I was diagnosed, and yes, I found the lump myself. Not only that, I have heard numerous stories of much younger women than myself who have battled breast cancer ~ even pregnant women and new mothers. How sad that the USPSTF would put this generation at further risk by taking away the very test that can detect the disease."

"As a breast cancer survivor, I am outraged by the guidelines that recently were announced. I was 46 years old when I went in for my annual mammogram. Like so many other women, there is no history of breast cancer in my family. The lump was so deep that neither myself nor my doctor felt the lump that had been growing for months. I was in stage 2 when it was discovered and if not for the mammogram, it would have been very advanced if I had to follow the guidelines that are now in discussion. ... My daughter, younger sister, and thousands of women are at risk and with policies such as this, insurance companies will have the ability to reject early screenings. I will do whatever is necessary to help make the changes that will save lives and raise awareness."

Clearly, these comments illustrate the concern many women have about the USPSTF recommendations. We continue to emphasize the points of agreement, as opposed to the points of disagreement. We have known for some time that mammography is an imperfect tool. However, we are concerned that the current debate about screening will be taken by many women to be an indictment of mammography, and that the fear and confusion will drive women away from screening, which we know was not the intent of the USPSTF.

Similarly, the change in recommendation for breast self-examinations has caused confusion and led some women to believe that they should not examine themselves or raise any concerns they have to their health care provider. In fact, the USPSTF recommendation on breast self-examinations did not change substantially, and it is in line with the recommendations of Komen for the Cure and other major cancer organizations. Instead, we recommend breast self-awareness — knowing your risk, getting screened, knowing what is normal for you, and making healthy lifestyle choices. While the evidence shows that a regular, routine monthly self-exam does not reduce mortality, it is never wrong for women to be familiar with their bodies, to know the look and feel of what is normal for her and to report any changes to her health care provider.

Need for Better Technology

Mammography is not perfect, but is still our best tool for early detection and successful treatment of this disease. We must close the technology gap in breast cancer screening. New screening approaches and more individualized recommendations for breast cancer screening are urgently needed. Komen for the Cure is currently funding research initiatives designed to improve screening, and we believe that it is imperative that this research move forward rapidly. But we can't do it alone. We need to work together — government, private industry, the public health community and patient advocates — to develop and deliver technology that is more predictive, available and personalized, but less expensive.

That is why, in 2010, Susan G. Komen for the Cure will host a Technology Summit where the top leaders from the public health, scientific, governmental, and advocacy communities will identify specific ways to close this gap.

We also ask the President and Congress to report to the American people on investments they've made in screening technology and to commit to us that they will redouble their efforts to create a technology that is more specific, has a higher level of sensitivity and is more accessible (that is, more affordable and more portable).

As Dr. Eric Winer, Komen for the Cure's Chief Scientific Advisor and director of the Breast Oncology Program at the Dana-Farber Cancer Institute, and Dr. Ann Partridge, Clinical Director of the Breast Oncology Program at the Dana-Farber Cancer Institute, recently commented in the *New England Journal of Medicine*, "Our understanding of the molecular basis of breast cancer continues to evolve, and we now view it as a family of distinct disease subtypes — which may well require their own screening tools. Moreover, the evolution of breast-cancer treatment is likely to have a profound effect on the way we conceptualize screening. There may be room for debate about the optimal age at which to begin screening and the optimal frequency of screening, but there is no debate that technical advances will make these controversies fade. Although we must optimize what is available today, we must also promote far better approaches for tomorrow."³

In addition to better screening technology, we need to identify the causes and ways to prevent breast cancer. Early detection, while important, is not the same as prevention. That is why Komen for the Cure invested \$20 million this year alone toward prevention research through our Promise Grants.

Ensuring Access to Screening for Underserved Women

When it comes to screening, our primary focus should be on the one-third of women — some 23 million women — who are not receiving regular recommended screenings due to lack of access,

³ Ann H. Partridge and Eric P. Winer, "On Mammography — More Agreement than Disagreement," *New England Journal of Medicine*, November 25, 2009, published online at <http://content.nejm.org/cgi/content/full/NEJMp0911288>.

education or awareness.⁴ Many women in the U.S. are getting their first mammogram later than recommended, not having mammograms at recommended intervals or not receiving appropriate and timely follow-up of positive screening results, which leads to advanced tumor sizes, later stage at diagnosis and lower survival rates.⁵

The Komen Advocacy Alliance believes there should be no impediments to screening for these women. Unfortunately, such barriers do exist.

Breast Cancer Screening and Health Insurance Status. Women who are uninsured or underinsured are more likely to skip potentially life-saving cancer screenings. In 2008, 46.3 million Americans lacked health insurance, and that number is climbing.⁶ Some estimates suggest rising unemployment over the past year has added an additional 4 million people to the ranks of the uninsured.⁷ Further, many Americans are just a pink slip, unexpected life event or major medical diagnosis away from losing their health insurance. Lack of adequate health insurance means lower screening rates, more advanced cancer at diagnosis and lower chances of survival. Patients with private insurance are more likely to be diagnosed at earlier stages, and are more likely to survive at all stages of diagnosis than the uninsured. Cancer patients who are uninsured (and those who were Medicaid-insured at time of diagnosis) are 60 percent more likely to die in 5 years than those with private insurance.⁸

- In the U.S., the lowest prevalence (33.2 percent) of mammography screening in the past two years occurred among women who do not have health insurance.⁹
- For women who are uninsured and underinsured, cost is a significant barrier to getting preventive care — only 67 percent of underinsured women over the age of 50 received a mammogram in the past two years, compared with 85 percent of adequately insured women.¹⁰
- For women with health insurance or Medicare, even a relatively small co-payment can significantly reduce mammography rates, particularly for underserved populations.¹¹

The Centers for Disease Control and Prevention's National Breast and Cervical Cancer Early Detection Program (NBCCEDP) was created to protect low-income women without health insurance; yet the program is dangerously underfunded. In fact, a recent study by the Government Accountability Office (GAO) reveals that the NBCCEDP, which serves low-income, uninsured and underinsured women, only screens about 15 percent of eligible women.

⁴ American Cancer Society, "Breast Cancer Facts and Figures 2009-2010." From the National Health Interview Survey, which is conducted by the Centers for Disease Control and Prevention's National Center for Health Statistics, with the help of the U.S. Census Bureau.

⁵ American Cancer Society, "Cancer Prevention and Early Detection Facts and Figures 2009." Available online at http://www.cancer.org/downloads/STT/CPED_2009.pdf.

⁶ U.S. Census Bureau, "Income, Poverty, and Health Insurance Coverage in the United States: 2008," September 2009. Available online: <http://www.census.gov/prod/2009pubs/p60-236.pdf>.

⁷ "One-Two Punch: Unemployed and Uninsured," Families USA, October 1009. Available online at <http://www.familiesusa.org/assets/pdfs/one-two-punch.pdf>.

⁸ Elizabeth Ward, et al., "Association of Insurance with Cancer Care Utilization and Outcomes," CA: A Cancer Journal for Clinicians, Vol. 58, No. 1, January/February 2008, p.9-31.

⁹ American Cancer Society, "Cancer Prevention and Early Detection Facts and Figures 2009."

¹⁰ Sheila Rustgi, et al., "Women at Risk: Why Many Women are Forgoing Needed Health Care," The Commonwealth Fund, Issue Brief, May 2009. (Available online: <http://www.commonwealthfund.org/content/publications/issue-briefs/2009/may/women-at-risk.aspx>.)

¹¹ Amal N. Trivedi, et al., "Effect of Cost Sharing on Screening Mammography in Medicare Health Plans," *The New England Journal of Medicine*, Vol. 358, January 24, 2008, pp. 375-383. (Available online: <http://content.nejm.org/cgi/content/full/358/4/375>.) The study examined 174 Medicare managed-care plans from 2001 through 2004, which included 550,082 individual-level observations for 366,475 women between the ages of 65 and 69 years.

About 26 percent of eligible women are screened by other providers, such as free clinics and mobile vans, some of which are funded by Komen Affiliates. (Komen Affiliates advocate for state funding and in FY09 provide more than \$30 million in grants to state and local NBCCEDP programs.) Yet, the GAO noted these resources are limited and often not available in rural or other underserved areas — shockingly, 60 percent of eligible women do not receive recommended breast cancer screening from any provider — a disturbing revelation that is much higher than previously understood and underscores the need for access to affordable insurance.

If we can improve access to high quality care among vulnerable populations, we could make more progress in the fight against breast cancer.

Breast Cancer Screening and Racial/Ethnic Disparities. Unfortunately, there are also racial and ethnic differences in access to screening services. In the U.S., white women age 40 and older were more likely to report a mammogram in the past two years (68 percent) than any other racial or ethnic group. Screening rates were 66.6 percent for American Indian/Alaska native, 64.9 percent in African American, 59.6 percent in Hispanic and 54.2 percent in Asian women.¹²

Disparities in access and utilization of breast cancer screening contributes to disparities in breast cancer survival rates: African American women have a 37 percent higher rate of mortality from breast cancer than white women, despite having an overall lower level of incidence of breast cancer.¹³ Some geographic areas are worse than others. Komen's work with the Metropolitan Chicago Breast Cancer Task Force, which was formed in response to the growing disparity in breast cancer mortality rates between African-Americans and whites in Chicago, revealed that the mortality rate for African American women in Chicago is 68 percent higher than for white women.¹⁴

USPSTF Recommendations and Health Care Reform

The Komen Advocacy Alliance believes all cancer patients deserve access to affordable, high-quality health care. Unfortunately, in today's health care system, not every patient is able to get the care they need.

We applaud this committee for considering the needs and challenges facing cancer patients and survivors as you developed proposals to reform the nation's health care system. The Komen Advocacy Alliance supports valuable patient protections in H.R. 3962, the "Affordable Health Care for America Act," that would increase access to affordable health insurance for all, prevent insurance companies from denying coverage due to pre-existing conditions such as cancer, protect patients from high out-of-pocket costs, and increase access to early detection services. We also hope that health care reform legislation will ensure that women, including women ages 40 to 49, have access to affordable screening mammography.

H.R. 3962 calls for "preventive services, including those services recommended with a grade of A or B by the Task Force on Clinical Preventive Services" to be included in a new minimum benefit package and for those services to be offered with no co-pay or cost sharing requirements. This will increase access to mammography, Pap smears and other preventive services for the millions of women who do not currently have access to screening services in the current health care system. Evidence shows that even a relatively small co-payment significantly reduces mammography rates, particularly for women with low incomes.

¹² American Cancer Society, "Cancer Prevention and Early Detection Facts and Figures 2009."

¹³ *Ibid.*

¹⁴ Hirschman J, Whitman S, Ansell D. "The Black:White disparity in breast cancer mortality: The example of Chicago." *Cancer Causes Control* 2007; Vol. 18, pages 323-333.

In light of the new recommendations by the USPSTF, we must ensure that women ages 40 to 49 will have access to the same coverage and cost-sharing benefits as women age 50 and older. We understand that the Task Force on Clinical Preventive Services is a new entity, and that current USPSTF guidelines are not necessarily binding on the new committee. We also understand that the current language does not necessarily *exclude* from the minimum benefits package services that are not rated A or B.

However, I urge you to ensure mammography services for women ages 40 to 49 are included in the essential benefit package and that cost sharing is waived for such services. While some women in the 40 to 49 age group may, after consulting with their doctor and weighing the evidence, respond to the task force recommendations by choosing to forgo a mammogram, women who choose to have a mammogram should still have *access* to such screenings on the same terms as women age 50 and older.

The Komen Advocacy Alliance appreciates that HR 3962 newly includes patient representatives as advisors to the Task Force on Clinical Preventive Services. As we have emphasized in the last several weeks, we strongly believe that patients have a unique and valuable perspective that should be better used to develop and disseminate appropriate messages about prevention and screening. We also appreciate that the Task Force must consider disparities in care when developing its recommendations.

About Susan G. Komen for the Cure and the Komen Advocacy Alliance

Susan G. Komen for the Cure began with a promise from Ambassador Nancy G. Brinker to her dying sister Suzy that she would do everything in her power to end breast cancer forever. In 1982, that promise became Susan G. Komen for the Cure and launched the global breast cancer movement.

Today, Komen for the Cure is the world's largest grassroots network of breast cancer survivors and activists fighting to save lives, empower people, ensure quality care for all and energize science to find the cures. Thanks to events like the Susan G. Komen Race for the Cure® Series, in our first 27 years, Komen has invested almost \$1.5 billion to fulfill our promise, becoming the largest source of nonprofit funds dedicated to the fight against breast cancer in the world. To continue this progress, Komen will invest another \$2 billion over the next decade into cutting-edge research and community programs.

The Komen Advocacy Alliance, a sister organization to Susan G. Komen for the Cure, is the nonpartisan voice for more than 2.5 million breast cancer survivors and the people who love them. The Alliance's mission is to translate the Komen promise to end breast cancer forever into action at all levels of government to discover and deliver the cures for cancer. With a network of more than 250,000 advocates, the Komen Advocacy Alliance promotes increased funding for cancer research and expanded access to cancer care services for all women.

Komen's goal is to reduce and one day eliminate suffering and death from cancer. To realize this goal, Komen promotes education and awareness to empower women to be advocates for their own health, and we invest in the tools to make it possible. Our investments span the entire continuum of cancer care — from cancer research about the biology of breast cancer to early detection to treatment to survivorship. We make significant grants to fund innovative community services, and advocate for improved access to high-quality cancer care and an increased commitment to the fight against breast cancer by the public and private sectors. We believe it is this three-pronged approach — research, community programs, and advocacy — that will make the biggest impact and the most progress toward our promise to end breast cancer forever.

Cancer Research. When Komen advocates for breast cancer research funding, it is as a full partner in the effort to discover and deliver the cures. Neither the federal government nor the private sector can accomplish this goal alone. Over the past three years alone, Komen for the Cure funded \$237

million in research grants to the best minds in cancer science all over the world, to take advantage of new breakthroughs and accelerate treatments for women with aggressive breast cancers that do not respond to current therapies. In fact, a Komen grant has touched every major breast cancer breakthrough in the past 25 years, including the basic discoveries in genetics and biology that have evolved into less invasive, personalized treatments for what was once a "one-treatment-fits-all" approach. In addition, Komen grants helped make possible:

- Discovery of the first breast cancer susceptibility gene (BRCA1), and a test for women to learn about their inherited risk. This has led to very early detection of breast cancer in some women and prevention in others.
- Understanding that breast cancer is not one disease – it is a collection of diseases, each with different characteristics that allow doctors to deliver tailored treatments that are more effective and involve fewer side effects.
- Insight into the role of hormonal factors in breast cancer risk, development and progression, leading to understanding of tamoxifen resistance, tools to identify women who are more likely to develop resistance, and development of new hormonal therapies such as aromatase inhibitors.
- Understanding the role of angiogenesis in providing the blood supply that allows cancer cells to continue to grow and leading to discovery of drugs like Avastin that kill cancer cells by starving them of their blood supply.
- Discovery of signaling pathways 'turned on' by the over-expression of HER2 receptors in some types of very aggressive breast cancers and the role of kinase inhibitors as potential therapeutic agents with fewer adverse effects than Herceptin.

Community Investment. Komen Affiliates operate in more than 120 communities across the country, and this year alone invested nearly \$160 million in their local communities to provide underserved populations with access to breast cancer education, screening and treatment. This includes \$93 million in community grants to more than 1,900 organizations that provide free or low-cost mammograms, as well as physical, emotional and financial support for breast cancer patients and survivors. Many Affiliates also fund treatment assistance programs that help breast cancer patients with day-to-day chores and provide monetary assistance with rent, utilities, and co-pays. This year alone, Komen has funded education/awareness programs reaching more than 3 million women; and has funded programs providing breast screenings to more than 500,000 women and men in under-served populations. This is part of our \$900 million investment in community programs since inception.

Public Policy and Advocacy. The Komen Advocacy Alliance directly engages policymakers and opinion leaders at the state and federal levels. This year, we opened a new office in Washington, DC and have expanded our presence in the nation's capital. Across the country, our Affiliates work to increase funding for state breast and cervical screening programs, expand access to Medicaid treatment for uninsured women diagnosed with breast and cervical cancer, require insurance companies to cover routine care costs for clinical trials, and require parity in the coverage of oral chemotherapy drugs, compared with intravenous therapy, among other legislative successes.

Mr. PALLONE. Thank you.
Dr. Sweet.

STATEMENT OF DONNA SWEET

Dr. SWEET. Good afternoon, and thank you, Chairman, for this opportunity. I am Donna Sweet, a general internist, and I am pleased to present the testimony of the American College of Physicians. I am a member of the ACP's clinical efficacy assessment subcommittee, which oversees the development of ACP's evidence-based guidelines, and I provide also comprehensive medical care to hundreds of patients in the State of Kansas.

Because ACP does not comment on the guidelines issued by other organizations, I am unable to express an ACP opinion of the task force recommendations but I can speak to the College's own guideline on screening mammography in women between ages 40 to 49 years which was published actually in 2007. We recommend that clinicians should perform individualized assessment of risk for breast cancer to help guide decisions about screening mammography, inform women about the potential benefits and harms of mammography, and base screening mammography decisions on benefits and harms of screening as well as a women's preferences and her own breast cancer risk profile. The purpose of ACP's clinical guidelines is to facilitate an informed and educated discussion between the patient and her trusted clinician so that together they can decide on a personalized plan of screening, diagnosis and treatment.

Not all women between 40 and 49 have the same risk for breast cancer. Factors that increase the risk include older age, family history of breast cancer, older age at the time of first birth, younger age at menarche, and history of breast biopsy. In my own practice I use ACP's guidelines to engage my female patients in a discussion. I explain that mammography, although a potentially valuable tool to screen for breast cancer, is an imperfect one. For some patients, I will detect cancer at a more treatable stage. It can also lead to false positives, which can lead to biopsies, scarring and potential infection. It can lead to false negatives, that is, mammography does miss cancers. It may result in aggressive treatment of cancers that may never have become life threatening.

Just in the past 3 days, I have had three different patients coming to see me who have been extremely confused over this whole issue. I was able to speak to each woman's risk profile and discuss with them the benefits and possible harms of getting a mammogram. One was a 66-year-old patient enrolled in Medicare who had come in for her routine visit for hypertension and clearly misunderstood most of the debate. She has a history of a sister with breast cancer. We have been doing yearly mammograms, and she was worried that I was not going to let her get a yearly mammogram because of these new recommendations. Another 71-year-old came in and she wanted to get her mammogram, which was scheduled in February, before January 1st—why she picked that date, I don't know—because she believed that the government would soon stop her from being able to get a mammogram and she didn't want that to happen. I was able to reassure her that I did not think mammograms would be rationed. The third, however, was a very good dis-

cussion, a 46-year-old woman whose mother had breast cancer. She wanted to discuss her own risk and actually was wondering if she had to have yearly mammograms. I was able to communicate to each of them that in them they did need yearly mammograms, that we did not do things from a cookie cutter. Women should not be treated all alike. And in all three cases, as I said, they did and will get their yearly mammograms but based on their individual risk factors and a discussion of why.

The controversy over the breast cancer screening guidelines gives physicians the opportunity to educate their patients on the importance of evidence-based guidelines to help them make the best choice for them. It also has important lessons for policymakers. One is that the public is ill served when assessments of clinical effectiveness are politicized. The U.S. Preventive Services Task Force is a highly regarded, credible and independent group of experts. Differences of opinion on the task force recommendations should be openly discussed but it is not constructive to undermine public confidence by making ill-founded attacks on the integrity, credibility, motivations and expertise of the clinicians and scientists on the task force. Such politicization if left unchallenged could result in future assessments being influenced by political or stakeholder interest instead of by science.

Second, the ACP is concerned that the public is misled by some into believing that cost was behind the task force recommendations. According to ARC, the task force does not consider economic costs in making recommendations.

Third, the public needs to understand that when health plans make decisions on covered benefits, they consider many different issues of which the evidence-based guidelines are just one. Under the bill passed by the House, health plans generally will be required to cover preventive measures for which a new constituted task force on clinical preventive services have given an A or a B. No limits are placed, though, on health plans' ability to provide benefits for other preventive services and to consult with other sources in making such determinations. Rather than limiting access to prevention, my patients will benefit from having a floor, not a limit on preventive services all health insurers will be required to cover usually with no out-of-pocket cost to them. And perhaps even more importantly as has been said here today many times, millions of women who have no access to health insurance will now have coverage and the ability to actually get screening mammograms.

Fourth, we need to communicate information to the public in a way that facilitates an understanding of how evidence-based effectiveness reviews support, not supplant, individual decision making by patients and their clinicians. They should be informed that they have the right to know about the current best evidence on the benefits and risks of different treatments and interventions. My patients have the right to know that physicians will offer intervention shown to positively impact health and patient outcomes and they have a right to know that we will not recommend intervention shown not to provide any benefit and possibly cause harm. Patients have the right to be treated as individuals with their own unique values and personal risk characteristics instead of being asked to

follow one-size-fits-all treatment protocols. And they have to know that the evidence comes from respected, independent and credible clinicians and other scientists protected from political and other stakeholder pressure.

I thank you for this opportunity.

[The prepared statement of Dr. Sweet follows:]



Testimony of the American College of Physicians

to the

House Energy and Commerce Committee

Subcommittee on Health

“The Breast Cancer Screening Recommendations”

December 2, 2009

I am Donna Sweet, MD, MACP. I am pleased to present the testimony of the American College of Physicians (ACP) on the role of evidence-based medicine in informing clinical decision-making and what we can learn from the release of the guidelines on mammography issued by the United States Preventive Services Task Force (the Task Force). ACP is the largest physician medical specialty society—and the second largest physician membership organization—in the United States, representing 129,000 internal medicine physician members and medical student members. I am a past chair of the ACP’s Board of Regents.

I have been involved in the practice of internal medicine as well as teaching and administration in Wichita, Kansas for over 20 years. I am professor of internal medicine at the University of Kansas School of Medicine-Wichita and director of internal medicine education at Via Christi Regional Medical Center-St. Francis in Wichita. I founded the Kansas AIDS Education Training Center, a part of the Mountain Plains Regional AIDS Education and Training Centers, and through this Center, I provide comprehensive medical care to hundreds of HIV-positive and AIDS patients throughout Kansas, many of whom reside in isolated rural communities. I also provide general primary care internal medicine to patients at the Via Christi Regional Medical Center.

My perspective on the role of evidence-based assessments comes not just from my patient care experiences, but also from my role as a member of ACP’s Clinical Efficacy Assessment Subcommittee (CEAS). The CEAS’s role is to oversee the development of ACP’s evidence-based guidelines that make recommendations that ultimately will improve the practice of medicine. The subcommittee makes recommendations regarding appropriate evidence-based clinical practices; provides guidance on the appropriate use of these guidelines; develops new methods to enhance College guideline application to clinical practice; and identifies technology assessment issues pertinent to the College and

internal medicine. ACP has been producing clinical practice guidelines since 1981 and is considered one of the pioneers in the field of guideline development methodology and evidence-based medicine.

The College appoints CEAS committee members, like me, who have expertise in primary care, health care administration, guideline development methodology and evidence-based medicine, and medical and health services research.

In my testimony, I will address three key questions:

1. Does ACP have an opinion on the breast cancer screening guidelines issued by the Task Force, or have its own clinical guidelines on mammography?
2. How are evidence-based clinical guidelines, such as those on breast cancer screening, used by clinicians in practice to engage their patients in shared decision-making to provide a personalized diagnosis and treatment plan?
3. What can be learned from the controversy over the breast cancer screening guidelines to guide future policy-making?

Guidelines on Breast Cancer Screening

The ACP is one of many organizations that are considered “partner organizations” of the Task Force, but as a matter of policy, we do not comment on the guidelines of other organizations, including those that come from the Task Force. The website of the Agency for Health Care Research and Quality (AHRQ), describes the Task Force’s relationship with partner organizations:

“Partner organizations provide ongoing liaison to the USPSTF. They include the major primary care societies and Federal agencies that are stakeholders in the process and products of the Task Force. Partner organization representatives contribute their expertise to the evaluation process and help disseminate the work of the USPSTF to their members and constituents. They are invited to attend and observe the USPSTF meetings and are permitted to comment on the proceedings during the meetings. Partners are sent drafts of the evidence report and recommendation statement and may arrange for these documents to be reviewed in detail by content experts within their organizations. This opportunity for comment by partners is in addition to the peer review that is obtained from experts who are not involved in the Task Force process, and the peer review provided by journals, as described in the next section. . . . Primary care partners currently include the American Academy of Family Physicians (AAFP), American Academy of Nurse Practitioners (AANP), American Academy of Pediatrics (AAP), American Academy of Physician Assistants (AAPA), American College of Obstetricians and Gynecologists (ACOG), American College of Physicians (ACP), American College of Preventive Medicine (ACPM), American Medical Association (AMA), American Osteopathic Association (AOA), America’s Health Insurance Plans (AHIP), National Committee for Quality Assurance (NCQA), and National Organization of Nurse Practitioner Faculties (NONPF).”

Under an arrangement between the AHRQ and the *Annals of Internal Medicine*, ACP's flagship journal, *Annals* has the opportunity to review and publish guidelines issued by the Task Force. Generally, *Annals* considers for publication only those Task Force recommendations that relate at least in part to the care of adults. The Task Force recommendation statements are accompanied by one or more background articles that assemble the evidence on which the Task Force bases their recommendations. This material is subject to *Annals*' rigorous peer review process, which includes review by *Annals*' editors and statisticians who have expertise in systematic review, meta-analysis, and modeling methodology. *Annals* bases its decision to publish the guidelines on the quality and transparency of the methodology used to formulate the recommendations and not on the specific recommendations themselves. Although *Annals* publishes the Task Force's recommendations, the Task Force recommendations do not represent official policy or opinion of the ACP or *Annals*.

I am unable to express an ACP opinion of the Task Force's breast cancer screening guidelines, but I can speak to the College's own guideline on screening mammography in women between ages 40- to 49 years, which was developed by our Clinical Efficacy Assessment Subcommittee, approved by the ACP Board of Regents, and published in the *Annals of Internal Medicine* in April, 2007, *Ann Intern Med.* 2007;146:511-515, www.acponline.org/pressroom/mam_guideline.htm. A copy of the ACP guideline is attached to this statement. I respectfully request that it be included in the official record of this hearing.

In choosing clinical issues for guideline development, the College's Clinical Efficacy Assessment Subcommittee has traditionally been interested in areas where evidence is equivocal, because these are the areas that are toughest for the physician to advise patients and choose therapies. Mammography for women between ages 40 to 49 is one issue where the evidence for annual screening is more complex than for other age groups, so we decided to tackle this issue. Evidence is very clear and not controversial for women between the ages of 50 to 75 and the ACP guideline did not address this age group. ACP's guideline recommends that for women between the ages of 40 and 49, clinicians should:

- Periodically perform individualized assessment of risk for breast cancer to help guide decisions about screening mammography.
- Inform women in this age group about the potential benefits and harms of screening mammography.
- Base screening mammography decisions on benefits and harms of screening as well as a woman's preferences and breast cancer risk profile.

Evidence-based Guidelines Can Support and Empower Patient Decision-making

Like all good evidence-based guidelines, *the purpose of ACP's clinical guideline on breast cancer screening is to facilitate an informed and educated discussion between the patient, and her trusted clinician, so that together they can decide on a personalized plan of screening, diagnosis, and treatment.*

Rather than taking decision-making away from patients, evidence-based guidelines *empower* patients to make the decision that is best for them. It does this by giving them and their clinician the best available evidence on clinical effectiveness to engage in a *shared* decision-making process.

ACP specifically encourages clinicians to use our mammography guideline to ensure that patients are part of the decision. Not all women between 40 and 49 have the same risk for breast cancer. In this age group, a 40-year old woman may have higher risk factors than a 49-year old woman depending on their individual risk profiles. Factors that increase the risk of breast cancer include older age, family history of breast cancer, older age at the time of first birth, younger age at menarche, and history of breast biopsy. In fact, women aged 40 to 49 who have any of the following risk factors have a risk of breast cancer higher than the average 50-year old woman: two first degree relatives with breast cancer; a history of two breast biopsies; one first degree relative with breast cancer and one prior breast biopsy; prior diagnosis of breast cancer or ductal carcinoma in situ or atypical hyperplasia; a history of prior chest irradiation or BRCA 1 or 2 mutation.

The ACP guideline encourages patients to talk to their doctor about the benefits and harms of screening mammography for women between age 40 and 49, based on their personal situation. Physicians should inform women ages 40 to 49 of the potential benefits and risks of screening mammography. Some will benefit from annual mammography screening between the ages of 40-49, and if a patient decides that she wants to be screened for mammography, her physician should support it. But if, based on risk factors, the patient decides that it is not necessary to have a mammography at age 40, the patient and physician should understand that is a valid decision also. And finally, there should be mutual understanding that either decision will be reevaluated at least every two years.

How do I incorporate the ACP recommendations into my own practice? I believe that my role is not to dictate to my patients what they should do. Instead, it is to use my professional training and skills to help my patients weigh the evidence so that they can make their own decisions on what is best for them, taking into account their individual risk factors, values, and preferences. This demands that I *personalize* the presentation of information on the efficacy of different cancer interventions, be straightforward with my patients on the limitations and ambiguity of such evidence, and discuss with them their own preferences.

In the case of mammography in women between the ages of 40 and 49, I use ACP's guideline to engage my female patients in a discussion of their personal risk profile. I also explain that mammography, although a potentially valuable tool to screen for breast cancer, is an imperfect one. For some patients, it will detect cancer at a more treatable stage. It can also lead to false positives, which can lead to biopsies and scarring. It can lead to false negatives (i.e. mammography misses cancers), It may result in aggressive treatment of cancers that may never have become life threatening. I believe that my female patients in their 40s benefit by knowing all of this, before they make their own decision on whether getting a mammogram is right for them.

I also explain to my patients that the point of using evidence-based medicine is so that physicians will offer or use interventions--be it screenings, diagnostic tests, or therapies--that have been shown to positively impact health and patient outcomes and for physicians not to offer interventions that have been shown not to provide any benefit and possibly cause harm. I explain to them that the point of screening is not just to detect cancer but rather to detect cancer that makes a difference to treat and the treatment leads to decreased risk of death (mortality) from the disease. I explain to them that by discussing all the benefits and harms of any intervention, they are better able to make more informed decisions and be prepared to anticipate outcomes that that may result from their choices.

Just in the past few days I have had patients coming in to see me because of concerns and confusion about screening mammograms. The first patient was a 66-year old enrolled in Medicare who had come in for her routine visit to follow up on her chronic hypertension. She has a history of a sister with breast cancer and voiced her concern that I might be considering canceling her yearly mammogram and "make her go" to every 2 years.

The second patient was 71-years old and was in with her husband for his chronic care visit. She wanted to know at this visit if she should get her exam before January 1 so the "government couldn't stop her from getting them."

The third was a 46-year old woman whose mother had breast cancer. She wanted to discuss her own risk and need for continuing yearly screenings. She was very rational with appropriate questions and concerns as to what would be best for her health

In these specific cases, I recommended that the patient continue to get regular mammogram screenings, because this was best for them based on their own individual case. I was able to speak to each woman's risk profile, discuss the benefits and possible harms of getting a mammogram, and we were able to reach an individualized decision for each woman. I was able to reassure the woman who was afraid that I would "not let" her get yearly mammograms if she so requested. I was able to dissipate the misconception of another who thought that mammograms would be "rationed." Most importantly I was able to communicate to each woman that they are not cut from a cookie cutter and that women should not be treated as a monolith. Rather, they are individuals with different risk profiles and preferences and together we came to clinical decisions that we agreed on and that we can re-visit at any time.

Another example of how evidence-based clinical assessments and guidelines can support and empower shared decision-making comes from my experience as the personal physician for hundreds of patients in Kansas who are HIV-positive or who have AIDs. Unlike other clinical questions, where the evidence of efficacy is less certain and more ambiguous, just about everything I know about care of patients who are HIV-positive, or who have AIDs, is informed by assessments of clinical effectiveness based on large scale clinical trials. So every time a new drug therapy is developed and approved for treatment of such patients, I am able to update my treatment protocols in consultation with the patient-- with both of us having the highest degree of confidence in the evidence on the efficacy of the new therapy.

It may be years before clinicians have the same degree of confidence in evidence-based assessments for screening for some cancers as we do for treatment of patients who are HIV-positive or have AIDS. The simple fact is that medical science has not yet yielded unambiguous evidence, based on large scale clinical trials, on how best to screen and treat many cancers. This speaks to the need to continue to support and increase funding for cancer research, including large clinical trials. It also speaks to the need for the public to continue to support the work for the U.S. Preventive Services Task Force, professional organizations like ACP, and the other experts to whom clinicians look for unbiased assessments on the effectiveness of interventions to diagnose and treat different cancers.

Implications of the Breast Cancer Screening Controversy for Policymaking

ACP believes that the controversy over the breast cancer screening guidelines creates important lessons for policymakers—including those of you who sit on this important congressional committee.

One lesson is that the public is ill-served when assessments of clinical effectiveness are politicized. For clinicians and patients alike to have confidence in the evidence, we need to know that it has been developed through a process that is independent of political pressure.

The U.S. Preventive Services Task Force is a highly-regarded, credible and independent group of experts that conducts its evidence-based assessments, on a purely advisory basis, to the Department of Health and Human Services, as it relates to interventions to prevent or detect diseases. As is often the case with evidence-based reviews, the Task Force's recommendations will not always be consistent with the guidelines established by other experts in the field, by professional medical societies, and by patient advocacy groups. Such differences of opinion, expressed in a constructive and transparent manner so that patients and their clinicians can make their own best judgment, are important and welcome. It is not constructive to make ill-founded attacks on the integrity, credibility, motivations, and expertise of the clinicians and scientists on the Task Force in an effort to discredit their recommendations and undermine public support for evidence-based medicine.

ACP is concerned that such politicization, if left unchallenged, could lead to efforts to eliminate the Task Force, cut its funding, or result in politically-driven changes so that future evaluations are influenced by political or stakeholder interests—instead of science. We would be concerned that this would also lead to political interference over other federally-funded entities involved in evidence-based research.

To support and empower patients in shared decision-making, they need to know that the independent clinicians and scientists charged with producing research on clinical effectiveness will be permitted by Congress to make their recommendations based solely on their assessment of the evidence, not the politics of the day or as the result of stakeholder pressure.

Second, ACP is concerned that some of the critics of the Task Force's recommendations may have erroneously created an impression among the public that the recommendations were driven by a desire to control cost and will lead to rationing. According to the Agency for Health Care Research and Quality, "the [Task Force] does not consider economic costs in making recommendations." The College believes that the policy question of whether or not cost-effectiveness should be considered, along with clinical efficacy, is an important one that merits a full debate, independent of the controversy over the breast cancer screening guidelines. Such an informed debate is not served, though, when some critics make unsubstantiated and erroneous statements that the cost was a factor in the Task Force's breast cancer screening guidelines or that the guidelines will lead to rationing of care.

Third, the public needs a better understanding of the role of evidence-based medicine when health plans make a decision on covered benefits. When health plans make decisions on covered benefits, they consider many different issues, of which the evidence-based guidelines from different entities are just one of many. Health plans have every right and flexibility to cover screening procedures of their choice, and nothing in the health reform bill recently passed by the House of Representatives, or the bill being debated by the U.S. Senate, will take this away from health plans, their subscribers, or the public.

Under the Affordable Health Care for America Act, H.R. 3962, passed by the House of Representatives, a new Task Force on Clinical Preventive Services would be created, which would take on many of the responsibilities of the current U.S. Preventive Services Task Force. This new entity will have an important role in making evidence-based recommendations on preventive services that insurers will be required to cover, but the only binding effect the recommendations of the Task Force will have on health plans is a requirement that preventive measures for which the Task Force has given an A or B rating must be covered. *The bill does not give the Task Force — or the federal government itself — any authority to put limits on coverage, ration care, or require that insurers deny coverage.* Health plans could offer additional preventive and other benefits of their choosing, and no restrictions would be placed on their ability to consider recommendations from sources other than the Task Force in making such coverage determinations.

Accordingly, my patients will benefit by having a floor – not a limit – on essential preventive services that would be covered by all health insurers, usually with no out-of-pocket cost to them. Patients will also benefit from having independent research on the comparative effectiveness of different treatments, as proposed in the bills before Congress.

Fourth, the controversy over the mammography guidelines illustrates the importance of communicating information on evidence-based reviews to the public in a way that facilitates an understanding of how such reviews are conducted and how they are

intended to support, not supplant, individual decision-making by patients and their clinicians.

ACP urges Congress, the administration, and patient and physician advocacy groups to respect and support the importance of protecting evidence-based research by respected scientists and clinicians from being used to score political points that do not serve the public's interest.

Conclusion

In conclusion, I believe that the controversy over the breast cancer screening guidelines offers us an opportunity to engage individual patients—and the public more generally—in an informed discussion of the importance of evidence-based clinical efficacy assessments in contributing to better care decisions.

My patients have the right to know about the current best evidence on the benefits and risks of different treatments and interventions.

They have the right to know that I will offer interventions--be it screenings, diagnostic tests, or therapies--that have been shown to positively impact health and patient outcomes.

They have a right to know that I will not recommend interventions that have been shown not to provide any benefit and possibly cause harm.

They have the right to be treated as individuals, with their own individual perspectives, values, health histories, and personal risk characteristics, instead of being asked to follow one-size-fits-all treatment protocols.

They have the right to be considered as individuals who are capable of making an informed decision on what is best for them, in consultation with a trusted clinician, even when the experts may not be in full agreement on recommended guidelines for care.

They have the right to know that the evidence that I discuss with them comes from respected, independent and credible clinicians and other scientists who are protected from political and stakeholder pressure.

I'd be pleased to answer your questions.

Screening Mammography for Women 40 to 49 Years of Age: A Clinical Practice Guideline from the American College of Physicians

Amir Qaseem, MD, PhD, MHA; Vincenza Snow, MD; Katherine Sherif, MD; Mark Aronson, MD; Kevin B. Weiss, MD, MPH; and Douglas K. Owens, MD, MS, for the Clinical Efficacy Assessment Subcommittee of the American College of Physicians*

Breast cancer is one of the most common causes of death for women in their 40s in the United States. Individualized risk assessment plays an important role when making decisions about screening mammography, especially for women 49 years of age or younger. The purpose of this guideline is to present the available

evidence for screening mammography in women 40 to 49 years of age and to increase clinicians' understanding of the benefits and risks of screening mammography.

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For author affiliations, see end of text.

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RECOMMENDATIONS

Recommendation 1: In women 40 to 49 years of age, clinicians should periodically perform individualized assessment of risk for breast cancer to help guide decisions about screening mammography.

A careful assessment of a woman's risk for breast cancer is important. The 5-year breast cancer risk can vary from 0.4% for a woman age 40 years with no risk factors to 6.0% for a woman age 49 years with several risk factors (1). Factors that increase the risk for breast cancer include older age, family history of breast cancer, older age at the time of first birth, younger age at menarche, and history of breast biopsy. Women 40 to 49 years of age who have any of the following risk factors have a higher risk for breast cancer than the average 50-year-old woman: 2 first-degree relatives with breast cancer; 2 previous breast biopsies; 1 first-degree relative with breast cancer and 1 previous breast biopsy; previous diagnosis of breast cancer, ductal carcinoma in situ (DCIS), or atypical hyperplasia; previous chest irradiation (1); or *BRCA1* or *BRCA2* mutation (2, 3). A family history can also help identify women who may have *BRCA* mutations that place them at substantially higher risk for breast and other types of cancer (Table). These women should be referred for counseling and recommendations specific to this population, as recommended by the U.S. Preventive Services Task Force (USPSTF) (4). Risk assessments should be updated periodically, particularly in women whose family history changes (for example, a relative receives a diagnosis of breast or ovarian cancer) and in women who choose not to have regular screening mammography. Although no evidence supports specific intervals, we encourage clinicians to update the woman's risk assessment every 1 to 2 years.

The risk for invasive breast cancer can be estimated quantitatively by using the Web site calculator provided by the National Institutes of Health (NIH) (<http://bcra.ni>

.nih.gov/brc/q1.htm) (1). This calculator is based on the Gail model, which takes into account many of the risk factors previously mentioned. However, clinicians who use the Gail model should be aware of its limitations. Although the model accurately predicts the risk for cancer for groups of women, its ability to discriminate between higher and lower risk for an individual woman is limited (5, 6). This limitation occurs because many women have similar, relatively low absolute risks for invasive breast cancer over 5 years, which makes discrimination among levels of risk difficult for an individual woman.

Recommendation 2: Clinicians should inform women 40 to 49 years of age about the potential benefits and harms of screening mammography.

Screening mammography for women 40 to 49 years of age is associated with both benefits and potential harms. The most important benefit of screening mammography every 1 to 2 years in women 40 to 49 years of age is a potential decrease in breast cancer mortality. A recent meta-analysis estimated the relative reduction in the breast cancer mortality rate to be 15% after 14 years of follow-up (relative risk, 0.85 [95% credible interval [CrI], 0.73 to 0.99]) (7). An additional large randomized clinical trial of screening mammography in women 40 to 49 years of age found a similar decrease in the risk for death due to breast

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*This paper, written by Amir Qaseem, MD, PhD, MHA; Vincenza Snow, MD; Katherine Sherif, MD; Mark Aronson, MD; Kevin B. Weiss, MD, MPH; and Douglas K. Owens, MD, MS, was developed for the Clinical Efficacy Assessment Subcommittee of the American College of Physicians (ACP). Douglas K. Owens, MD, MS (Chair); Mark Aronson, MD; Patricia Barry, MD, MPH; Donald E. Casey Jr., MD, MPH, MBA; J. Thomas Cross Jr., MD, MPH; Nick Fitterman, MD; E. Rudney Horrocks, MD; Katherine D. Sherif, MD; and Kevin B. Weiss, MD, MPH (Immediate Past Chair). Approved by the ACP Board of Regents on 15 July 2006.

Table. Family History Patterns Associated with an Increased Risk for *BRCA1* or *BRCA2* Gene Mutations*

Both maternal and paternal family histories are important
Women not of Ashkenazi Jewish heritage
Two first-degree relatives with breast cancer, 1 of whom received the diagnosis at age ≤ 50 years
A combination of ≥ 3 first- or second-degree relatives with breast cancer regardless of age at diagnosis
A combination of both breast and ovarian cancer among first- and second-degree relatives
A first-degree relative with bilateral breast cancer
A combination of ≥ 2 first- or second-degree relatives with ovarian cancer regardless of age at diagnosis
A first- or second-degree relative with both breast and ovarian cancer at any age
A history of breast cancer in a male relative
Women of Ashkenazi Jewish heritage
Any first-degree relative (or 2 second-degree relatives on the same side of the family) with breast or ovarian cancer

* Adapted from data from the U.S. Preventive Services Task Force (4).

cancer, although the decrease did not reach statistical significance (relative risk, 0.83 [95% CI, 0.66 to 1.04]) (8). Potential risks of mammography include false-positive results, diagnosis and treatment for cancer that would not have become clinically evident during the patient's lifetime, radiation exposure, false reassurance, and procedure-associated pain. False-positive mammography can lead to increased anxiety and to feelings of increased susceptibility to breast cancer, but most studies found that anxiety resolved quickly after the evaluation.

Recommendation 3: For women 40 to 49 years of age, clinicians should base screening mammography decisions on benefits and harms of screening, as well as on a woman's preferences and breast cancer risk profile.

Because the evidence shows variation in risk for breast cancer and benefits and harms of screening mammography based on an individual woman's risk profile, a personalized screening strategy based on a discussion of the benefits and potential harms of screening and an understanding of a woman's preferences will help identify those who will most benefit from screening mammography. For many women, the potential reduction in breast cancer mortality rate associated with screening mammography will outweigh other considerations. For women who do not wish to discuss the screening decision, screening mammography every 1 to 2 years in women 40 to 49 years of age is reasonable.

Important factors in the decision to undergo screening mammography are women's preferences for screening and the associated outcomes. Concerns about risks for breast cancer or its effect on quality of life will vary greatly among women. Some women may also be particularly concerned about the potential harms of screening mammography, such as false-positive mammograms and the resulting diagnostic work-up. When feasible, clinicians should explore women's concerns about breast cancer and screening mammography to help guide decision making about mammography.

The relative balance of benefits and harms depends on women's concerns and preferences and on their risk for breast cancer. Clinicians should help women to judge the balance of benefits and harms from screening mammography. Women who are at greater-than-average absolute risk for breast cancer and who are concerned that breast cancer would have a severely adverse effect on quality of life may derive a greater-than-average benefit from screening mammography. Women who are at substantially lower-than-average risk for breast cancer or who are concerned about potential risks of mammography may derive a less-than-average benefit from screening mammography.

If a woman decides to forgo mammography, clinicians should readdress the decision to have screening every 1 to 2 years.

Recommendation 4: We recommend further research on the net benefits and harms of breast cancer screening modalities for women 40 to 49 years of age.

Methodological issues associated with existing breast cancer screening trials, such as compliance with screening, lack of statistical power, and inadequate information about inclusion or exclusion criteria and study population, heighten the need for high-quality trials to confirm the effectiveness of screening mammography in women in this age group. Furthermore, harms of screening in this age group, such as pain, radiation exposure, and adverse outcomes related to false-positive results, should also be studied.

INTRODUCTION

Breast cancer is the second leading cause of cancer-related death among women in the United States. In 2005, an estimated 211 240 new cases of invasive breast cancer will be diagnosed, and 40 410 women will die of the disease (9). Screening mammography reduces breast cancer mortality in women 50 to 70 years of age. Although 25% of all diagnosed cases are among women younger than 50 years of age (9), screening mammography in this age group has remained a topic of debate because of the difficulty in determining the benefit of mammography in this age group. A meta-analysis performed for the USPSTF estimated that screening mammography every 1 to 2 years in women 40 to 49 years of age resulted in a 15% decrease in breast cancer mortality rate after 14 years of follow-up (7). However, the 95% credible interval for this estimate is wide and indicates that the reduction could be as much as 27% or as little as 1%. This relative risk reduction corresponds to about 5.6 deaths prevented per 10 000 women screened (95% CrI, 0.9 to 13.1 deaths prevented per 10 000 women screened). Because screening mammography is also associated with potential harms, a discussion of risks (biopsies, surgery, radiation exposure, false-positive results, and false reassurance), benefits (early detection of breast cancer), and patient preferences should be the basis for screening decisions.

The purpose of this guideline is to present the avail-

able evidence and to increase clinicians' understanding of the benefits and risks of screening mammography in women 40 to 49 years of age. The target audience is clinicians who are caring for women in this age group. The target patient population is all women 40 to 49 years of age. These recommendations are based on the systematic review of the evidence in the background paper in this issue (6). The systematic evidence review does not include breast cancer risk in men and genetic risk markers, such as *BRCA*.

The goal for this guideline was to answer the following questions:

1. What are the benefits of screening mammography in women 40 to 49 years of age?
2. What are the risks associated with screening mammography in women 40 to 49 years of age?
3. Does the balance of risks and benefits vary according to the individual woman's characteristics?
4. What are the methodological issues that affect the interpretation of the results of previous meta-analyses?

BENEFITS

Of the 8 currently published meta-analyses, 7 estimated that screening women 40 to 49 years of age reduced breast cancer mortality rates, but only 3 of these found a statistically significant reduction (7). The most recent meta-analysis found that screening mammography every 1 to 2 years in women 40 to 49 years of age results in a 15% decrease in breast cancer mortality rate after 14 years of follow-up (relative risk, 0.85 [95% CI, 0.73 to 0.99]) (7). However, concerns about study quality and whether some of the observed benefit may be due to screening that occurred after the women turned 50 years of age complicate interpretation of the evidence. The use of death due to breast cancer as an end point can be criticized because cause of death could have been misclassified, and therefore some authors have suggested using overall mortality as the primary end point. However, estimation of the effect of screening mammography on total mortality would require very large study samples to detect any differences between screened and unscreened groups. Finally, the benefit of screening mammography in younger women remains controversial because of concerns about the quality of the trials that showed this result. Some of the trials had inadequate and inconsistent reporting of randomization, differences in baseline characteristics between study groups, and women in the control group who were screened outside the study protocol. Depending on how stringently the quality criteria were applied, meta-analyses could vary from the 2001 Cochrane meta-analysis that included only 2 of the 8 trials that targeted women between 40 and 49 years of age (10) to the recent USPSTF report that included all trials but the Edinburgh trial (7). A recent study (11) based on 7 model-based analyses concluded that screening mammography resulted in a 7.5% to 22.7% reduction in the breast cancer

mortality rate but did not specifically evaluate the effect of screening mammography in women 40 to 49 years of age. On balance, however, we concurred with authors of the meta-analysis for the USPSTF guideline, who concluded that the limitations of the trials were not sufficient to exclude them (7). We believe the weight of the evidence supports a modest reduction in breast cancer mortality rate with mammography screening of approximately 15% in women 40 to 49 years of age, but the wide CIs for this estimate reflect that the reduction could be larger or nearly zero.

Some uncertainty exists in measuring the absolute impact of screening on morbidity associated with breast cancer and its treatment. Early diagnosis through screening is more likely to be associated with breast-conserving surgery. An observational study found that screening is associated with an absolute increase in lumpectomy (0.7 per 1000 women) and a decrease in absolute risk for mastectomy (0.5 per 1000 women) (12).

In summary, evidence demonstrates that screening mammography in women age 40 to 49 years, compared with women who do not get screened, decreases breast cancer mortality. However, the reduction in the mortality rate is smaller than the 22% (95% CrI, 0.70 to 0.87) reduction seen in women who are screened when they are older than 49 years of age (6, 7). In addition, the estimate of the mortality rate reduction may be affected by biases in the trials or the effects of screening after the age of 49 years.

RISKS

Risks of mammography include false-positive results, diagnosis of cancer that would not have become clinically evident during the patient's lifetime, radiation exposure, false reassurance, and procedure-associated pain. Women 40 to 49 years of age may have a higher risk for a false-positive result, and false-positive rates vary widely among several studies. Mushlin and colleagues' meta-analysis (13) of the sensitivity and specificity of screening mammography showed false-positive rates of 0.9% and 6.5%, respectively. However, other analyses have demonstrated cumulative rates of false-positive mammograms of 38% after 10 mammograms (14) and 21% after 10 mammograms (15). Some studies show no difference in the false-positive rates between women 40 to 49 years of age and those older than 49 years of age (16–19). Outcomes associated with false-positive screening mammograms included small increases in general anxiety and depression, anxiety specific to breast cancer, and perceived increased susceptibility to breast cancer; however, anxiety generally resolved quickly after evaluation (6).

Use of mammography has been associated with increased diagnosis of DCIS. The natural history of DCIS is unknown, as is the percentage of these tumors that will progress to more serious disease. In 1999, 33% of women

in whom DCIS was diagnosed had mastectomy, 64% had lumpectomy, and 52% had radiation (20). Not all DCIS cases may have required aggressive treatment, but reliable predictors of biological aggressiveness are difficult to categorize.

No direct evidence links cancer risk with radiation exposure from mammography. Reported pain varied from 28% of women in 1 study to 77% of women in another study. However, pain associated with the mammographic procedure was described by few women as a disincentive from having any future screening (21–24).

ESTIMATING INDIVIDUALIZED BENEFITS AND HARMS

Current evidence shows variation among women in terms of benefits and harms associated with screening mammography between 40 and 49 years of age (6). The decision to have screening mammography should be guided by the balance of benefits and harms for an individual woman. This balance will be affected by a woman's view about how breast cancer and the outcomes associated with screening mammography will influence her quality of life and by her risk for breast cancer. Although the balance will favor screening for many women, it is less certain in women who are very concerned about the potential harms of mammography and who are at substantially lower-than-average risk for breast cancer.

The main benefit of screening mammography every 1 to 2 years in women 40 to 49 years of age is a decrease in breast cancer mortality. Harms of screening mammography include false-positive results, radiation exposure, false reassurance, pain related to the procedure, and possible treatment for lesions that would not have become clinically significant. The probability of false-positive mammograms was also higher in women with dense breasts, if the interval since the last mammography was long, and in women who had previous breast biopsy (25, 26). In addition, women place substantially different value on a false-positive mammogram, a negative mammogram, and the reduction in the rate of mortality associated with breast cancer (27).

A woman's risk for breast cancer is influenced by age, family history of breast cancer, reproductive history, age at menarche, and history of breast biopsy. For example, the risk for breast cancer is higher for women 40 to 49 years of age if they have a history of breast cancer in a first-degree relative: 4.7 cases per 1000 examinations among women with family history versus 2.7 cases per 1000 examinations among those without family history. Older age, younger age at menarche, older age at the time of first birth, and history of breast biopsy also increase the risk for breast cancer.

The absolute risk for breast cancer for a woman at a given age and with certain risk factors can be estimated by using the Web site calculator provided by the NIH that is based on the Gail model (1). However, the accuracy of the Gail model is better when predicting the average level of

risk in a group of women who are at similar risk than when discriminating between women who will and will not develop breast cancer. In addition, a clinician may be unable to assess the risk for breast cancer because of a lack of family history or in women who were adopted.

SUMMARY

Screening mammography probably reduces breast cancer mortality in women 40 to 49 years of age modestly. However, the reduction in this age group is smaller than that in women 50 years of age or older, is subject to greater uncertainty about the exact reduction in risk, and comes with the risk for potential harms (such as false-positive and false-negative results, exposure to radiation, discomfort, and anxiety).

Because of the variation in benefits and harms associated with screening mammography, we recommend tailoring the decision to screen women on the basis of women's concerns about mammography and breast cancer, as well as their risk for breast cancer. Assessment of an individual woman's risk for breast cancer is important because the balance of harms and benefits will shift to net benefit as a woman's baseline risk for breast cancer increases, all other factors being equal. For many women, the potential reduction in risk for death due to breast cancer associated with screening mammography will outweigh other considerations.

RECOMMENDATIONS OF OTHER ORGANIZATIONS

The 2006 American Cancer Society guideline (28) recommends yearly mammograms starting at age 40 and continuing for as long as a woman is in good health.

The 2003 American College of Obstetricians and Gynecologists guideline (29) recommends that women aged 40 to 49 years have screening mammography every 1 to 2 years.

The 2002 USPSTF guideline (30) recommends screening mammography, with or without clinical breast examination (CBE), every 1 to 2 years for women aged 40 and older.

The 2001 Canadian Task Force on Preventive Health Care (31) says that current evidence regarding the effectiveness of screening mammography does not suggest the inclusion of the maneuver in, or its exclusion from, the periodic health examination of women 40 to 49 years of age who are at average risk for breast cancer. Upon reaching 40 years of age, Canadian women should be informed of the potential benefits and risks of screening mammography and assisted in deciding at what age they wish to initiate the maneuver.

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Northwestern University, Chicago, Illinois; and Veterans Affairs Palo Alto Health Care System and Stanford University, Stanford, California.

Note: Clinical practice guidelines are guides only and may not apply to all patients and all clinical situations. Thus, they are not intended to override clinicians' judgment. All ACP clinical practice guidelines are considered automatically withdrawn or invalid 5 years after publication or once an update has been issued.

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Screening Mammography for Women 40 to 49 Years of Age: A Clinical Practice Guideline from the American College of Physicians

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Breast cancer is one of the most common causes of death for women in their 40s in the United States. Individualized risk assessment plays an important role when making decisions about screening mammography, especially for women 49 years of age or younger. The purpose of this guideline is to present the available

evidence for screening mammography in women 40 to 49 years of age and to increase clinicians' understanding of the benefits and risks of screening mammography.

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RECOMMENDATIONS

Recommendation 1: In women 40 to 49 years of age, clinicians should periodically perform individualized assessment of risk for breast cancer to help guide decisions about screening mammography.

A careful assessment of a woman's risk for breast cancer is important. The 5-year breast cancer risk can vary from 0.4% for a woman age 40 years with no risk factors to 6.0% for a woman age 49 years with several risk factors (1). Factors that increase the risk for breast cancer include older age, family history of breast cancer, older age at the time of first birth, younger age at menarche, and history of breast biopsy. Women 40 to 49 years of age who have any of the following risk factors have a higher risk for breast cancer than the average 50-year-old woman: 2 first-degree relatives with breast cancer; 2 previous breast biopsies; 1 first-degree relative with breast cancer and 1 previous breast biopsy; previous diagnosis of breast cancer, ductal carcinoma in situ (DCIS), or atypical hyperplasia; previous chest irradiation (1); or *BRCA1* or *BRCA2* mutation (2, 3). A family history can also help identify women who may have *BRCA* mutations that place them at substantially higher risk for breast and other types of cancer (Table). These women should be referred for counseling and recommendations specific to this population, as recommended by the U.S. Preventive Services Task Force (USPSTF) (4). Risk assessments should be updated periodically, particularly in women whose family history changes (for example, a relative receives a diagnosis of breast or ovarian cancer) and in women who choose not to have regular screening mammography. Although no evidence supports specific intervals, we encourage clinicians to update the woman's risk assessment every 1 to 2 years.

The risk for invasive breast cancer can be estimated quantitatively by using the Web site calculator provided by the National Institutes of Health (NIH) (<http://bcra.ni>

<http://bcra.ni.nih.gov/brc/q1.htm>) (1). This calculator is based on the Gail model, which takes into account many of the risk factors previously mentioned. However, clinicians who use the Gail model should be aware of its limitations. Although the model accurately predicts the risk for cancer for groups of women, its ability to discriminate between higher and lower risk for an individual woman is limited (5, 6). This limitation occurs because many women have similar, relatively low absolute risks for invasive breast cancer over 5 years, which makes discrimination among levels of risk difficult for an individual woman.

Recommendation 2: Clinicians should inform women 40 to 49 years of age about the potential benefits and harms of screening mammography.

Screening mammography for women 40 to 49 years of age is associated with both benefits and potential harms. The most important benefit of screening mammography every 1 to 2 years in women 40 to 49 years of age is a potential decrease in breast cancer mortality. A recent meta-analysis estimated the relative reduction in the breast cancer mortality rate to be 15% after 14 years of follow-up (relative risk, 0.85 [95% credible interval [CrI], 0.73 to 0.99]) (7). An additional large randomized clinical trial of screening mammography in women 40 to 49 years of age found a similar decrease in the risk for death due to breast

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Table. Family History Patterns Associated with an Increased Risk for *BRCA1* or *BRCA2* Gene Mutations*

Both maternal and paternal family histories are important
Women not of Ashkenazi Jewish heritage
Two first-degree relatives with breast cancer, 1 of whom received the diagnosis at age ≤ 50 years
A combination of ≥ 3 first- or second-degree relatives with breast cancer regardless of age at diagnosis
A combination of both breast and ovarian cancer among first- and second-degree relatives
A first-degree relative with bilateral breast cancer
A combination of ≥ 2 first- or second-degree relatives with ovarian cancer regardless of age at diagnosis
A first- or second-degree relative with both breast and ovarian cancer at any age
A history of breast cancer in a male relative
Women of Ashkenazi Jewish heritage
Any first-degree relative (or 2 second-degree relatives on the same side of the family) with breast or ovarian cancer

* Adapted from data from the U.S. Preventive Services Task Force (4).

cancer, although the decrease did not reach statistical significance (relative risk, 0.83 [95% CI, 0.66 to 1.04]) (8). Potential risks of mammography include false-positive results, diagnosis and treatment for cancer that would not have become clinically evident during the patient's lifetime, radiation exposure, false reassurance, and procedure-associated pain. False-positive mammography can lead to increased anxiety and to feelings of increased susceptibility to breast cancer, but most studies found that anxiety resolved quickly after the evaluation.

Recommendation 3: For women 40 to 49 years of age, clinicians should base screening mammography decisions on benefits and harms of screening, as well as on a woman's preferences and breast cancer risk profile.

Because the evidence shows variation in risk for breast cancer and benefits and harms of screening mammography based on an individual woman's risk profile, a personalized screening strategy based on a discussion of the benefits and potential harms of screening and an understanding of a woman's preferences will help identify those who will most benefit from screening mammography. For many women, the potential reduction in breast cancer mortality rate associated with screening mammography will outweigh other considerations. For women who do not wish to discuss the screening decision, screening mammography every 1 to 2 years in women 40 to 49 years of age is reasonable.

Important factors in the decision to undergo screening mammography are women's preferences for screening and the associated outcomes. Concerns about risks for breast cancer or its effect on quality of life will vary greatly among women. Some women may also be particularly concerned about the potential harms of screening mammography, such as false-positive mammograms and the resulting diagnostic work-up. When feasible, clinicians should explore women's concerns about breast cancer and screening mammography to help guide decision making about mammography.

The relative balance of benefits and harms depends on women's concerns and preferences and on their risk for breast cancer. Clinicians should help women to judge the balance of benefits and harms from screening mammography. Women who are at greater-than-average absolute risk for breast cancer and who are concerned that breast cancer would have a severely adverse effect on quality of life may derive a greater-than-average benefit from screening mammography. Women who are at substantially lower-than-average risk for breast cancer or who are concerned about potential risks of mammography may derive a less-than-average benefit from screening mammography.

If a woman decides to forgo mammography, clinicians should readdress the decision to have screening every 1 to 2 years.

Recommendation 4: We recommend further research on the net benefits and harms of breast cancer screening modalities for women 40 to 49 years of age.

Methodological issues associated with existing breast cancer screening trials, such as compliance with screening, lack of statistical power, and inadequate information about inclusion or exclusion criteria and study population, heighten the need for high-quality trials to confirm the effectiveness of screening mammography in women in this age group. Furthermore, harms of screening in this age group, such as pain, radiation exposure, and adverse outcomes related to false-positive results, should also be studied.

INTRODUCTION

Breast cancer is the second leading cause of cancer-related death among women in the United States. In 2005, an estimated 211 240 new cases of invasive breast cancer will be diagnosed, and 40 410 women will die of the disease (9). Screening mammography reduces breast cancer mortality in women 50 to 70 years of age. Although 25% of all diagnosed cases are among women younger than 50 years of age (9), screening mammography in this age group has remained a topic of debate because of the difficulty in determining the benefit of mammography in this age group. A meta-analysis performed for the USPSTF estimated that screening mammography every 1 to 2 years in women 40 to 49 years of age resulted in a 15% decrease in breast cancer mortality rate after 14 years of follow-up (7). However, the 95% credible interval for this estimate is wide and indicates that the reduction could be as much as 27% or as little as 1%. This relative risk reduction corresponds to about 5.6 deaths prevented per 10 000 women screened (95% CrI, 0.9 to 13.1 deaths prevented per 10 000 women screened). Because screening mammography is also associated with potential harms, a discussion of risks (biopsies, surgery, radiation exposure, false-positive results, and false reassurance), benefits (early detection of breast cancer), and patient preferences should be the basis for screening decisions.

The purpose of this guideline is to present the avail-

able evidence and to increase clinicians' understanding of the benefits and risks of screening mammography in women 40 to 49 years of age. The target audience is clinicians who are caring for women in this age group. The target patient population is all women 40 to 49 years of age. These recommendations are based on the systematic review of the evidence in the background paper in this issue (6). The systematic evidence review does not include breast cancer risk in men and genetic risk markers, such as *BRCA*.

The goal for this guideline was to answer the following questions:

1. What are the benefits of screening mammography in women 40 to 49 years of age?
2. What are the risks associated with screening mammography in women 40 to 49 years of age?
3. Does the balance of risks and benefits vary according to the individual woman's characteristics?
4. What are the methodological issues that affect the interpretation of the results of previous meta-analyses?

BENEFITS

Of the 8 currently published meta-analyses, 7 estimated that screening women 40 to 49 years of age reduced breast cancer mortality rates, but only 3 of these found a statistically significant reduction (7). The most recent meta-analysis found that screening mammography every 1 to 2 years in women 40 to 49 years of age results in a 15% decrease in breast cancer mortality rate after 14 years of follow-up (relative risk, 0.85 [95% CI, 0.73 to 0.99]) (7). However, concerns about study quality and whether some of the observed benefit may be due to screening that occurred after the women turned 50 years of age complicate interpretation of the evidence. The use of death due to breast cancer as an end point can be criticized because cause of death could have been misclassified, and therefore some authors have suggested using overall mortality as the primary end point. However, estimation of the effect of screening mammography on total mortality would require very large study samples to detect any differences between screened and unscreened groups. Finally, the benefit of screening mammography in younger women remains controversial because of concerns about the quality of the trials that showed this result. Some of the trials had inadequate and inconsistent reporting of randomization, differences in baseline characteristics between study groups, and women in the control group who were screened outside the study protocol. Depending on how stringently the quality criteria were applied, meta-analyses could vary from the 2001 Cochrane meta-analysis that included only 2 of the 8 trials that targeted women between 40 and 49 years of age (10) to the recent USPSTF report that included all trials but the Edinburgh trial (7). A recent study (11) based on 7 model-based analyses concluded that screening mammography resulted in a 7.5% to 22.7% reduction in the breast cancer

mortality rate but did not specifically evaluate the effect of screening mammography in women 40 to 49 years of age. On balance, however, we concurred with authors of the meta-analysis for the USPSTF guideline, who concluded that the limitations of the trials were not sufficient to exclude them (7). We believe the weight of the evidence supports a modest reduction in breast cancer mortality rate with mammography screening of approximately 15% in women 40 to 49 years of age, but the wide CIs for this estimate reflect that the reduction could be larger or nearly zero.

Some uncertainty exists in measuring the absolute impact of screening on morbidity associated with breast cancer and its treatment. Early diagnosis through screening is more likely to be associated with breast-conserving surgery. An observational study found that screening is associated with an absolute increase in lumpectomy (0.7 per 1000 women) and a decrease in absolute risk for mastectomy (0.5 per 1000 women) (12).

In summary, evidence demonstrates that screening mammography in women age 40 to 49 years, compared with women who do not get screened, decreases breast cancer mortality. However, the reduction in the mortality rate is smaller than the 22% (95% CI, 0.70 to 0.87) reduction seen in women who are screened when they are older than 49 years of age (6, 7). In addition, the estimate of the mortality rate reduction may be affected by biases in the trials or the effects of screening after the age of 49 years.

RISKS

Risks of mammography include false-positive results, diagnosis of cancer that would not have become clinically evident during the patient's lifetime, radiation exposure, false reassurance, and procedure-associated pain. Women 40 to 49 years of age may have a higher risk for a false-positive result, and false-positive rates vary widely among several studies. Mushlin and colleagues' meta-analysis (13) of the sensitivity and specificity of screening mammography showed false-positive rates of 0.9% and 6.5%, respectively. However, other analyses have demonstrated cumulative rates of false-positive mammograms of 38% after 10 mammograms (14) and 21% after 10 mammograms (15). Some studies show no difference in the false-positive rates between women 40 to 49 years of age and those older than 49 years of age (16–19). Outcomes associated with false-positive screening mammograms included small increases in general anxiety and depression, anxiety specific to breast cancer, and perceived increased susceptibility to breast cancer; however, anxiety generally resolved quickly after evaluation (6).

Use of mammography has been associated with increased diagnosis of DCIS. The natural history of DCIS is unknown, as is the percentage of these tumors that will progress to more serious disease. In 1999, 33% of women

in whom DCIS was diagnosed had mastectomy, 64% had lumpectomy, and 52% had radiation (20). Not all DCIS cases may have required aggressive treatment, but reliable predictors of biological aggressiveness are difficult to categorize.

No direct evidence links cancer risk with radiation exposure from mammography. Reported pain varied from 28% of women in 1 study to 77% of women in another study. However, pain associated with the mammographic procedure was described by few women as a disincentive from having any future screening (21–24).

ESTIMATING INDIVIDUALIZED BENEFITS AND HARMS

Current evidence shows variation among women in terms of benefits and harms associated with screening mammography between 40 and 49 years of age (6). The decision to have screening mammography should be guided by the balance of benefits and harms for an individual woman. This balance will be affected by a woman's view about how breast cancer and the outcomes associated with screening mammography will influence her quality of life and by her risk for breast cancer. Although the balance will favor screening for many women, it is less certain in women who are very concerned about the potential harms of mammography and who are at substantially lower-than-average risk for breast cancer.

The main benefit of screening mammography every 1 to 2 years in women 40 to 49 years of age is a decrease in breast cancer mortality. Harms of screening mammography include false-positive results, radiation exposure, false reassurance, pain related to the procedure, and possible treatment for lesions that would not have become clinically significant. The probability of false-positive mammograms was also higher in women with dense breasts, if the interval since the last mammography was long, and in women who had previous breast biopsy (25, 26). In addition, women place substantially different value on a false-positive mammogram, a negative mammogram, and the reduction in the rate of mortality associated with breast cancer (27).

A woman's risk for breast cancer is influenced by age, family history of breast cancer, reproductive history, age at menarche, and history of breast biopsy. For example, the risk for breast cancer is higher for women 40 to 49 years of age if they have a history of breast cancer in a first-degree relative: 4.7 cases per 1000 examinations among women with family history versus 2.7 cases per 1000 examinations among those without family history. Older age, younger age at menarche, older age at the time of first birth, and history of breast biopsy also increase the risk for breast cancer.

The absolute risk for breast cancer for a woman at a given age and with certain risk factors can be estimated by using the Web site calculator provided by the NIH that is based on the Gail model (1). However, the accuracy of the Gail model is better when predicting the average level of

risk in a group of women who are at similar risk than when discriminating between women who will and will not develop breast cancer. In addition, a clinician may be unable to assess the risk for breast cancer because of a lack of family history or in women who were adopted.

SUMMARY

Screening mammography probably reduces breast cancer mortality in women 40 to 49 years of age modestly. However, the reduction in this age group is smaller than that in women 50 years of age or older, is subject to greater uncertainty about the exact reduction in risk, and comes with the risk for potential harms (such as false-positive and false-negative results, exposure to radiation, discomfort, and anxiety).

Because of the variation in benefits and harms associated with screening mammography, we recommend tailoring the decision to screen women on the basis of women's concerns about mammography and breast cancer, as well as their risk for breast cancer. Assessment of an individual woman's risk for breast cancer is important because the balance of harms and benefits will shift to net benefit as a woman's baseline risk for breast cancer increases, all other factors being equal. For many women, the potential reduction in risk for death due to breast cancer associated with screening mammography will outweigh other considerations.

RECOMMENDATIONS OF OTHER ORGANIZATIONS

The 2006 American Cancer Society guideline (28) recommends yearly mammograms starting at age 40 and continuing for as long as a woman is in good health.

The 2003 American College of Obstetricians and Gynecologists guideline (29) recommends that women aged 40 to 49 years have screening mammography every 1 to 2 years.

The 2002 USPSTF guideline (30) recommends screening mammography, with or without clinical breast examination (CBE), every 1 to 2 years for women aged 40 and older.

The 2001 Canadian Task Force on Preventive Health Care (31) says that current evidence regarding the effectiveness of screening mammography does not suggest the inclusion of the maneuver in, or its exclusion from, the periodic health examination of women 40 to 49 years of age who are at average risk for breast cancer. Upon reaching 40 years of age, Canadian women should be informed of the potential benefits and risks of screening mammography and assisted in deciding at what age they wish to initiate the maneuver.

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Northwestern University, Chicago, Illinois and Veterans Affairs Palo Alto Health Care System and Stanford University, Stanford, California.

Note: Clinical practice guidelines are guides only and may not apply to all patients and all clinical situations. Thus, they are not intended to override clinicians' judgment. All ACP clinical practice guidelines are considered automatically withdrawn or invalid 5 years after publication or once an update has been issued.

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Mr. PALLONE. Thank you, Doctor.
Ms. Visco.

STATEMENT OF FRAN VISCO

Ms. VISCO. Thank you. I am Fran Visco, president of the National Breast Cancer Coalition and a 22-year breast cancer survivor.

As you know, NBCC is a coalition of hundreds of groups from around the country dedicated to our mission to end breast cancer. One of our roles is to train advocates to understand the process, concepts and language of scientific research. We analyze scientific information for our members and the public from the perspective of lay advocates.

Our number one priority for many years has been guaranteeing access to quality health care to everyone. We believe we cannot achieve our mission without it. We have been working with Congress and the Administration on this goal based on our framework for access to quality health care developed over a number of years of hard work by our grass roots leadership and a key component of that framework is making certain that trained consumers have a seat at every table where decisions are made on health care policy.

We believe in evidence-based approaches to health care as a key to quality care. So what is the evidence behind mammography screening? As we are all well aware and as many people have said, mammography has significant limitations and there has been much controversy over the years about screening programs: at what age are they effective, how do we balance risk and benefits, how can we communicate the very real limitations of screening and the harms associated with it. In 1997, an NIH consensus conference recommended against routine screening of women under the age of 50, but political and outside organizational pushback, not evidence, torpedoed that recommendation. So in fact, we have known the issues with screening for decades.

We also know that 40,000 women will die of breast cancer this year. Tens of millions of people in this country are uninsured. Many, many millions lack access to quality care. We know we have a great deal of work to do to fix this situation. We know that breast cancer is a complex disease, that while we have learned more about the biology of the disease, in the 4 decades since mammography screening programs have been instituted, we have not yet learned how to detect life-threatening breast cancer at a point where we can make a difference how to cure it for every woman, how to prevent it.

Given all of this, we were frankly stunned at the reaction of the media and many in the cancer community and in government to the task force recommendations. The task force is a body of the right experts who looked carefully at updated evidence and objectively made recommendations not that different from their prior recommendations. Given all of this, the amount of time and attention given to these revised recommendations seems just a bit unseemly.

The public has increasingly put their faith in screening and early detection, even though we have never had good evidence that this

would have a significant impact, but too many did not want to highlight the known limitations of mammography. They wanted simple messages: once a year for a lifetime, early detection saves lives. The overemphasis on the importance of screening caused some people to state over and over again that mammograms prevent breast cancer, and please, let us be very clear, mammograms do not prevent breast cancer.

We had hoped that the task force recommendations would cause all of us to stop and think about screening, take the time to look carefully at the evidence and put screening and its limitations into proper perspective, and that can still happen. It is important also to put this in the context of a population where screening programs are for a healthy population for the millions and millions of women, the vast majority of whom will never get breast cancer. The question then is how we devise a screening program that appropriately balances risks and benefits for these healthy women.

So what did the task force actually say? To women in their 40s, they said there are benefits and harms from mammography screening that you should know about and you should make an individual decision at what age you will begin a screening program. So the task force actually recommends giving women control over their own health care decisions. On self-examination, Dr. Brawley pointed out that the self-examination touched on by the task force was that routine, regimented monthly search for cancer. It has been represented as saying that women shouldn't know their bodies. Of course they should. This isn't about that.

Some are concerned that the new guidelines will prevent underserved women from entering the medical system at all, and we would counter that the solution to that is to enact universal access to health care for all, not to depend on a faulty test that exposes women to radiation and the risks of false positives in order to get them to a doctor. Disadvantaged women deserve the same access as all other women to quality evidence-based care and the right information. We do need to move forward because none of this is good enough for women.

We can use this and we should have used this as an opportunity to educate the public about science, about evidence-based care to help alleviate the unwarranted fear, not to feed it. Some argue that public health messages need to be simple and changing guidelines will confuse women. We would argue that while messages need to be simple, they need to be truthful. Women deserve the facts.

We have all heard from women over the past month who are outraged and who believe that a mammogram saved their life. These anecdotes are not evidence. They may be compelling sound bites, great media stories but they are not evidence on which we should base this Nation's public health agenda. That should be based on the type of scientific work done by the task force. We can't believe in science only when we like the answers it produces.

I want to end with an anecdote. Carolina Hinestrosa was the executive vice president of the National Breast Cancer Coalition, and her breast cancer was detected early in her late 30s, probably was not life threatening and she had treatment. She died this past June as a result of her treatment. Her story and all of the anecdotes just tell us how little we know about breast cancer, how we need to be

so very careful about evidence and push for the right answers no matter how unhappy we are with what those answers are. Let us save our outrage for the reality that we know too little and women deserve so much more. Thank you.

[The prepared statement of Ms. Visco follows:]



**Testimony of
Fran Visco, J.D.
President
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**Submitted to the
House Energy and Commerce Committee
Health Subcommittee**

December 2, 2009

Thank you, Chairman Pallone and members of the House Energy and Commerce Health Subcommittee, for the opportunity to testify at this hearing on breast cancer screening recommendations. As always, the National Breast Cancer Coalition commends your attention to our shared mission to eradicate breast cancer. We welcome the opportunity to explain our position on screening and to clear up some of the confusion over the new guidelines issued by the United States Preventive Services Task Force (Task Force).

I am Fran Visco, a 22-year breast cancer survivor, a wife and mother, lawyer, and President of the National Breast Cancer Coalition (NBCC). I was diagnosed at age 39 when my son David was 14 months old. As you may know, NBCC is made up of hundreds of organizations from across the country. Our Board of Directors consists of 25 of these organizations and represents the diversity that is breast cancer. These groups come together under our umbrella to focus on systems change in public policy, health care and research. NBCC's mission is to eradicate breast cancer. NBCC's main goals are to increase federal funding for breast cancer research and collaborate with the scientific community to implement new models of research; improve access to high quality health care and breast cancer clinical trials for all women; and expand the influence of breast cancer advocates wherever breast cancer decisions are made.

NBCC trains advocates to understand the process, concepts and language of scientific research and we analyze scientific information for our members and the public from the perspective of lay advocates. We have no agenda other than our mission to end breast cancer. We believe in evidence based approaches to health care as the key to quality care.

Before I speak to the Task Force recommendations, I want to focus on the goal that we all share, and that is to make certain that everyone has access to the quality health care they need. That goal is NBCC's number one priority because we know that we will not end breast cancer until we achieve it. There are many components to that goal. One is legislation reforming the system to guarantee coverage to everyone.

Another component is achieving quality in health care. What do we mean by quality care? While we can legislate some aspects of achieving quality, as the Institute of Medicine (IOM) pointed out in its report *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001), a key aspect of quality health care is evidence. Legislation can support the science of generating evidence, but the scientific process is what gives us the evidence. The IOM explained

that to achieve quality, the system must provide “services based on scientific knowledge to all who could benefit and refrain from providing services to those not likely to benefit (avoiding underuse and overuse respectively).” This applies to screening interventions as well as treatments.

We should look at the Task Force recommendations in the context of an analysis of quality, effective health care. What is the evidence of benefit? What is the evidence of harm? How do we balance the two and does this change along a continuum of age and known risk?

US Preventive Services Task Force Guidelines

The US Preventive Services Task Force (“Task Force”) released revised breast cancer screening guidelines on November 16, 2009. The Task Force recommends against routine mammography screening for women 40-49 years old. They instead encourage these women to make individual decisions regarding screening based on assessment of the risks and benefits. The Task Force recommends biennial screening for women 50-74 years old. The recommendations are based on a systematic review of randomized, controlled trials with 10 or more years of follow-up, and on six statistical models of screening outcomes.

The Task Force also recommends against teaching breast self exam based on the evidence, again, from large randomized, controlled clinical trials.

Reaction to the Task Force Recommendations

We want to note that the attacks against the makeup of the Task Force are misplaced. Screening is an issue of primary care; it is a health intervention for a healthy population. The experts in this area – those with the scientific training and the objectivity to do the necessary analyses – are primary care health professionals and methodologists such as epidemiologists and biostatisticians, not radiologists or medical oncologists.

The outrage that met the new recommendations was unsettling to us as individuals and organizations that are dedicated to ending breast cancer. The outrage seemed to be based on a misunderstanding of what the Task Force actually did and said. Could the Task Force have communicated the changes better? Without question. But that does not change the fact that they were the right experts, looking carefully at the evidence and objectively making recommendations.

Many in the public were shocked by these changes in breast cancer screening guidelines, but these guidelines and this controversy are not new. The new recommendations do not differ dramatically from the prior guidelines. Moreover, the American College of Physicians released similar guidelines a few years ago. A National Institutes of Health (NIH) consensus panel came to similar conclusions in 1997. In fact, historically, the scientific evidence has not supported the breast cancer screening methods that have been vigorously promoted in our country. Today, we have even more evidence and a greater understanding of breast cancer, but it appears that once again, emotion and conventional wisdom are taking precedent over science, evidence, and progress.

Because a health message has been given over and over again and has become rooted in the public consciousness does not make it correct. Indeed, too many times, policy, messaging and

beliefs have taken hold when there was in fact no real evidence behind them, and these actions resulted in harm to women. We are all familiar with the story of Autologous Bone Marrow Transplants (ABMT) in treating breast cancer. The community believed more chemotherapy would be better and that transplants worked in some cancers so why not breast cancer? While clinical trials were launched, too many women received the treatment outside of the trials, the trials did not accrue and it took many more years than it should have to get the real answer. Women died from the treatment itself. NBCC said from the beginning that we needed the trials to get the answers. When we finally had the evidence, it was clear that ABMT was not better than conventional chemotherapy. And yet laws were passed in various states mandating insurance coverage of this treatment, an example of misplaced advocacy when evidence did not exist.

We also know the story of hormone replacement therapy (HRT) becoming a widely used intervention for women based on the belief, without evidence, that it would help cardiac health among other benefits. Yet when the clinical trials were completed, we found out that HRT increased a women's risk of breast cancer and other harms. Many women took HRT when we had no evidence of its effectiveness and many women were harmed, which has now been recognized in the legal system.

NBCC has taken the position many times before and we do so again today, that we cannot afford to waste our limited resources on public and other health interventions that have not been shown effective. These resources would be better spent on identifying interventions that really do work, such as better ways to detect, treat, and prevent breast cancer.

NBCC Analysis

The NBCC hopes that the Task Force revised, evidence-based guidelines on breast cancer screening will help to put screening and its limitations into proper perspective. For over ten years, NBCC has expressed concern about public health screening messages that were not backed up by the evidence. Women have followed the lead of many in the health care arena over the years and have increasingly put their faith in faulty screening methods.

Progress has always required the ability to adjust, but because of how deeply these messages have been ingrained in the American public, changes are being met with resistance and a firestorm has erupted. These recommendations have challenged deeply held beliefs, the reasons some organizations exist, and not only significant financial interests of those who provide screening and follow-up services, but also of the significant number of companies that use the public health messages to market their products. Further adding to the backlash, these recommendations have also been seized on, and the facts manipulated by, those wishing to derail health care reform.

The result has been an incredible amount of misinformation presented to the public regarding breast cancer, screening, and these guidelines.

I would like to address several of the misconceptions.

First, let me say strongly and loudly, mammograms do NOT prevent breast cancer. I have read and heard a number of statements to that effect. Mammograms may find cancer that is already present but they do nothing to stop tumors from forming.

Next, to those that claim these changes represent an example of rationing of care, I would like to point out that the Task Force did not consider cost when developing their recommendations, and in fact increased recommended screening to include women up to 74 years old. The Task Force began its review of the evidence over two years ago. The Task Force recommendations became tied in with the health care reform debate because of legislative proposals to use their recommendations to decide which screening and preventive services should be covered free of charge, not in deciding what should be covered at all. It just makes good fiscal sense and good health sense to cover preventive services that have been proven effective. If we continue on a course of health care reform based on beliefs and politics, rather than science and evidence, we will continue to have one of the most expensive, but least effective health care systems in the world.

Some are concerned that screening guidelines that do not recommend mammography under 50 as a matter of routine will prevent underserved women from entering the medical system at all. We would counter that the solution is to enact universal access to medical care for all, not to depend on a faulty test that exposes women to radiation and the risks of false positives, in order to gain them medical care. Disadvantaged women deserve the same access to quality, evidence-based care as advantaged women. Disadvantaged women have the same rights as all women to learn the facts and understand the evidence behind medical procedures.

Others have expressed concern about those women who do have breast cancer in their 40s – how will it be detected under these new guidelines? The truth is, based on evidence from randomized clinical trials, the highest level of scientific evidence, mammography and breast self exams do not work in finding life-threatening cancers in this age group or in reducing mortality. The new recommendations give these women control over the decision of whether to undergo screening, after understanding harms and possible benefits.

What about finding the cancers with breast self exam? Large well designed clinical trials have shown us that regimented, monthly exams do not lead to detection of more or earlier cancers and in fact cause harm by leading to twice as many women having unnecessary biopsies and additional imaging.

Does this mean women should not “know” their bodies? Of course not. The majority of women DO find their breast cancers because they feel them, while going about their lives, in the shower, getting dressed, during lovemaking. This is different from the regimented breast self examination that is the subject of the Task Force recommendations. Being familiar with your breasts, and reporting any changes or concerns to your doctor, is different from a monthly self examination done with a certain technique in order to search for cancer.

The harms from screening are not to be taken lightly. Harms include over diagnosis and false positives. According to research cited by the Task Force, false positives are 60% more likely when mammography is started at 40, rather than 50. False positives lead to increased imaging and radiation exposure, and increased biopsies and scarring which can interfere with future mammography. Over diagnosis would include treatment of cancers that would never have been life threatening, and treatment of cancers that may have regressed, or gone away on their own. The treatments for breast cancer are toxic and can be life threatening. The scenario of over diagnosis should not be dismissed as unimportant.

Is any of this good enough as our only method for detecting breast cancer in women of any age? No, it is not. We can do better and we must. But by refusing to look at the evidence and continuing to put faith in faulty methods, despite the evidence of their limitations and the harm they cause, society has become complacent. The urgency to develop new methods that will save women's lives has been lost.

Moving Forward

NBCC has always pushed for research to find better methods for detecting breast cancer and for ways to distinguish between lethal and non-threatening cancers. We have made progress in our knowledge of breast cancer over the past few decades and the screening tools we have at present do not take into account the differences we now see in the biology of breast cancer. We know that all breast cancers are not the same. Some breast cancers are slow-growing and have a good prognosis, whenever they are found, whether small or large. Some may be more threatening, but respond to treatment at whatever stage they are found. Other breast cancers are aggressive and fast growing, and we do not have the tools to find them early enough. We desperately need better methods for detecting these cancers, and better treatments once we find them.

The Task Force did not condemn breast cancer screening. It carefully looked at the updated evidence, at the long term evidence of benefit and harms and recommended that for women between the ages of 40 and 50, the decision to have a screening mammography be made on an individual basis, after an analysis of the benefits and harms. The recommendations give women control over their health care decisions. From its prior recommendation of screening every one to two years for women over 50, the Task Force recognized that the updated evidence and the various scientific modeling analyses performed, support screening every two years.

What do we tell women? Some argue that public health messages need to be simple and that changing the guidelines will only confuse women. We would argue that while public health messages may need to be simple, they also need to be truthful. We believe women deserve to know the facts. Women are capable of understanding the complexities of breast cancer and screening and have the right to make informed decisions regarding their health care.

The Task Force recommendations and the attention surrounding them also present an excellent opportunity to educate the public about the importance of science and evidence and to help them understand that as we learn more about health issues, recommendations will change to reflect that knowledge. And the public needs to know, not just possible benefits of medicine, but also the risks often associated with it. The public is ready to learn. Recently, NBCC received the results of its commissioned annual survey of Breast Cancer Awareness and Knowledge (Penn, Schoen and Berland, October 2009). Women across all age groups named comparative effectiveness research as the most beneficial tool in achieving quality in health care. Electronic medical records came in second. Clearly the public is becoming more sophisticated about these issues and the present discussion can help move us closer to public acceptance of a system based on quality care.

NBCC is committed to seeking what is best for women and their health. We will continue to push for universal access to quality health care for all, a thorough look at the evidence, and for public health officials to base guidelines and recommendations on that evidence. We must

address the facts about breast cancer and not rely on what we wish were true. We firmly believe that this is the only way we will make progress in eradicating this disease.

Mr. Chairman, I thank you so very much for this opportunity to testify before this Committee and for the Committee's commitment to our mission.

Mr. PALLONE. Thank you, and we will try to get this done before the votes. I don't know if that is possible. I will start with myself.

You know, I really want to apologize to you maybe on behalf of Congress, if I could that, because I was listening to what Dr. Sweet said, and you are absolutely right, that this has been totally politicized and I guess, you know, the problem is that Congress is political and maybe this isn't the vehicle for it. I mean, it is sort of interesting to see that in the first panel most of the members were here and most of the media were here and now we are on the second panel, which is not the political panel, and the situation is reversed, you know. And Ms. Visco talked about how essentially—and I don't want to put words in your mouth but, you know, after listening today, I can't help but say I am not sure there really was that much of a difference between what the task force said now versus what the recommendation was a few years ago or even between what you are saying and the previous panel said. It is just amazing how these differences, if there are any, have been exaggerated and politicized. I guess that is just the nature of the process around here so I don't know what we can do about it or make it any different, and I say that out of sadness, really.

Let me ask you just a couple questions because I know the time is running out here. I will start with Dr. Brawley and also Ms. Luray. A few days after the task force recommendations, the Cancer Society issued a statement urging that health care reform create a transparent and evidence-based process for making task force recommendations, and I guess Komen echoed those concerns. But your statement, Dr. Brawley, listed a number of changes you would like to see in health reform and you discussed the importance of transparency and the task force's process of arriving at its recommendations. Now, I believe that the bill H.R. 3962 actually addresses those concerns, so I wanted you to really, you know, answer that. I mean, the importance of stakeholder input and those recommendations you made about that, does the bill H.R. 3962 address those concerns?

Dr. BRAWLEY. Well, sir, I believe that it does. I think the most important thing is that the task force continue to provide objective evidence but also provide the objective evidence in an open arena where people can actually see the process.

Mr. PALLONE. And then Ms. Luray, from Komen's perspective, do you agree that the provisions in H.R. 3962 would improve the task force recommendations process? I mean, you don't have to just say yes or no, but go ahead.

Ms. LURAY. Sir, actually yes. I mean, H.R. 3962 has a stakeholder panel that would advise the new clinical services task force and we think that makes a lot of sense. Such a panel I think could have helped to really communicate the findings of this task force, and even though people might not—there still may have been disagreement within the scientific community, I think the message could have been delivered in a way that was much more helpful to women and their providers.

Mr. PALLONE. I was just trying to make the point really that the issues that the American Cancer Society and Komen raised months ago well before these task force recommendations emerged, you know, that we felt on the House side we were listening to, and I

am trying to point out that as a result of your efforts and this collaboration that the bill contains the changes to the task force necessary to improve the process. That was my only point.

And then the second one, and I am going to ask all of you this quickly, and that is, as you know, my colleagues on the Republican side have repeatedly raised concerns about the House-passed health reform bill in light of the task force recommendations, and they have repeatedly asserted that H.R. 3962 somehow—well, I don't want to put words in their mouth but I think there is a suggestion that somehow the bill, you know, is a step backward on the issue of breast cancer or breast cancer screening, so I just want to ask each of you on the whole, do you think the House-passed health reform bill, H.R. 3962, is actually more helpful, is a step forward or a step backward with regard to women with breast cancer and these screening issues? And I will just ask each of you to comment on that briefly.

Dr. BRAWLEY. Mr. Chairman, if I can just say there are thousands of American women who die today because of lack of access. There are thousands of women who die today because they are detected early but they don't have insurance to get access to reasonable and good care. Any effort that gets those people reasonable and good care is a good effort that is going to save lives. We have been talking about the number of lives that would be lost due to this recommendation of, maybe it was a recommendation not to get screened for women in their 40s, maybe it wasn't, but the number of lives that we could just fix, that we could just save through a logistical fix is tremendous. Just get them access to care.

Mr. PALLONE. Ms. Luray.

Ms. LURAY. I would add in addition to the universal access that Dr. Brawley mentioned, also the limitations on preexisting conditions and out-of-pocket costs are currently a huge burden for breast cancer patients and one of the main items that our advocacy community throughout the country asks that we followed very closely in health care reform, and those protections are included in H.R. 3962.

Mr. PALLONE. Thank you.

Dr. Sweet.

Dr. SWEET. Absolutely. This bill will help the health of American women with and without breast cancer. There are a number who do manage to get diagnosed and then have no access to reasonable care, as Dr. Brawley said. The number of women even in my own practice that are locked into jobs that they would rather not stay in, they can't move because of lack of health insurability. They know if they leave their job and leave that health insurance, when they try to get the next one they are going to be uninsurable, and I think the fact that this bill addresses getting rid of preexisting conditions and guaranteeing health insurance to all at a reasonable cost is extremely important.

And then the third thing is, the bill does address some of the health care workforce issues. Access means having a trusted clinician, as the woman from Florida said, and there are not enough of the primary care people out there anymore to be trusted clinicians for all the people we are going to give access to, and your bill does put in provisions to have an improved, I think, primary care work-

force by improving payment and other things. So I think this bill is an absolute improvement. The millions of lives that we lose because of true lack of health insurance is much, much greater than what we are going to lose by a few women who decide not to have screening once they think about it.

Mr. PALLONE. Thank you.

Ms. Visco.

Ms. VISCO. Well, as you know, Mr. Chairman, the National Breast Cancer Coalition has endorsed the House bill and we completely support it. We believe it is an incredibly important tool in eradicating breast cancer. We think it will move us forward tremendously in getting everyone access to health care and helping save lives from breast cancer, and I hope that this controversy does not cause the Congress to interfere in any way with the independence and objectivity of the task force. We cannot allow that to happen. We need evidence-based quality care. And I also truly wanted to ask the question that if the bill was changed to mandate C-level recommendations in a basic benefit package if everyone who spoke to that issue today would then support the bill. I tend to doubt that. So I really think that if we want to save lives, if we want to move forward, if we want to end breast cancer, we need guaranteed access to health care reform and the House bill is very important to achieving that end.

Mr. PALLONE. Thank you.

Let me mention, I was under the impression we had votes. In fact, we are in recess on the Floor so there is actually not any real time constraints here.

Chairman Dingell.

Mr. DINGELL. I want to thank the panel and congratulate them for their very fine presentation. I am going to begin by reading something which appeared, and you will recognize this, in the statement of Dr. Sweet. "Under Affordable Health Care for America Act, H.R. 3962, passed by the House of Representatives, a new task force on clinical preventive services would be created which would take on many of the responsibilities of the current U.S. Preventive Services Task Force. This new entity will have an important role in making evidence-based recommendations on preventive services that insurers would be required to cover but the only binding effect the recommendations of the task force will have on health plans is a requirement that preventive measures for which the task force has been given an A or B rating must be covered. The bill does not give the task force and the federal government itself any authority to put limits on coverage, ration care or require that insurers deny coverage. Health plans could offer additional preventive and other benefits of their choosing and no restrictions would be placed on their ability to consider recommendations from sources other than the task force in making such coverage recommendations. And now, if you please, starting with you, Dr. Brawley, do you agree with that statement?"

Dr. BRAWLEY. Well, sir, I am not a policy person, I am just a simple doctor.

Mr. DINGELL. Well, just yes or no.

Dr. BRAWLEY. But I do agree with your statement.

Mr. DINGELL. Thank you. I am not trying to lay traps here. I want that clear.

Ms. Luray.

Ms. LURAY. Yes, Congressman. As I said in my testimony, we also see the role of the task force as creating more of a floor than a ceiling, so in that sense, I would agree with you.

Mr. DINGELL. Obviously, Dr. Sweet, you agree.

Mr. SWEET. Yes, I do, and I have some very good policy people behind me that agree. That is important too.

Mr. DINGELL. I am just trying to lay to rest some of the nasty untruths that are being circulated about this legislation.

Ms. Visco.

Ms. VISCO. Yes, I agree.

Mr. DINGELL. Now, each of your organizations has supported the legislation, H.R. 3962. Do you have any apprehension that the provisions that we are discussing today or any other part of this legislation will trigger a nasty program of rationing health care?

Dr. BRAWLEY. No, sir.

Mr. DINGELL. Ma'am?

Ms. LURAY. No, sir.

Dr. SWEET. No.

Mr. DINGELL. Ms. Visco?

Ms. VISCO. No.

Mr. DINGELL. Mr. Chair, I guess that is all the questions I have got. I think we have laid to rest some of the unfortunate misapprehensions of our colleagues and I can only express my great regret that they are not here to participate and to learn from the wisdom of our witnesses. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Chairman Dingell.

Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman. I apologize for being in and out but we have both Secretary Gates, Secretary Clinton and the Joint Chiefs of Staff and the Foreign Affairs Committee talking about Afghanistan, although this is such an important issue for the district I represent.

I represent a majority Hispanic district that is also a federally medically underserved area, and we face many, many issues to encourage women to see primary and preventive care services. We rely on our Harris County Hospital District and our community-based health clinics to provide the services and screening for our constituents. I worry that the revised recommendations will discourage the safety-net providers from aggressively educating and screening for breast cancer in these underserved populations. I often say we have one of the premier medical centers in the world including M.D. Anderson Cancer Center located in our backyard but my constituents can see the medical center, it is just hard for them to get there because they are substantially uninsured. And unfortunately, most do not have the access to the medical services. Could you briefly speak about the current access barriers for breast cancer screening minority in those residing in medically underserved districts face and what impact these recommendations may have on these populations? Dr. Brawley?

Dr. BRAWLEY. Well, Congressman, I hope the recommendations of the task force will have very little effect on your constituents

with the exception that perhaps the discussions that we have in the news over the last few weeks will bring breast cancer much more to the forefront. I have some hope. I said in my testimony about half of all women in their 40s and 50s who are diagnosed with breast cancer are actually diagnosed not through a traditional breast self-exam but through what we prefer to call breast awareness; they notice when they're getting dressed or when they in the shower, that sort of thing. Perhaps people will hear this national conversation we have had and actually be a little bit freer to come forth and get evaluated by a doctor should they find an abnormality. I also hope that people will continue listening to the other organizations like the American Cancer Society that have said that women age 40 and above should continue getting mammography on an annual basis but also I think it is important to realize that there is controversy about how good mammography is. And I will just leave you with one last statement. Mammography is imperfect but right now it is the best technical tool that we have other than awareness for early detection.

Mr. GREEN. Mammography is much more valid than the PSA test is for males.

Dr. BRAWLEY. Oh, yes, absolutely. You are absolutely correct. There are nine studies in the literature that show that mammography saves lives. There are two randomized trials on PSA, one that shows it saves lives and another that fails to confirm that first finding.

Mr. GREEN. Ms. Luray.

Ms. LURAY. Congressman, I would like to comment on that as well. As you know, we partner closely with the CDC and other providers to support free clinics and mobile vans in districts such as yours, and so we are very familiar with the kinds of constituents you have and really a very fragile relationship they have with the health care system, many of whom are uninsured, and so we have been working very hard in these last few weeks to make sure that the hullabaloo around the release of these recommendations doesn't cause women who really already have that fragile relationship who may just be coming into mammography clinics for the first time in their lives to say well, gee, maybe I don't need to come at all. So we are working very hard to ensure that that message doesn't get twisted around and be taken as a sign that mammography can't provide help to them.

Dr. SWEET. And I would hope as a clinician doing this, just as in my practice, women will come in talking about it. There is nothing more likely to get a patient to bring something up than to see it on CNN or in the controversial position and maybe it will sort of nudge many of our clinicians who perhaps haven't taken the time to have that discussion to actually make it an individualized, personalized discussion with that woman about what she needs along with the fact, as we said earlier, that many, many of those women if health care reform can occur and we do have access to health insurance for the poor and the people who need it the most, we will be able to offer screening to some of these women in a clinical situation that have never had that available. So I truly see this as a critical time, and the hullabaloo, it is a political sort of system and there is a lot of things out there that just aren't true, I think,

but it does bring women to discuss it, and once they bring it up, then the doctor, the clinician has to follow through.

Mr. GREEN. Thank you.

Ms. Visco.

Ms. VISCO. Yes, we are working very, very hard on making certain that everyone in this country has guaranteed access to quality health care, and that will certainly solve the problem. We are spending the majority of our resources on that issue. There are also a number of studies out there looking at what are the barriers to access for underserved population, why do they not access the health care system, and of course, one of the reasons is, because they don't have coverage for treatment. That is why the National Breast Cancer Coalition a number of years ago worked very hard to get enacted into law the CDC Breast and Cervical Cancer Treatment Act we knew that screening even if you do get a mammogram, you have to have access to treatment if you want to save a life. And so that is our number one concern and that is where we focus most of our work.

Mr. GREEN. Thank you, Mr. Chairman. I know I am out of time. My concern about the furor over this is that women will make that decision not to, and again, early detection is still the answer, and particularly in underserved communities. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, and I think that concludes our questions. I just want to thank all of you again. Once again, I said to the previous panel, you certainly cleared up a lot of the misconceptions. I just hope we can get that message out to the media, which is often difficult.

Some of the members may submit written questions, and we try to get those to you within the next 10 days, so you might get some additional questions. Of course, the clerk would notify you of that and the time period to get back to us. But I do want to thank you again.

Without objection, this meeting of the subcommittee is adjourned. Thanks.

[Whereupon, at 3:05 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

**Statement of U.S. Rep. Ed Whitfield
Before the Energy and Commerce Health Subcommittee
Hearing on "Breast Cancer Screening Recommendations"
December 2, 2009**

- Mr. Chairman and Ranking Member Deal, thank you for holding this hearing on the recent breast cancer screening recommendations.
- This certainly is an issue that impacts all Americans and I doubt there is anyone in this room that has not been impacted by breast cancer.
- In fact, one in nine women will develop breast cancer at some point in their lifetime. In Kentucky there will be an estimated 2,840 new cases of invasive breast cancer diagnosed this year.
- As with most cancers, early detection is the key. That is why I find the recommendations of the U.S. Preventative Task Force especially troubling.
- On November 16, 2009, the U.S. Preventive Services Task Force (USPSTF) announced it would no longer recommend routine mammograms for women between the ages of 40 and 49, a group that accounts for about 1 out of 6 instances of breast cancer.
- Not only do I find this to be bad policy, but I find it **irresponsible**.
- According to the National Cancer Institute, the 5 year survival rate for a woman who is diagnosed early and catches the breast cancer in Stage 0 or 1 is 100%.
- Contrast that with a woman who is diagnosed in Stage IV, where the survival rate is 20%. Clearly this shows the importance of early screenings.
- What is even more troubling is that this new Health Benefits Advisory Committee, which would be established under the Health Reform legislation, could have the power to not reimburse those seeking early screenings.
- As I have stated numerous times before, I simply cannot and will not support the rationing of healthcare in our country.

Again, I thank you for your time and attention to this important matter.

HENRY A. WAXMAN, CALIFORNIA
 URBANMAN

JOHN D. DORNELL, MICHIGAN
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ONE HUNDRED ELEVENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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January 26, 2010

Dr. Ned Calonge
 Chair, US Preventive Services Task Force
 Colorado Department of Health and Environment
 4300 Cherry Creek Drive South
 Denver, CO 80246-1530

Dear Dr. Calonge:

Thank you for appearing before the Subcommittee on Health on December 2, 2009, at the hearing entitled "Breast Cancer Screening Recommendations."

Pursuant to the Committee's Rules, attached are written questions for the record directed to you from certain Members of the Committee. In preparing your answers, please address your response to the Member who submitted the questions.

Please provide your responses by February 9, 2010, to Earley Green, Chief Clerk, in Room 2125 of the Rayburn House Office Building and via e-mail to Earley.Green@mail.house.gov. Please contact Earley Green or Jennifer Berenholz at (202) 225-2927 if you have any questions.

Sincerely,



Henry A. Waxman
 Chairman

Attachment



February 9, 2010

The Honorable Henry A. Waxman
 Chairman, Committee on Energy and Commerce
 2125 Rayburn House Office Building
 Washington, DC 20515-6115

Dear Chairman Waxman

I write in response to your letter of January 26, 2010, with answers to questions posed by the Honorable Michael Burgess.

In response to the first question, neither the US Preventive Services Task Force (USPSTF) members nor the supporting Agency for Health Research and Quality (AHRQ) staff record the individual votes of USPSTF members. However, I have excerpted the tallies on the votes for the individual elements of the recommendations from our minutes:

Action: The Task Force voted unanimously that in all recommendations about breast cancer screening, the frequency of screening should be biennial.

Action: The Task Force voted on the following recommendation:

- The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of clinical breast examination (CBE) beyond screening mammography in women aged 40 years and older. I statement

The vote was unanimously in favor of the I statement.

Action: There was a motion and second on the following recommendation:

- The USPSTF recommends against routine screening mammography in women **aged 40 to 49 years of age**. There may be considerations that support mammography in an individual patient. (Enhance statement for needed discussion between patient and provider.) C recommendation

The Task Force voted 11 in favor, 1 opposed, 1 abstention.

Action: The Task Force voted on the following recommendation:

- The USPSTF recommends against clinicians teaching women Breast Self Examination (BSE).D recommendation

The Task Force voted 12 in favor, 0 opposed, 2 abstentions to the recommendation.

Chairman Henry A. Waxman
February 9, 2010
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Action: It was moved and seconded to vote on the following recommendation:

- The USPSTF concludes that current evidence is insufficient to assess additional benefits and harms of either digital mammography or MRI instead of film screen mammography as screening modalities for breast cancer.I statement

The vote was 13 in favor, 0 opposed.

Action: The Task Force voted on the following statement

- The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of screening mammography in women aged 75 years and older. I statement

The vote was 13 in favor, opposed to the I statement.

Action: The Task Force voted on the following recommendation:

The USPSTF recommends biennial screening mammography for women aged 50 to 74 years of age.B recommendation.

The Task Force voted 12 in favor 2 opposed to the recommendation.

Note that there were 14 members present for the discussion of the systematic evidence report, and that no fewer than 11 members voted for the recommendations as ultimately published. Ten votes are required to adopt a recommendation. The number of members voting varied from 12-14 due to departures made necessary by travel arrangements.

Regarding the second question, the USPSTF OB/GYN members participating in the breast cancer screening recommendation discussion and vote were Dr. Kim Gregory and Dr. George Sawaya. Both have been in practice for more than 15 years, and both are recognized experts in the field. I've attached a summary of their biographies for your review.

In terms of consultants, the USPSTF uses peer reviewers at critical points in the systematic evidence review and recommendation development process. This process is outlined in detail on our website, and can be found at <http://www.ahrq.gov/clinic/uspstf08/methods/procmanual.htm>.

Chairman Henry A. Waxman
 February 9, 2010
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The following is a list of reviewers for the Draft Evidence Report, along with their training (according to our records) and when relevant, organization:

Donald Berry, PhD, biostatistics
 Suzanne Fletcher, MD, internal medicine
 Stephen W. Duffy, MSc, epidemiology
 Anthony B. Miller, MD, internal medicine and epidemiology
 Eugenio Paci, MD, epidemiology
 Nancy Baxter, MD, PhD, internal medicine and epidemiology
 Barnett Kramer, MD, National Cancer Institute, internal medicine and oncology
 Robert C. Smith, MD Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), radiology
 Ronald Kaczmarek, MD, MPH, CDRH, FDA, epidemiology
 Helen J. Barr, MD, Director, of Mammography Quality and Radiation Programs, CDRH, FDA, radiology
 Lisa Richardson MD, Centers for Disease Control and Prevention (CDC), internal medicine and oncology
 Hershel W. Lawson, MD, CDC, obstetrics and gynecology

The following is a list of reviewers for the Draft Recommendation Statement:

Lowell Sensintaffer, MD, Department of Defense (Military Health System), family medicine
 Val Finnell, DOD (Military Health System), family medicine
 Linda Kinsinger, MD, Veterans Administration, internal medicine
 Magda Barini-Garcia, MD, MPH, Center for Quality, Health Resources and Services Administration (HRSA), obstetrics and gynecology
 Hope Baluh, MD, Chief Clinical Consultant for Surgery, Indian Health Service, surgery
 Doug Campos-Outcalt, DO, American Academy of Family Physicians, family medicine
 Beverly Green, MD, MPH, Group Health Research Institute, American Health Insurance Plans (AHIP), family medicine and epidemiology
 Michael Fusco, MD, Mercy Health Plans, AHIP, internal medicine
 Jacqueline Miller, MD, CDC, general surgery
 Barry Kramer, MD, NCI, internal medicine and oncology
 Rachel Ballard-Barbash, MD, NIH, internal medicine
 Hal Lawrence, MD, American College of Obstetricians and Gynecologists (ACOG), obstetrics and gynecology
 Mary Gemignani, MD, ACOG, obstetrics and gynecology, gynecologic oncology
 Mary Mitchell, ACOG staff
 Amir Qaseem, MD, American College of Physicians, internal medicine
 Heidi Nelson, MD, MPH, Oregon Evidence-based Practice Center, internal medicine.

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February 9, 2010
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Other than ACOG, which we identify as a partner organization due to their national representation, their primary mission of supporting primary care clinicians offering comprehensive services, and the significant involvement of their members in primary care, we did not communicate or deliberate directly with other professional organizations including the American College of Surgeons or the American College of Radiology. However, you can discern from the review list that we did consult with noted radiologists, oncologists and surgeons.

I hope this information meets your needs. I am certainly at your disposal for additional information and clarification.

Sincerely,



Ned Calonge, MD, MPH
Chair
US Preventive Services Task Force

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Dr. Kimberly Gregory, MD, MPH –**Obstetrician gynecologist**

Kimberly D. Gregory, MD, MPH, is Vice Chair of Women's Healthcare Quality and Performance Improvement at Cedars-Sinai. She has been affiliated with the Medical Center since 1992. Dr. Gregory also serves as Associate Professor at the University of California, Los Angeles, (UCLA) School of Medicine and as Associate Professor at the UCLA School of Public Health. Dr. Gregory received her bachelor's degree from UCLA and her medical degree from Charles Drew University School of Medicine and Science. She completed her internship and residency in obstetrics and gynecology at Beth Israel Hospital in Boston and her fellowship in maternal-fetal medicine at Los Angeles County + University of Southern California Medical Center. Dr. Gregory received her Master's of Public Health (MPH) from Harvard School of Public Health in 1991.

- Director of Maternal-Fetal Medicine at Cedars-Sinai Medical Center, Los Angeles, California
- Advisor, Department of Health, Services Maternal and Child Health Branch
- Member, County of Los Angeles Fetal Infant Mortality Review Board
- Member, California Perinatal Quality Care Collaborative
- President, Perinatal Advisory Council Los Angeles Communities
- Director, Women's Health Services Research at Cedars-Sinai Medical Center

Dr. Gregory is Board Certified and a member of the American College of Obstetrics and Gynecology (ACOG). She has served on a variety of ACOG committees including OB Practice Committee. She brings nationally respected expertise in primary care and methodology to the USPSTF and has served with the Task Force since 2004.

Dr. George F. Sawaya, M.D.

Obstetrician gynecologist

Dr. George Sawaya is an obstetrician-gynecologist and an associate professor in the Department of Obstetrics, Gynecology and Reproductive Sciences. His main research interest is in cervical cancer screening with particular interest in screening older women, cost-effectiveness and cost-utility as well as new approaches to population-based screening. He is the director San Francisco General Hospital's Colposcopy and Cervical Dysplasia Clinic.

Dr. Sawaya completed his medical degree at the Vanderbilt University School of Medicine, his internship and residency at UCSF and a fellowship in UCSF's Department of Epidemiology and Biostatistics. He is a frequent lecturer and author or coauthor of articles in peer-reviewed journals and book chapters.

Dr. George Sawaya is a Board certified Obstetrician-Gynecologist who is Associate Professor in Residence Department of Obstetrics, Gynecology and Reproductive Sciences, Department of Epidemiology and Biostatistics, University of California, San Francisco (July 2003-Present)

Co-Investigator – Medical Effectiveness Research Center for Diverse Populations, University of California, San Francisco

Attending Physician, Department of Obstetrics, Gynecology and Reproductive Sciences, San Francisco General Hospital

Director, Colposcopy and Cervical Pathology Clinic, Department of Obstetrics, Gynecology and Reproductive Sciences, San Francisco General Hospital

Staff Physician, Department of Obstetrics and Gynecology, Saint Luke's Hospital San Francisco California

American Board of Obstetrics and Gynecology: Certified 11/97
Fellow, American College of Obstetricians and Gynecologists: 1998- present

Vanderbilt University School of Medicine, Sept. 1986 – May 1990

