Testimony of the American College of Physicians

to the

House Energy and Commerce Committee

Subcommittee on Health

"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.