REPORT 6 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (A-12) Screening Mammography (Resolution 509-A-10, Resolve 1) (Reference Committee E)

EXECUTIVE SUMMARY

<u>Objectives.</u> In November 2009, the United States Preventive Services Task Force (USPSTF) updated its guidelines on routine screening for breast cancer. The updated recommendations are different from those of several other guideline-making groups and have contributed to the continuing debate about when routine screening mammography should begin and what its frequency should be. This report will highlight current screening mammography guidelines, explore the established benefits and harms of mammography, review the process by which the USPSTF developed its updated recommendations on screening mammography, and update the AMA's current policy recommendations.

<u>Data Sources.</u> Literature searches were conducted in the PubMed database for English-language articles published between 2000 and 2012 using the search terms "screening mammography," and "mammography AND USPSTF," and "mammography AND 40." To capture reports that may not have been indexed on PubMed, as well as news articles and press releases, periodic Google searches were conducted using the search terms "mammography," "mammography AND USPSTF," and "mammography," and "mammography," the search terms "mammography," "mammography AND USPSTF," and "mammography AND 40." Additional articles were identified by review of the literature citations in articles found in the PubMed and Google searches. Specific information on the USPSTF was obtained from its website.

<u>Results.</u> Screening mammography reduces mortality from breast cancer, including in women younger than age 50 years. However, screening mammography carries harms such as false-positive results that can lead to additional imaging and invasive biopsy procedures, and overdiagnosis that could lead to treatment in patients who may not benefit from it. The USPSTF considered the balance of benefits and harms using a commissioned targeted systematic evidence review of randomized clinical trials and a decision analysis that compared the expected health outcomes of starting and ending mammography at different ages and using annual and biennial screening strategies; it concluded (in part) that routine screening should begin at age 50 years and continue biennially until age 74 years. Several medical specialty societies, patient advocacy groups, and individuals offered either support for or opposition to the recommendations. Some groups have concurrently called for reform in the guideline development process.

<u>Conclusions.</u> Mammography is a proven method for detecting breast tumors, with demonstrated reductions in mortality for women who undergo regular screening. Associated harms exist, which underlie differences in recommendations regarding the frequency and age at which to begin and end screening. Groups developing guidelines have placed different emphasis on these harms, resulting in varied conclusions about whether benefits outweigh harms, and whether that balance changes in different age groups. Mammography screening guidelines themselves regularly undergo review and update processes; the Council believes that it is appropriate for AMA policies referencing such guidelines to be reviewed and updated as well, and offers revisions to AMA policy H-525.993 [Mammography Screening in Asymptomatic Women Forty Years and Older]. The foundation of the Council's recommendation is the notion that every woman age 40 years and older who wants a routine screening mammogram and whose physician believes it is clinically appropriate should receive one, regardless of her insurance coverage status.

Action of the AMA House of Delegates 2012 Annual Meeting: Council on Science and Public Health Report 6 Recommendations Adopted as Amended, and Remainder of Report filed.

CSAPH Report 6-A-12

Subject:	Screening Mammography (Resolution 509, A-10, Resolve 1)
Presented by:	Lee R. Morisy, MD, Chair
Referred to:	Reference Committee E (Frederick R. Ridge, Jr., MD, Chair)

1 INTRODUCTION

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3 Resolution 509-A-10, introduced by the Illinois Delegation, asked that our American Medical

Association (AMA): (1) recommend that physicians and patients continue to follow the guidelines of the American Cancer Society regarding screening mammography and patient breast self-

6 examination; and (2) encourage government panels and task forces dealing with specific disease

entities to have representation by physicians with expertise in those diseases. Resolve 1 was

8 referred for decision; Resolve 2 was adopted.

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The Board of Trustees considered Resolve 1 and referred it to the Council on Science and Public Health, asking for a report back on the issue of screening mammography, especially with regard to screening women ages 40-49 years. Accordingly, this report will highlight current screening mammography guidelines, explore the established benefits and harms of mammography, review the process by which the United States Preventive Services Task Force (USPSTF) developed its updated recommendations on screening mammography, and update the AMA's current policy recommendations.

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20 Literature searches were conducted in the PubMed database for English-language articles published between 2000 and 2012 using the search terms "screening mammography," and "mammography 21 AND USPSTF," and "mammography AND 40." To capture reports that may not have been 22 23 indexed on PubMed, as well as news articles and press releases, periodic Google searches were conducted using the search terms "mammography," "mammography AND USPSTF," and 24 "mammography AND 40." Additional articles were identified by review of the literature citations 25 in articles found in the PubMed and Google searches. Specific information on the USPSTF was 26 27 obtained from its website.

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- 29 BACKGROUND

METHODS

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From 2002-2009, the USPSTF recommendations on breast cancer screening supported routine screening mammography, with or without a clinical breast exam, every 1-2 years for women age 40 years and older.¹ These recommendations were similar to the recommendations of several other medical professional societies and cancer advocacy groups, including the American Cancer Society

Action of the AMA House of Delegates 2012 Annual Meeting: Council on Science and Public Health Report 6 Recommendations Adopted as Amended, and Remainder of Report filed.

(ACS), American College of Radiology (ACR), American Congress of Obstetricians and 1 2 Gynecologists (ACOG), and the National Comprehensive Cancer Network (NCCN). 3 4 In November 2009, the USPSTF updated its guidelines on screening for breast cancer.² These 5 guidelines recommend against routine screening mammography in women aged 40-49 years, and recommend biennial screening mammography in women aged 50-74 years.² The USPSTF 6 7 concluded that the evidence was insufficient to recommend for or against routine screening 8 mammography in women older than age 74 years.² In December 2009, the USPSTF updated the 9 language of its recommendation regarding women under age 50 years to clarify its original and 10 continued intent. That recommendation now states: "The decision to start regular, biennial 11 screening mammography before the age of 50 years should be an individual one and take patient 12 context into account, including the patient's values regarding specific benefits and harms."² 13 14 The USPSTF also updated recommendations on clinical breast examination (CBE), self-breast 15 examination (SBE), digital mammography, and magnetic resonance imaging (MRI), however this 16 report will focus on the recommendations for screening mammography. 17 18 **RELEVANT AMA POLICY** 19 20 AMA policy strongly supports mammography screening for the early detection of breast cancer (see Appendix I). Policy H-55.993 [Early Detection of Breast Cancer, AMA Policy Database] 21 22 encourages recognition of mammography as an effective screening technique and additionally 23 encourages education and awareness about breast self-examination. Policies H-55.984 [Screening 24 and Treatment for Breast and Cervical Cancer], H-55.985 [Screening and Education Programs for 25 Breast and Cervical Cancer Risk Reduction], and D-525.998 [Mammography Screening for Breast 26 Cancer] support funding for screening programs, including for low-income women; H-55.985 27 additionally encourages educational programs to inform women about screening. 28 29 With regard to recommendations directly addressing screening mammography in women between 30 the ages of 40-49 years, AMA policy is the following: 31 H-525.993 Mammography Screening in Asymptomatic Women Forty Years and Older 32 33 1. Our AMA strongly endorses the positions of the American College of Obstetrics and 34 Gynecology, the American Cancer Society, and the American College of Radiology that all 35 women have screening mammography as per current guidelines. 2. Our AMA favors 36 participation in and support of the efforts of the professional, voluntary, and government 37 organizations to educate physicians and the public regarding the value of screening 38 mammography in reducing breast cancer mortality. 3. Our AMA advocates remaining alert to 39 new epidemiological findings regarding age-specific breast cancer mortality reduction 40 following mammography screening. 4. Based on recent summary data our AMA recommends 41 annual screening mammograms and continuation of clinical breast examinations in 42 asymptomatic women 40 years and older. 5. Our AMA encourages the periodic 43 reconsideration of these recommendations as more epidemiological data become available. 6. 44 Our AMA supports seeking common recommendations with other organizations. 7. Our AMA 45 reiterates its longstanding position that all medical care decisions should occur only after 46 thoughtful deliberation between patients and physicians. (CSA Rep. F, A-88; Reaffirmed: Res. 47 506, A-94; Amended: CSA Rep. 16, A-99; Appended: Res. 120, A-02) 48 49 The original iteration of this policy was adopted in 1988, based on the recommendations in Council 50 on Scientific Affairs Report F-A-88.³ The report recommended supporting annual screening

51 mammography in women age 50 and older, and mammography screening every 1-2 years in

women aged 40-49 years.³ The policy was updated in 1999 by CSA Report 16-A-99, which
recommended supporting annual screening mammography in asymptomatic women age 40 years
and older.⁴ In 2002, with the adoption of Resolution 120-A-02, the policy was further amended to
endorse the screening guidelines of ACOG, ACS, and ACR.

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CURRENT MAMMOGRAPHY SCREENING GUIDELINES

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8 Many organizations have developed or endorsed guidelines regarding screening mammography.

9 The Table below summarizes the recommendations of several groups in this country, as well as

those from the Canadian Task Force for Preventive Health Care⁵ and Britain's National Health
 Service.⁶

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The USPSTF recommends routine screening mammography beginning at age 50 years and continuing biennially through age 74 years; the American Academy of Family Physicians (AAFP) endorses the recommendations of the USPSTF.^{2,7} For women aged 40-49 years, the USPSTF (with AAFP endorsing) and the American College of Physicians (ACP) recommend individual patient assessment for breast cancer risk, along with patient education about the benefits and limitations of mammography, as the basis for a decision to screen.^{2,7,8}

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ACOG, ACR, ACS, and NCCN recommend annual routine screening mammography beginning at 20 age 40 years.⁹⁻¹² ACOG, ACS, and NCCN include in their guidelines a recommendation to discuss 21 with women the predictive value of mammography and its limitations.^{9,11,12} ACOG states that 22 based on individual risk, biennial screening may be appropriate for some women.9 ACOG, ACR, 23 ACS, and NCCN guidelines do not specify an age at which screening should end. While NCCN 24 states that the appropriate upper age limit has not yet been determined,¹² ACR recommends 25 continuation until life expectancy reaches less than five to seven years,¹⁰ and ACS recommends 26 continuation as long as the patient is in good health.¹¹ ACOG notes that women 75 years or older 27 should, in consultation with their physicians, decide whether or not to continue mammographic 28

29 screening.⁹

Organization (year recommendation updated)	Age at which <u>routine</u> screening should begin	Frequency	Age at which <u>routine</u> screening should end
AAFP (2009) ^a	50	Biennial	75
ACOG (2011)	40 (with discussion ^c)	Annual (Biennial may be appropriate for some)	Not specified
ACR/SBI ^b (2010)	40	Annual	Life expectancy <5-7 years
ACS (2003)	40 (with discussion ^c)	Annual	As long as patient is in good health
NCCN (2011)	40 (with discussion ^c)	Annual	Not yet established
USPSTF (2009)	50	Biennial	75
CTFPHC (2011)	50	Triennial	75
NHS (2011)	50 (expanding to 47)	Triennial	70 (expanding to 73)

Table: Screening mammography recommendations of several groups. Abbreviations are as follows: AAFP: American Academy of Family Physicians; ACOG: American Congress of Obstetricians and Gynecologists; ACR: American College of Radiology; SBI: Society of Breast Imaging; ACS: American Cancer Society; NCCN: National Comprehensive Cancer Network; USPSTF: United States Preventive Services Task Force; CTFPHC: Canadian Task Force for Preventive Health Care; NHS: National Health Service (Britain)

- a. The AAFP endorses the USPSTF's recommendations
- b. ACR and SBI have joint recommendations.

c. Recommendation includes the discussion of the predictive value and limitations of mammography.

1 A survey of the International Breast Cancer Screening Network shows that 5 of 19 member

2 countries recommend screening beginning at age 40 years, with most screening biennially.¹³ The

3 recommendations of the different countries are, by and large, based on the same data, but reflect a

4 difference of opinion in data interpretation.¹³

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It is important to note that the guidelines discussed in this report are for <u>routine</u> screening
mammography, i.e., mammography for women who are at average risk for breast cancer. They are
not appropriate for women at increased risk due to underlying genetic mutations (such as *BRCA1* or *BRCA2*), family history, previous chest radiation, or other risk factors; guidelines for women at
increased risk are substantially different.^{11,12}

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12 BENEFITS AND HARMS OF SCREENING MAMMOGRAPHY

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Breast cancer is the most common cancer in women in the U.S., with more than 200,000 women 14 15 receiving a diagnosis of invasive breast cancer each year and nearly 40,000 dying.¹⁴ The average woman's lifetime risk of developing breast cancer is 1 in 8, or 12%,¹⁴ however factors such as age, 16 17 family or personal history of cancer, dense breasts, and previous exposure to chest radiography can increase risks.¹⁵ In the U.S., digital mammography has rapidly replaced the older method of film 18 mammography.¹⁶ Though mammography is the most reliable breast cancer screening tool for the 19 20 general population, it carries potential harm along with its benefits. Recommendations regarding 21 screening frequency and age of initiation are based on the balance of benefits and harms.

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23 Benefits of screening mammography

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Mortality reduction. There is wide agreement that screening mammography leads to a reduction in 25 breast cancer mortality,¹⁷ although disagreements exist about how to calculate such reductions. 26 Randomized controlled trials (RCTs) have estimated the reduction in mortality across all age 27 groups to be approximately 15-30%,¹⁸⁻²² while observational and modeling studies have estimated 28 mortality reduction across all age groups to be higher, with a range of 30% to more than 40%.²³⁻²⁶ 29 30 In RCTs, mortality reduction is based on the number of women invited to screen, rather than those 31 who have actually undergone screening in the trial. This "number invited to screen" includes those 32 women who are part of the screening arm of the trial but who decline screening. Those who fit into this category and who also die of breast cancer will be counted in the larger number of women in 33 the screening arm that died of breast cancer.²⁶ Based on this method, noncompliance to the 34 screening protocol potentially underestimates the mortality reduction derived from screening.²⁶ 35 36 Similarly, women who are assigned to the control, non-screening arm sometimes seek mammography on their own, skewing the potential mortality reduction downward.²⁶ 37 38

39 There have been few RCTs designed to determine mortality reduction from mammography 40 screening in specific age groups; estimates have been derived from subanalyses of trials designed 41 for other outcomes. Pooled data from RCT subanalyses show mortality reduction from mammography screening to be greatest in women aged 60-69 years (approximately 32%).¹⁸ For 42 women aged 39-49 years and 50-59 years, pooled data show mortality reduction to be 15% and 43 14%, respectively.^{18,21,27-32} Although these values appear to indicate a similar mortality reduction 44 for both of these age groups, it should be noted that estimated reductions are based on *relative* risk 45 (risk of breast cancer mortality in women of a particular age group who undergo mammography 46 47 versus those in the same age group who do not undergo mammography). Because a woman's risk 48 for breast cancer increases sharply with age, *absolute* mortality risk reduction (reduction in the 49 overall risk of breast cancer mortality) from screening is greater for women aged 50-59 years than that for women aged 40-49 years.^{2,18} Mortality reduction estimates for women age 70 years and 50 older are lacking because of insufficient data.¹⁸ 51

1 Subanalyses of trials designed to estimate benefit across larger age groups, as well as more recent 2 retrospective studies, have shown benefits for women aged 40-49 years who undergo screening 3 mammography.^{21,26,30} Between 40-49 years of age, tumors detected by mammography are smaller 4 with less nodal metastasis (compared to those tumors detected without mammography), and 5-year and disease-free survival are improved.³³ Additionally, a 2010 study showed that mammography 5 6 in women younger than age 50 years with a family history of breast cancer increases cancer detection, reduces risk of advanced stage disease, and is associated with lower mortality and higher 7 8 10-year survival from invasive cancer.³⁴ 9 Based on analyses of breast cancer mortality reduction before and after the implementation of

10 11 screening programs, some argue that the observed reduction is only partially due to screening, with 12 the rest due to improved therapy and management of breast cancer disease and to changes in staging techniques.^{25,35,36} However, this is refuted by others. In regions without formal screening 13 14 but with access to improved treatments, the mortality rate did not decrease until screening was introduced.^{37,38} 15

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It is possible that the mortality reduction associated with screening mammography could be 17 greater. Only approximately 65% of women age 40 years or older report having undergone 18 screening mammography within the last two years.³⁹ Increasing adherence to recommendations 19 could potentially increase the number of women in whom cancer is detected early, leading to 20 greater mortality reduction.^{2,39} 21

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23 Harms of screening mammography

24 Although there is broad agreement that screening mammography reduces mortality from breast 25 26 cancer, it is not a perfect tool. Along with the intended early detection of invasive breast cancer, 27 mammography carries with it potential harms, such as false-positive results, overdiagnosis, and 28 exposure to radiation.

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30 False-positive results. A false positive is defined as an abnormal screening mammography result that does not end in a diagnosis of invasive carcinoma or ductal carcinoma in situ (DCIS) within 31 one year of the screening examination.⁴⁰ The reported specificity of mammography is 94-97%.^{20,41} 32 33 In other words, 94-97% of mammograms correctly rule out the presence of disease in disease-free individuals. Though this specificity appears to be high, it must be considered in the context of the 34 35 number of mammograms performed. More than 33 million screening mammograms are performed in the U.S. each year.⁴² Taking into account the annual incidence of breast cancer (approximately 36 124 cases per 100,000 women),⁴³ the reported specificity implies that every year, approximately 1-37 38 2 million women receive an abnormal mammography result that will turn out not to be breast 39 cancer. Many of these women will undergo further imaging and invasive procedures.⁴⁴

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A 2011 study, designed to address limitations in previous estimates of false-positive rates.⁴⁵⁻⁴⁸ 41 42 found that after 10 years of annual screening, the probability of receiving a recall (recommendation for immediate follow-up imaging) is 61.3%; this probability drops to 41.6% for 10 years of 43 biennial screening.⁴⁴ These estimates are similar whether screening begins at age 40 or 50 years. 44 Older studies report that false-positive mammograms occur in 21-49% of all women after 10 45 mammography examinations, and in up to 56% for women aged 40-49 years.¹⁸ The probability of 46 a false-positive biopsy recommendation (recommendation for biopsy, fine-needle aspiration, or 47

surgical consult after imaging work-up) is 7-9% after 10 years of annual screening and 4-6% after 48

49 10 years of biennial screening.⁴⁴ While biennial screening appears to decrease the probability of a

false-positive mammography result, it may be associated with an increase in the probability of a 1 2 late-stage cancer diagnosis.⁴⁴

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Many women who have been recalled for further screening become distressed, and some report persistent anxiety despite eventual negative results.^{18,49} Others report only transient anxiety.^{18,37}

5 False-positive results appear to affect breast cancer-specific distress, anxiety, apprehension, and 6

- perceived risk rather than general depression and anxiety.^{18,50} 7
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9 False-positive results can also affect adherence to screening recommendations. In a 2011 study, 10 women who received a false-positive result were less likely to return for routine screening compared with women who received negative results.⁵¹ However, reattendance improved with the 11 12 number of completed screening participations, suggesting that abnormal results in younger women 13 (who have completed relatively few screens) are more likely to negatively impact reattendance than in women who have undergone several routine screens.⁵¹ 14

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16 Variation in screening mammography specificity has been noted among physicians and facilities.

For example, recall rates are lower and specificity rates higher among radiologists who have more years of experience interpreting mammograms.^{52,53} Higher specificity is seen at facilities that offer 17

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screening mammography alone (versus those that offer both screening and diagnostic 19

mammography), have a breast-imaging specialist interpreting mammograms, and conduct audit 20

reviews two or more times each year.⁵⁴ AMA policy (H-525.985 Safety and Performance 21

22 Standards for Mammography; see Appendix I) supports high quality standards of performance for

23 those administering and interpreting mammograms, including "evidence of appropriate training and 24 competence for professionals."

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Overdiagnosis. Overdiagnosis is the detection of cancer that would not have clinically surfaced in 26 a person's lifetime, usually because of lack of progressive potential.²⁴ Overdiagnosis is easily 27 confused with false-positive results, i.e., a positive screening result that is subsequently determined 28 29 not to be cancer. In contrast, an overdiagnosis represents a case in which the pathological criteria 30 for cancer has been fulfilled.⁵⁵ Stable disease including some DCIS, indolent cancers, and slowgrowing tumors are thought to be most commonly overdiagnosed by mammography.^{55,56} Some 31

32 reports have concluded that a small percentage of mammography-detected cancers may

spontaneously regress, although others have criticized this assertion.⁵⁶⁻⁵⁸ 33

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35 Evidence for overdiagnosis comes from RCTs designed to demonstrate the benefit of 36 mammography. In these trials, women are randomly assigned to screening mammography and non-screening mammography arms; since the assignments are random, the number of breast 37 cancers that develop over time should be the same in each group.⁵⁹ In the group receiving 38 39 screening mammography, the number of women receiving breast cancer diagnoses will initially be 40 higher than in the non-screening group, since the mammograms will detect tumors too small to be

41 detected otherwise. With time, as the small tumors in women in the non-screening group grow and

42 become detectable, the number of breast cancer diagnoses should become similar to those in the

43 screening group. However, some trials have shown that breast cancer diagnoses in the screening group are persistently higher, even after many years. This persistent difference represents

- 44 overdiagnosis.59 45
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Quantification of overdiagnosis is difficult; it is not ethically possible to set up prospective clinical 47

trials to determine which cancers will remain indolent if left untreated.⁶⁰ Therefore, the proportion 48

49 of mammography-detected breast cancers that are estimated to be overdiagnoses is widely variable,

50 ranging between 1-30%; estimates are derived from screening programs in several countries that

are statistically difficult to combine.¹⁸ Observational and modeling studies have attempted to 51

narrow the range. For example, a 2012 study used data from different geographic regions in 1 2 Norway, where screening mammography began at staggered times over a nine-year period.⁶¹ By 3 comparing breast cancer incidence in regions with a screening program to incidence in regions that 4 had yet not implemented screening, the study estimated that 15-25% of mammography-detected breast cancers were overdiagnoses.⁶¹ Within different age groups, modeling studies have shown 5 only small differences in the rate of overdiagnosis.²¹ In general, the risk for overdiagnosis 6 7 increases with age, likely because in older age groups, rates of competing causes of mortality 8 increase.²⁴ The difficulty in accurately estimating rates of overdiagnosis has led to arguments that 9 the estimates are artificially high, and are complicated by follow-up times, lead-time, and changes in breast cancer incidence over several years.⁶ 10 11 Overdiagnosis is regarded by some as the most serious harm associated with mammography:⁵⁹ at 12 13 the time of diagnosis, clinicians cannot know who has been overdiagnosed, so all are treated for potentially lethal cancer.^{55,56} These patients will not benefit from treatment and almost certainly 14

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A perceived benefit of mammography screening is that it reduces the need for mastectomies and 17 increases the potential for breast-conserving treatment.⁶³ However, a 31% increase in breast 18 surgery and 20% increase in mastectomy for women exposed to screening has been reported.¹⁹ A 19 2011 Norwegian study corroborated these findings, and concluded that overdiagnosis is likely to

20 have contributed to the increases in surgical intervention.^{63,64} Other studies have reported no increase in the rate of mastectomy.^{65,66} 21

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will be harmed.55

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24 Radiation exposure. Little evidence exists to suggest that low-dose radiation exposure from mammography is a significant risk.¹⁸ Widely-ranging cumulative radiation doses of 0.3-43.4 Gy 25 are thought to significantly increase the risk for breast cancer;⁶⁷ the average dose for a bilateral, 26 two-view mammogram is 7 mGy or less,^{68,69} and for women aged 40-49 years, annual 27 mammography screening for 10 years (with potential additional imaging) exposes the individual to 28 approximately 60 mGy.⁶⁷ The number of radiation-induced breast cancer deaths associated with 29 biennial screening between the ages of 50-74 years has been modeled at 1.6 per 100,000 women 30 31 screened. This model also predicts that extending the biennial screening period to women between the ages of 40-74 years results in 3.7 radiation-induced breast cancer deaths per 100,000 women.⁶⁹ 32 These rates are considered negligible, with screening benefits far outweighing the risk of radiation 33 exposure.^{18,69} For comparison, the ratio of breast cancer deaths prevented by mammography to the 34 35 number of deaths induced by radiation exposure is 684:1 for women aged 50-74 years, and 349:1 36 for women aged 40-74 years.⁶⁹

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38 Special consideration of the effects of radiation exposure should be given to women who have 39 previously undergone diagnostic chest radiographs or had therapeutic radiation for other cancers. 40 These women are at increased risk for cancer since cumulative radiation exposure is increased.⁷⁰

THE USPSTF AND ITS RECOMMENDATIONS FOR SCREENING MAMMOGRAPHY

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44 Background

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The mission of the USPSTF is to review the scientific evidence for clinical preventive services and 46 47 to develop evidence-based recommendations for primary care physicians as well as the broader

- health care community.⁷¹ Congress codified the USPSTF as an independent body in 1998. Though 48
- the Agency for Healthcare Research and Quality (AHRQ) is mandated to convene the USPSTF, its 49
- 50 sole role is to support the USPSTF by providing meeting space, organizing conference calls,

managing contracts for systematic reviews, and providing staffing.⁷¹ No individual at AHRQ has a
 vote in the recommendations, or otherwise influences the priorities or decisions of the USPSTF.⁷¹

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4 The USPSTF comprises 16 members who serve terms of 4-6 years; members are appointed by the 5 AHRQ director based on recommendations developed by the USPSTF Chair and Vice-Chair following a public nomination process.⁷¹ Members are experts in primary care and preventive 6 7 health-related disciplines, and collectively possess expertise in evidence-based clinical research, 8 screening, clinical epidemiology, behavioral science, health services research, outcomes and effectiveness in clinical preventive medicine, and decision modeling.⁷¹ The USPSTF does not 9 10 deliberately seek out task force members who are experts on specific topics; experts bring 11 substantial knowledge regarding guideline development processes but also may retain inherent biases.^{72,73} It is sometimes difficult for experts to fairly assess and critique studies that they or their 12 colleagues have conducted, contradict beliefs entrenched since training, and recommend against 13 services that may benefit themselves or their specialties.⁷² Also, many experts in specific topic 14 areas lack training in epidemiology and biostatistics.⁷² The USPSTF is considered unique in that it 15 convenes primary care providers and scientists with skills in objectively critiquing studies without 16 preconceived views or a stake in the outcome.⁷² 17

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The USPSTF follows a detailed protocol for guideline development.⁷⁴ For each topic under consideration, an AHRQ evidence-based practice center conducts a systematic review of the evidence, which enables a subcommittee of the USPSTF to develop estimates of the magnitude and certainty of benefits and harms. These estimates are extensively reviewed by the full USPSTF in order to reach consensus and vote on recommendations. Cost and cost-effectiveness are not considered in the guideline development process.⁷¹ A full explanation of the USPSTF's evidence grading and subsequent recommendation system is published on the USPSTF website.⁷⁴

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Subspecialist experts in the disease at hand, as well as partner organizations, are asked to review and comment on USPSTF work at three points in the recommendation development process: 1. the initial analytic framework and key questions that drive the systematic review; 2. the systematic review itself; and 3. the draft recommendation statement. USPSTF partner organizations that are also members of the AMA Federation of Medicine are AAFP, ACOG, ACP, the American College of Preventive Medicine (ACPM), the American Academy of Pediatrics, and the American Osteopathic Association.

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Recommendations for screening mammography

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Plans for the update of the 2002 USPSTF recommendations on screening mammography began in 37 late 2006. In 2007, the USPSTF commissioned two reviews: a targeted systematic evidence review 38 of the benefits and harms of screening⁷⁵ and a decision analysis based on modeling techniques that 39 40 compared the expected heath outcomes of starting and ending mammography at different ages and using annual and biennial screening strategies.²⁴ The systematic review excluded studies other than 41 RCTs and systematic reviews or those without breast cancer mortality as an outcome.^{18,75} The 42 43 systematic review included analyses of evidence regarding CBE, SBE, digital mammography, and 44 MRI, but this section will focus on the evidence analyzed to develop recommendations on 45 screening mammography.

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47 In its 2009 update, the USPSTF recommended against routine screening mammography for women

48 aged 40-49 years, and instead recommended an individualized decision to screen during this time

- 49 period. This recommendation is partially based on findings in the commissioned systematic
- 50 review.¹⁸ The systematic review was carried out by the Oregon Evidence-based Practice Center,
- 51 funded by AHRQ. Prior to its finalization, the draft report was reviewed by 15 experts not

affiliated with the USPSTF. These reviewers included one oncologist, an expert in modeling, two 1

2 radiologists, one breast surgeon, and three physician/epidemiologists.⁷⁶ The names of the

3 reviewers are included in the full systematic review available on the National Library of Medicine

- 4 website.75
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Mortality reduction was considered an important outcome in the formation of the 6

7 recommendations.² The systematic review estimated the mortality reduction for women aged 39-

8 49 years, 50-59 years, and 60-69 years to be 15%, 14%, and 32% respectively.¹⁸ These estimates

are similar to those established in the USPSTF's 2002 systematic review, but include new data 9

- 10 from an update of a previously completed trial,³⁰ and another clinical trial completed after 2002.^{2,20,31} Since these mortality reduction estimates are based on relative risk, the USPSTF 11
- 12 considered calculations of the number needed to invite for screening to prevent one death from
- 13 breast cancer, which more clearly explains mortality reduction.² The "number needed to screen"
- calculation is based on absolute risk, so it takes into account the background risk for breast 14
- 15 cancer.^{77,78} This number can more clearly reflect the benefit of mammography in each age group
- since it includes the increasing absolute risk of breast cancer with advancing age. The number 16
- needed to invite for screening (to prevent one death) is 1904 for women aged 40-49 years, 1339 for 17
- women aged 50-59 years, and 377 for women aged 60-69 years.² 18
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20 In addition to the mortality reduction benefit associated with mammography, the USPSTF considered harms. In some studies, the probability of receiving a false-positive mammography 21 result is slightly higher in women aged 40-49 years.¹⁸ A false-positive mammography result often 22 23 leads to additional imaging, and after several years participating in a screening program, nearly 10% of women receive a false-positive biopsy recommendation.⁴⁴ Though the range of reported 24 overdiagnosis is large, between 1-30%, and therefore difficult to estimate precisely, it is a risk that 25 many agree is serious, since it leads to treatment that may not be necessary.¹⁸ Radiation exposure 26

was not considered to be a serious risk of screening mammography, except for the small percentage 27

28 of the population previously exposed to chest radiography and therapeutic radiation.⁷⁰ 29 30 The USPSTF-commissioned decision analysis compared the expected health outcomes of starting 31 and ending mammography at different ages and using annual and biennial screening strategies.²⁴

32 For the screening models compared, biennial screening retains 70-99% of the reduction in

mortality that occurs with annual screening, depending on the age range for screening.²⁴ The 33 34 models predict that beginning screening at age 40 years yields an additional 3% mortality benefit

compared with beginning screening at age 50 years.²⁴ This additional mortality benefit is the same 35 with either annual or biennial screening beginning at age 40 years.²⁴ Extending screening to age 79 36

years yields an additional 8% or 7% mortality benefit compared with screening programs ending at 37

age 69 years, for annual and biennial screening, respectively.²⁴ If the two strategies are compared, 38

39 these data indicate that greater mortality reduction could be achieved by continuing screening past 40 age 69 years rather than by initiating it at age 40 years. However, if life-years gained is considered,

41 models show that initiating screening in younger women rather than extending screening in older

42 women results in more benefit; this is not surprising since younger women have longer life

43 expectancies than older women. Annual screening between the 29 year period comprising ages 40-

44 69 years yields a median of 33 life-years gained per 1000 women screened, whereas annual

screening between the 29 year period comprising ages 50-79 years yields a median of 24 life-years 45 gained per 1000 women screened.²⁴ Biennial screening with these parameters yielded 25 and 23.5 46

47 life-years gained in the two groups, respectively.

48

49 The decision analysis also compared the harms associated with different screening models. Annual

50 screening between ages 40-69 years yields 2,250 false positive results for every 1000 women

screened over the 29 year period, almost twice as many as that of a biennial screening period.²⁴ 51

1 Consequently, many more women who are screened annually will undergo biopsy compared with

2 those who are screened biennially.²⁴ The models also predict an increase in the risk of

3 overdiagnosis as age increases. Overall, initiating screening at age 40 years (compared to age 50

4 years) had a smaller effect on overdiagnosis than extending screening beyond age 69 years.²⁴

5 Overdiagnosis risk was smaller with biennial screening, but by less than half.²⁴

6

7 The USPSTF studied the balance of benefits and harms of mammography, as well as the results of 8 the systematic review and the decision analysis study, to develop its final recommendations. It 9 concluded that compared with initiating screening at age 50 years, screening mammography 10 provides a small benefit when performed annually in women aged 40-49 years, but is more likely to be accompanied by false-positives and overdiagnosis, resulting in a smaller net benefit.^{2,71} The 11 ages at which the balance of benefits and harms becomes acceptable to individuals and society are 12 not clearly resolved by available evidence.¹⁹ Because of the small net benefit, the USPSTF 13 concluded that mammography in women aged 40-49 years should not be automatic, but should 14 15 instead be initiated as a result of an individual decision based on the woman's specific clinical situation, preferences, and values regarding the potential benefits and harms.^{2,71} 16

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18 REACTION TO USPSTF RECOMMENDATIONS

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20 The 2009 USPSTF screening mammography recommendations were met with opposition by 21 several medical specialty societies, public advocacy groups and individuals in the medical 22 community. ACR stated that the USPSTF recommendations were "ill-advised" and would result in "countless unnecessary breast cancer deaths each year."^{79,80} ACOG, ACS, the Radiological Society 23 of North America, the Society of Breast Imaging, the American Society of Breast Disease, and 24 other groups also publicly stated opposition to the recommendations.⁸⁰⁻⁸⁴ Most reiterated support 25 of guidelines that recommend routine screening mammography beginning at age 40 years. Several 26 27 publications addressing perceived flaws in the interpretation of data by the USPSTF have appeared in peer-reviewed journals.^{23,26,38,85-88} 28

29

30 Among the criticisms of the USPSTF process was reliance on only RCTs in the evidence review, 31 with the exclusion of additional observational studies showing higher mortality benefit and reduced numbers needed to screen.⁷⁹ Several studies, including some RCTs, did not meet the USPSTF's 32 strict inclusion criteria; others received only a grade of "fair" for their shortcomings.^{74,75} Another 33 criticism was the use of the "number needed to invite for screening" value, rather than the number 34 actually screened.²⁶ The USPSTF reported that the level of participation in the trials was high, and 35 that data from trials with lower participation rates was graded as lower quality.^{71,74,75} The USPSTF 36 also reported that the use of only participating women, rather than those who were merely invited 37 to screen, yielded only a slightly higher benefit.⁷¹ 38

39

40 In contrast to the opposition, several organizations, including those representing primary care

41 physicians and public health providers, expressed public support for the 2009 USPSTF

42 recommendations. In a letter to members of Congress, 11 health care organizations, including the

43 AAFP, ACP, and ACPM defended the recommendations.⁸⁹ The AAFP also joined with four of its

44 affiliate groups to urge the Secretary of the Department of Health and Human Services to reject

45 calls to remove the USPSTF recommendations from the AHRQ website.⁹⁰ Advocacy groups,

46 including the National Breast Cancer Coalition, Breast Cancer Action, and the National Women's 47 Use the Natural also multiple summaries of the USPSTE measurement of the State and State

47 Health Network also publicly supported the USPSTF recommendations.⁹¹⁻⁹³

48

49 Media coverage of the USPSTF recommendations was often controversy-oriented.⁹⁴⁻⁹⁷ A recent

50 study reported that more than half of media reports about the recommendations took an

51 unsupportive stance; nearly 70% of reports included the belief that "delayed screening leads to

more breast cancer and related deaths" or concern over "cost and government rationing of health 1 2 care."⁹⁸ Seventeen percent of the reports took a supportive stance, based on beliefs that "the recommendations were based on science" and that there is "potential harm in mammography."98 3 4 Not surprisingly, laywomen who had, or currently have, breast cancer were angered by the 5 recommendations, strongly believing that mammography saved their lives.⁹⁹ The opinions of 6 women who have not experienced breast cancer also were strongly influenced by media coverage, 7 with women who had viewed commentary that was critical of the USPSTF guidelines more likely 8 to overestimate individual risk for breast cancer and feel uncomfortable about delaying 9 mammography until age 50 years, compared to those who viewed commentary that supported the USPSTF guidelines.¹⁰⁰ 10 11

12 At the time that the recommendations were released, the country was deeply involved in the debate 13 about health care reform. Since the USPSTF is convened by a government agency (AHRQ), several media outlets and others expressed serious concern that the recommendations would be 14 15 binding in government health care policy. Several journal publications expressed the opinion that USPSTF is an "opponent of screening" and that its recommendations were intended to restrict patient access to mammography.^{26,38,86} Others joined in suggesting that the recommendations 16 17 would directly affect costs and insurance coverage for breast cancer screening, and calls were made 18 19 for Congress to intervene. In response, in early December 2009, the Senate passed 2 amendments 20 to its proposed health care reform legislation: one requiring the federal government to effectively 21 ignore the new recommendations, and the other guaranteeing no-cost breast screening for women 22 in their 40s. These provisions were signed into law in 2010 as part of the Affordable Care Act. 23

24 25

INDIVIDUAL AND RISK-BASED SCREENING

The USPSTF is not the first group recommending an individualized, risk-based approach to mammography screening in women aged 40-49 years,⁸ but the attention paid to the mammography recommendation has highlighted consideration of that approach. Individualized screening refers to screening mammography at an age and frequency decided upon by both physician and patient, based on the physician's assessment of patient clinical factors that influence breast cancer risk and the patient's values regarding the balance of benefits and harms of screening mammography.

32

Data suggest that women themselves want to be involved in the decision to initiate screening mammography, and often request specific information prior to their first mammogram, including information about benefits and harms.¹⁰¹ Women acknowledge anxiety about false positives, but show little awareness of overdiagnosis.¹⁰² Physicians have an ethical obligation to educate women with balanced information appropriate to the desire expressed by each patient for such information.¹⁰² Model physician-patient dialogue and patient decision aids have been developed as resources to support the shared decision-making underlying the individualized screening approach.¹⁰³⁻¹⁰⁵

41

42 Some argue that the individualized risk-based screening approach will fall short in effectively 43 detecting early cancer. A large percentage of cancers are diagnosed in women with no apparent 44 risk factors, suggesting that relying on the identification of personal or family risk factors to indicate the need for mammography will miss many cancers that could have been detected by 45 mammography.^{106,107} Also, randomized data are lacking to support a risk-based approach between 46 the ages of 40-49 years since no RCTs have stratified participants by risk.¹⁰⁶ However, there are 47 48 hints that a risk based approach may be effective. In a recent single arm (non-controlled) study, 49 women ages 40-50 years at intermediate risk for breast cancer (those with at least one first-degree 50 relative with breast cancer) who were screened annually had smaller tumors that were less likely to be node-positive when compared to control groups from other studies.³⁴ Additionally, a meta-51

1 analysis and systematic review examining several risk factors found that breast cancer in a first-

 $\frac{2}{108}$ degree relative and extremely dense breasts were associated with increased risk in women ages 40-

- 3 49 years.¹⁰⁸ An accompanying modeling study found that for women with either one of those two
- 4 risk factors, biennial screening mammography beginning at the age of 40 years has the same
- balance of benefits and harms as that for biennial screening mammography beginning at age 50 $\frac{109}{100}$
- 6 years in women without those risk factors.¹⁰⁹
- 7

8 The individualized approach relies heavily on the identification of red flags in a patient's family 9 history, yet many patients do not receive adequate familial cancer risk assessment in the primary care setting.¹¹⁰⁻¹¹³ Further, a patient's family history will change over time as family members' 10 health status changes. Clinically relevant family history changes substantially during early and 11 middle adulthood (between the ages of 30-50 years), particularly for breast cancer.¹¹⁰ If a patient's 12 family history is not updated adequately during those years, risk factors that would indicate a need 13 for more intensive screening will be missed.¹¹⁰ Some physicians also do not follow 14 recommendations for referral of women for high-risk cancer genetic counseling, suggesting that 15 estimation of breast cancer risk by these physicians is faulty.¹¹⁴ This behavior may reflect a 16 misunderstanding of what constitutes "high risk," since definitions are variable.^{2,8,115,116} 17

18

19 GUIDELINE REFORM

20

The controversy stemming from the 2009 USPSTF recommendations has brought attention to the 21 22 process of guideline development. ARHQ's National Guideline Clearinghouse contains close to 23 2,700 clinical practice guidelines, and the number of groups issuing guidelines has proliferated, along with substantially different development methodologies.¹¹⁷ The Clearinghouse was 24 originally created by AHRO in partnership with the AMA and the American Association of Health 25 26 Plans (now America's Health Insurance Plans). With the growth in the number of guidelines being 27 developed, physicians, consumer groups, and other stakeholders have expressed concern about the quality of the processes used to develop guidelines, and the resulting questionable validity of many 28 29 guidelines.^{117,118} Concerns stem from limitations in the scientific evidence base, a lack of 30 transparency in the methodologies used by guideline-developing groups, conflict of interest among 31 guideline-developing group members and funders, and uncertainty regarding how to reconcile conflicting guidelines.¹¹⁷ Additionally, significant variability in the recommendations of guidelines 32 can lead to confusion and frustration on the part of health care providers and patients.¹¹⁹ 33

34

35 Specific to mammography guidelines, a recent study suggests that guideline development reform is 36 needed. The study assessed the quality of guidelines that provide recommendations on mammography screening in asymptomatic women aged 40-49 years, and concluded that both the 37 evidence reviews underlying the guidelines, as well as the guidelines themselves, were of vastly 38 different quality.¹¹⁹ Based on quality assessment instruments, the study assigned an overall 39 40 assessment for use in clinical practice to each of the guidelines. Of the 11 guidelines studied, only three received "strongly recommend" or "recommend" assessments.¹¹⁹ The remaining guidelines 41 were found to have deficiencies in their development processes, and were given "unsure" or 42 "would not recommend" assessments.¹¹⁹ 43

44

In response to concerns that the guideline development process is widely variable, thus leading to guidelines that are variable in quality, the Institute of Medicine (IOM) recently undertook a project to define standards for guideline development.¹¹⁷ The standards, released in Spring 2011, promote the development of unbiased, valid, and trustworthy guidelines that incorporate a grading system for characterizing the quality of evidence and strength of clinical recommendations.¹¹⁹ Standards are focused on establishing transparency, managing conflicts of interest, composition of the

50 are focused on establishing transparency, managing connects of interest, composition of the 51 development group, systematic review use, evidence strength, articulation of recommendations,

external review, and updating.¹¹⁷ The ACS recently announced that it plans to change its guideline 1 2 development process to more closely follow the standards recommended by the IOM.¹²⁰

3 4

CONCLUSIONS

5

6 Mammography is a proven method for detecting breast tumors, with demonstrated reductions in 7 mortality for women who undergo regular screening. The potential for harm exists, which 8 underlies differences in recommendations regarding the frequency and age at which to begin and 9 end screening. Groups developing guidelines have placed different emphasis on these harms, 10 resulting in varied conclusions about whether benefits outweigh the harms, and whether that 11 balance changes in different age groups. The USPSTF carefully considered the balance of harms 12 and benefits while studying this issue, commissioning a systematic evidence review and a 13 modeling study to inform its recommendations. It has endured criticism from those who disagree with its recommendations but has stood by them. The USPSTF and others, some of whom disagree 14 15 with the USPSTF recommendations, have stated that this issue is a case in which qualified and 16 competent physicians and researchers can review and interpret the same evidence but come to different conclusions.^{76,84} 17 18

19 The Council is respectful of the time, expertise, and thought that guideline-developing groups,

20 many of whom are represented in the AMA House of Delegates (HOD), have devoted to the topic 21 of mammography screening. Importantly, all are working toward one goal, to optimize the health 22 outcomes for those with breast cancer and to minimize harms to those without. Previous 23 consideration of this subject in the context of Resolution 509-A-10 revealed deep disagreements 24 within the HOD, but the Council notes that agreements exist as well: that mammography is the best existing tool for the routine detection of breast cancer and that it has its shortcomings. The Council 25 26 also strongly believes that every woman age 40 years or older who wants a screening mammogram 27 and whose physician recommends one should receive one, regardless of her insurance coverage 28 status.

29

30 AMA POLICY CONSIDERATIONS

31

32 The Council has given much thought to the mammography screening policies of the AMA. Most remain valid and important, even in light of the recent controversy following the USPSTF 33 34 recommendations. Mammography screening guidelines themselves regularly undergo review and 35 update processes, and the Council believes that it is appropriate for AMA policies referencing such 36 guidelines to be reviewed and updated as well. Indeed the very policy under consideration, Policy 37 H-525.993 [Mammography Screening in Asymptomatic Women Forty Years and Older], 38 encourages periodic review of its recommendations. There are several parts to this policy, which 39 the Council addresses in turn below.

40

41 Part 1 of H-525.993 states: "Our AMA strongly endorses the positions of the American College of Obstetrics and Gynecology, the American Cancer Society, and the American College of Radiology 42 that all women have screening mammography as per current guidelines." Given the role of the 43 44 AMA in representing hundreds of different medical societies, the Council does not believe it is appropriate to single out support for the guidelines of particular societies. This is not a comment 45 on the content of such guidelines, rather it reflects the equity of all members of the HOD and 46 47 respect for their professional expertise.

48

49 Part 2 of H-525.993 states: "Our AMA favors participation in and support of the efforts of the

50 professional, voluntary, and government organizations to educate physicians and the public

51 regarding the value of screening mammography in reducing breast cancer mortality." The Council

strongly supports educating physicians and the public about mammography, including its value and 1 2 its limitations.

3

4 Part 3 of H-525.993 states: "Our AMA advocates remaining alert to new epidemiological findings 5 regarding age-specific breast cancer mortality reduction following mammography screening." The 6 Council agrees.

7

8 Part 4 of H-525.993 states: "Based on recent summary data our AMA recommends annual 9 screening mammograms and continuation of clinical breast examinations in asymptomatic women 10 40 years and older." The Council recognizes the difficulty faced by guideline-making groups when balancing the proven and quantifiable mortality reduction of screening mammography with the 11 12 nearly impossible task of quantifying harms, including overdiagnosis and anxiety/mental anguish 13 associated with false-positives. Not having undergone the rigorous processes of guideline-making groups (and not equipped to do so), the Council cannot in good faith recommend a frequency and 14 15 specific age at which screening mammography should begin, nor does it believe that the AMA, 16 representing the divergent views of many guideline-making groups who are also members of the 17 HOD, should do so. However, the Council strongly supports the autonomy of physicians and their responsibility to care for patients in a manner in which they believe is appropriate; this includes 18 19 beginning annual mammography at age 40 years when it is believed to be clinically appropriate. 20 Support for clinical breast examination is included in a separate policy, H-525.985 [Safety and Performance Standards for Mammography]. 21

22

23 Part 5 of H-525.993 states: "Our AMA encourages the periodic reconsideration of these 24 recommendations as more epidemiological data become available." The Council agrees.

25

Part 6 of H-525.993 states "Our AMA supports seeking common recommendations with other 26 organizations." The Council is aware that differing recommendations can cause confusion and 27 28 frustration for physicians and patients, and therefore believes that common recommendations are in 29 the best interest of the clinical practice and patients. The Council cites as a best practice the 30 "Consensus Points on Screening Mammography," (see Appendix II) jointly developed by the ACP and ACR to assist physicians and patients in their discussions of mammography.¹²¹ For common 31 recommendations to retain value, it is important that they be based on an approach that is unbiased, 32

33 valid, and trustworthy.

34

35 Part 7 of H-525.993 states: "Our AMA reiterates its longstanding position that all medical care 36 decisions should occur only after thoughtful deliberation between patients and physicians." The Council strongly agrees and notes that this is the foundation of recommendations that advocate an 37 38 individualized approach to screening mammography between the ages of 40-49. Specific to the 39 USPSTF, AMA policy H-410.967 [Guide to Clinical Preventive Services] states that the USPSTF 40 guidelines "...should not take the place of clinical judgment and the need for individualizing care 41 with patients; physicians should weigh the utility of individual recommendations within the context of their scope of practice and the situation presented by each clinical encounter." 42

- 43
- 44 RECOMMENDATIONS
- 45

The Council on Science and Public Health recommends that the following statement be adopted in 46 47 lieu of Resolve 1, Resolution 509-A-10, and the remainder of the report be filed:

48

49 That Policy H-525.993 "Mammography Screening in Asymptomatic Women Forty Years and

50 Older" be amended by insertion and deletion as follows:

S	creening Mammography Screening in Asymptomatic Women Forty Years and Older
<u>0</u>	ur AMA:
1. <u>st</u>	Our AMA a. recognizes the mortality reduction benefit of screening mammography and upports its use as a tool to detect breast cancer. while also recongizing that there are small, but of inconsequential, harms risks associated with it, including false positive results and
0	verdiagnosis.
b. in o' G	Recognizes that as with all medical screening procedures, there are small, but not consequential <u>associated</u> risks including false positive <u>and false negative</u> results and verdiagnosis. strongly endorses the positions of the American College of Obstetrics and ynecology, the American Cancer Society, and the American College of Radiology that all
₩	omen have screening mammography as per current guidelines.
2. aı sc	Our AMA <u>c.</u> favors participation in and support of the efforts of the professional, voluntary, and government organizations to educate physicians and the public regarding the value of creening mammography in reducing breast cancer mortality, as well as its limitations.
3. <u>m</u> €€ r€	Our AMA d. advocates remaining alert to new epidemiological findings regarding screening ammography age-specific breast cancer mortality reduction following mammography preening as well as associated harms, 4. Based on recent summary data our AMA commends annual screening mammograms and continuation of clinical breast examinations
in re	asymptomatic women 40 years and older. 5. Our AMA and encourages the periodic econsideration of these recommendations as more epidemiological data become available.
<u>e.</u> m sc	ammography. Physicians should regularly discuss with their individual patients whether recently mammography is appropriate for them. This discussion should include reminders
al	yout the benefits and harms of mammography, an update of the patient's family history,
<u>e</u>	mideration of other breast cancer risk factors, and the mammography recommendations of
<u>₩</u>	rganizations.
<u>f.</u> ri	encourages physicians to regularly discuss with their individual patients the benefits and
si	tuation given that the balance of benefits and risks will be viewed differently by each patient.
<u>e</u> .	g. encourages physicians to inquire about and update each patient's family history to detect
re	ed flags for herditary cancer, and to consider other education on the identification of risk
fa	ctors for breast cancer, including the value of taking a thorough family history to detect red
fl	ags for hereditary cancer, so that recommendations for screening will be appropriate.
f	h. supports insurance coverage for screening mammography.
6	Our AMA g, i.supports seeking common recommendations with other organizations.
in di	formed and respectful dialogue as guideline-making groups address the similarities and ifferences among their respective recommendations, and adherence to standards that ensure
gı	uidelines are unbiased, valid, and trustworthy.

- 1 7. Our AMA <u>h.j.</u>reiterates its longstanding position that all medical care decisions should
- 2 occur only after thoughtful deliberation between patients and physicians. (Modify HOD Policy)

Fiscal note: Less than \$500

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Appendix I. Relevant AMA Policies on Screening Mammography

H-55.993 Early Detection of Breast Cancer

(1) The AMA supports public education efforts to help women recognize their important role in breast self-examination and to encourage them to report immediately to their physicians any changes that they notice. (2) The AMA encourages physicians to educate their patients in the process of breast cancer detection, emphasizing the technique of self-examination of their breasts. (3) Physicians requesting mammographic examinations should refer their patients to radiologists who use properly functioning equipment that provides the best image resolution at the lowest level of radiation exposure. (4) Physicians are encouraged to recognize the importance of mammography as an effective screening device to detect early breast cancer. (5) The AMA encourages pharmaceutical companies to include in the package and correct techniques of breast self-examination, and which stress the importance of physician breast examinations and appropriate use of screening mammography. (CSA Rep. A, I-83; Reaffirmed: CLRPD Rep. 1, I-93; Res. 501, I-95; Reaffirmed and Modified: CSA Rep. 8, A-05)

H-55.984 Screening and Treatment for Breast and Cervical Cancer

The AMA: (1) supports increased funding for comprehensive programs to screen low income women for breast and cervical cancer and to assure access to definitive treatment; and (2) encourages state and local medical societies to monitor local public health screening programs to assure that they are linked to treatment resources in the public or private sector. (Res. 411, A-92; Reaffirmed: CSA Rep. 8, A-03)

H-55.985 Screening and Education Programs for Breast and Cervical Cancer Risk Reduction

Our AMA supports (1) programs to screen all women for breast and cervical cancer and that government funded programs be available for low income women and (2) the development of public information and educational programs with the goal of informing all women about routine cancer screening in order to reduce their risk of dying from cancer. (Res. 418, I-91; Reaffirmed: Sunset Report, I-01; Reaffirmed: CSAPH Rep. 1, A-11)

D-525.998 Mammography Screening for Breast Cancer

In order to assure timely access to breast cancer screening for all women, our AMA shall advocate for legislation that ensures adequate funding for mammography services. (Res. 120, A-02)

H-525.993 Mammography Screening in Asymptomatic Women Forty Years and Older

1. Our AMA strongly endorses the positions of the American College of Obstetrics and Gynecology, the American Cancer Society, and the American College of Radiology that all women have screening mammography as per current guidelines. 2. Our AMA favors participation in and support of the efforts of the professional, voluntary, and government organizations to educate physicians and the public regarding the value of screening mammography in reducing breast cancer mortality. 3. Our AMA advocates remaining alert to new epidemiological findings regarding age-specific breast cancer mortality reduction following mammography screening. 4. Based on recent summary data our AMA recommends annual screening mammograms and continuation of clinical breast examinations in asymptomatic women 40 years and older. 5. Our AMA encourages the periodic reconsideration of these recommendations as more epidemiological data become available 6. Our AMA supports seeking common recommendations with other organizations. 7. Our AMA reiterates its longstanding position that all medical care decisions should occur only after thoughtful deliberation between patients and physicians. (CSA Rep. F, A-88; Reaffirmed: Res. 506, A-94; Amended: CSA Rep. 16, A-99; Appended: Res. 120, A-02)

H-525.985 Safety and Performance Standards for Mammography

Our AMA actively encourages the development of new activities, and supports the coordination of ongoing activities, to ensure the following: (1) that the techniques used in performing mammograms and in interpreting mammograms meet high quality standards of performance, including evidence of appropriate training and competence for professionals carrying out these tasks; (2) that the equipment used in mammography is specifically designed and dedicated. The performance of mammography imaging systems is assessed on a regular basis by trained professionals; (3) that the American College of Radiology Breast Imaging Reporting and Database System is widely used throughout the United States and that mammography outcome data in this database are used to regularly assess the effectiveness of mammography screening and diagnostic services as they are provided for women in the United States; and (4) regular breast physical examination by a physician and regular breast self-examination should be performed in addition to screening mammography. (BOT Rep. JJ, A-91; Reaffirmed: Sunset Report, I-01; Reaffirmed: CSAPH Rep. 1, A-11)

Appendix II. ACP-ACR Consensus Points on Screening Mammography

- 1. Screening mammography has been shown to decrease the number of deaths from breast cancer in women ages 40-74.
- 2. The benefits and harms associated with screening vary by age, and women will view these benefits and harms differently. Thus, all women should discuss the benefits and harms of breast cancer screening with their primary care provider.
- 3. Breast cancer incidence increases steadily with age. There is no abrupt change in incidence at age 50. Additionally, the outcomes of screening (recall rates, biopsy recommendation rates, and cancer detection rates) also change steadily with increasing age, without any sudden change at the age of 50.
- 4. Younger women have a lower risk of breast cancer but more potential years of life saved by detection and successful treatment.
- 5. Since women over the age of 74 were not included in the randomized, controlled trials, there is no proof that screening saves lives in older women. Decisions about screening in this age group should be individualized and made between a woman and her primary care provider.
- 6. The majority of breast cancers occur in women without major risk factors.
- 7. There are false positive screening studies at all ages that result in women being recalled for additional evaluation that ultimately shows no evidence of cancer. With increasing age, there is a gradual decrease in the percentage of false positives as the incidence of breast cancer increases.
- 8. It is important to note that mammography does not find all cancers, and some cancers that are detected may not be found early enough to result in a cure. If a woman discovers a lump, even after having had a negative mammogram, she should bring it to her doctor's attention. If a clinician remains concerned about a clinically evident finding, even after a negative mammogram, the finding should be evaluated further.
- 9. The primary benefit of screening mammography is a reduction in mortality from breast cancer.
- 10. The potential harms associated with screening mammography include:
 - a. Transient discomfort from the study
 - b. Recall for a false positive mammogram resulting in anxiety and inconvenience; the majority of these are resolved by additional mammographic views and/or ultrasound
 - c. The need for biopsy of a lesion that is ultimately proven to be benign
 - d. Treatment of a cancer that would not have become clinically significant. At present, we are unable to distinguish cancers that have lethal potential from those

that do not, whether or not they are clinically evident or detected by screening mammography. Consequently, all women being evaluated for breast cancer, no matter how it was detected, should be informed that it is possible they may undergo treatment for a cancer that might not have lethal potential.

11. Third-party payers should cover screening mammography for all women ages 40 and above who elect to be screened.