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September 4, 2014

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Bureau of Consumer Protection  
Federal Trade Commission  
600 Pennsylvania Avenue, NW  
Washington, DC 20580

Mary K. Engle  
Associate Director  
Division of Advertising Practices  
Bureau of Consumer Protection  
Federal Trade Commission  
600 Pennsylvania Avenue, NW  
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Dear Ms. Rich and Ms. Engle:

Public Citizen, a consumer advocacy group with more than 350,000 members and supporters nationwide, is writing to request that the Federal Trade Commission (FTC) investigate the advertising and promotional activities of HealthFair, a for-profit company that uses direct-to-consumer marketing to promote inappropriately broad, nonselective cardiovascular disease screening to people across the U.S. There is evidence that the company's advertising and promotional materials contain numerous statements that may be deceptive within the meaning of the Federal Trade Commission Act. These materials make unsubstantiated medical-benefit efficacy claims about HealthFair's cardiovascular disease screening packages and omit information material to consumers regarding the risks of adverse health-related outcomes and financial harms that may result from the screening.

Appendices A and B provide a detailed analysis explaining why the nonselective cardiovascular disease screening programs promoted by HealthFair are medically inappropriate and unethical and can result in avoidable adverse health-related outcomes and financial harms.

### **The FTC's Legal Requirements for Advertising**

Sections 5 and 12 of the FTC Act prohibit advertisements that contain false or misleading representations or material omissions. The FTC Act broadly defines a "false advertisement" as any "advertisement, other than labeling, which is misleading in a material respect," whether through affirmative "representations made or suggested" by the advertisement or through a "fail[ure] to reveal facts material in light of such representations."<sup>1</sup>

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<sup>1</sup> 15 U.S.C. § 55(a)(1).

When assessing whether advertising claims are deceptive, the FTC determines whether there is a “reasonable basis” to support the claims. In explaining the reasonable-basis requirement, the FTC noted the following:<sup>2</sup>

The Commission intends to continue vigorous enforcement of this existing legal requirement that advertisers substantiate express and implied claims, however conveyed, that make objective assertions about the item or service advertised. Objective claims for products or services represent explicitly or by implication that the advertiser has a reasonable basis supporting these claims. These representations of substantiation are material to consumers. That is, consumers would be less likely to rely on claims for products and services if they knew the advertiser did not have a reasonable basis for believing them to be true.[\*] Therefore, a firm’s failure to possess and rely upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act.

[\*] Nor presumably would an advertiser have made such claims unless the advertiser thought they would be material to consumers.

According to the FTC, advertising claims fall into two basic categories for substantiation purposes: *efficacy* and *establishment* claims. An efficacy claim “is a message that a given product successfully performs the advertised benefit, such as preventing or treating a medical condition.”<sup>3</sup> The FTC applies a multifactor analysis, known as the *Pfizer* analysis, “to determine, on a case-by-case basis, the level of substantiation needed for an efficacy claim.”<sup>4</sup> The factors considered in this analysis are: (1) the type of claim; (2) the type of product; (3) the benefits of a truthful claim; (4) the ease of developing substantiation for the claim; (5) the consequences of a false claim; and (6) the amount of substantiation experts in the field would agree is reasonable.<sup>5</sup>

In contrast, an establishment claim “is a message that the advertiser has scientific evidence backing up its efficacy claim.”<sup>6</sup> The FTC does not apply the multifactor *Pfizer* analysis in determining the substantiation needed for these claims: “Instead, [i]f an advertisement represents that a particular claim has been scientifically established, the advertiser must possess a level of proof sufficient to satisfy the relevant scientific community of the claim’s truth.”<sup>7</sup>

The FTC has emphasized that “it is particularly important to enforce substantiation requirements in the area of medical-benefit claims” because “[f]or centuries, many sellers of health products have made highly misleading claims that their products fight particular diseases, and they often cite ostensibly promising medical experiments that turn out to have been flawed or nonprobative. Such claims have nonetheless duped millions of consumers, in part because products sold for

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<sup>2</sup> Federal Trade Commission. FTC policy statement regarding advertising substantiation. March 11, 1983. <http://www.ftc.gov/public-statements/1983/03/ftc-policy-statement-regarding-advertising-substantiation>. Accessed August 26, 2014.

<sup>3</sup> Brief of Respondent FTC, *POM Wonderful LLC v. FTC*. D.C. Cir. No. 13-1060, at 6, filed March 25, 2014. [http://www.ftc.gov/system/files/documents/cases/2014-03\\_pomwonderful\\_dccir\\_ftcoppbrieffinal.pdf](http://www.ftc.gov/system/files/documents/cases/2014-03_pomwonderful_dccir_ftcoppbrieffinal.pdf). Accessed August 26, 2014.

<sup>4</sup> See *In re Pfizer Inc.*, 81 F.T.C. 23 (1972).

<sup>5</sup> *Ibid.*

<sup>6</sup> Brief of Respondent FTC, *POM Wonderful v. FTC*, at 7.

<sup>7</sup> *In re Removatron Int’l Corp.*, 111 F.T.C. 206, 297-99 (1988), *aff’d*, 884 F.2d 1489 (1st Cir. 1989).

their medical benefits are ‘credence goods’ — products whose efficacy consumers cannot easily ascertain before or even after purchasing them.<sup>8</sup>

In the context of dietary supplements, the Commission “will closely scrutinize the scientific support that an advertiser cites as substantiation for a disease claim—i.e., for an advertisement that suggest[s], either directly or indirectly, that a product will provide a disease benefit.”<sup>9</sup> The FTC “usually requires two well-controlled clinical tests” to substantiate generalized claims that scientific evidence supports a product’s purported medical benefits.<sup>10</sup> The FTC has extended that substantiation requirement to simple efficacy claims.<sup>11</sup>

The FTC is well aware that disease efficacy claims that are inadequately substantiated and inadequately qualified can harm consumers both financially and medically. With respect to financial harms, the Commission has noted that “like victims of any marketing fraud, consumers deceived into believing that a product will help prevent or treat diseases are more likely to buy the product and pay a premium for it than if they knew the whole truth.”<sup>12</sup> Both financial and medical concerns independently justify the FTC’s long-standing insistence on rigorous scientific evidence for disease claims.

### **Public Citizen’s Assessment of HealthFair’s Advertising**

Our review and analysis of HealthFair’s current website and recent print solicitations mailed directly to consumers’ homes found numerous medical-benefit efficacy claims that we believe to be deceptive because they are not substantiated by the level of evidence widely accepted in the medical community and by the FTC as necessary to support such claims: rigorous scientific evidence from well-controlled clinical tests of the company’s cardiovascular disease screening tests in the broad consumer population targeted by HealthFair. The most egregious claims in this regard are those explicitly stating or strongly implying that the cardiovascular disease screening packages offered by the company save lives, extend life, and prevent heart attacks and strokes. Key examples of such statements include the following:

- *HealthFair has performed over 1,000,000 screenings nationwide since 1998 and has saved thousands of lives.* (joint solicitation letter from INOVA and HealthFair mailed directly to consumers’ homes in July 2014; copy enclosed)
- *The INOVA Heart and Vascular Institute has teamed up with HealthFair to bring these life-saving screenings to your neighborhood. ... We’ve performed over 1,000,000 screenings since 1998, and have helped save thousands of lives.* (trifold insert accompanying joint solicitation letter from INOVA and HealthFair mailed directly to consumers’ homes in July 2014; copy enclosed)
- *How long has HealthFair offered these health testing services? HealthFair’s health screenings have been offered since 1998 with over 500,000 people tested and hundreds of*

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<sup>8</sup> Brief of Respondent FTC, *POM Wonderful v. FTC*, at 7-8.

<sup>9</sup> FTC, *Dietary Supplements: An Advertising Guide for Industry*, at 1 (Apr. 2001).

<sup>10</sup> *In re Thompson Med. Co.*, 791 F.2d 189, 194 (D.C. Cir. 1984).

<sup>11</sup> *Id.*, at 195-96.

<sup>12</sup> Brief of Respondent FTC, *POM Wonderful v. FTC*, at 10.

*lives saved. Starting with one vehicle and one mission—to offer life-saving health screenings to communities around the nation at an affordable rate—HealthFair now operates a nationwide fleet of mobile health testing units.*

(<http://healthfair.com/resources/faq>, accessed September 2, 2014; copy enclosed)

- *Early detection with abdominal aortic aneurysm screenings are the key to successful treatment and a longer life.* (<http://healthfair.com/health-screenings/screenings/abdominal-aortic-aneurysm>, accessed September 2, 2014; copy enclosed)
- *How to avoid a heart attack or stroke. ... Get a health screening.* (cover of trifold insert accompanying joint solicitation letter from INOVA and HealthFair mailed directly to consumers' homes in July 2014; copy enclosed)
- *Think an annual checkup is enough? Ultrasound technology looks inside your arteries to identify health problems your doctor may not see, before symptoms even show. Don't wait until you have a stroke. PREVENT IT with an ultrasound screening today.* (flyer accompanying joint solicitation letter from INOVA and HealthFair mailed directly to consumers' homes in July 2014; copy enclosed)
- *HealthFair screens over 100,000 people per year and every week we hear from people who first learned about potentially urgent conditions because of our services. This adds up to nearly 1,000 heart attacks and strokes prevented every year.* (<http://healthfair.com/response-to-public-citizen-criticism>, accessed September 2, 2014; copy enclosed)

These statements claim that HealthFair's cardiovascular screenings have saved thousands of lives since 1998 and prevent approximately 1,000 heart attacks and strokes annually. More broadly, such statements misleadingly imply that HealthFair's cardiovascular disease screenings save lives and prevent heart attacks and strokes when used in unselected, asymptomatic individuals in the general population age 45 or older, regardless of their cardiovascular risk factor profile, which is the very consumer population targeted by HealthFair. We are not aware of any rigorous scientific evidence from well-controlled clinical tests substantiating such claims.

Instead, to back up claims that its cardiovascular disease screening tests save lives and prevent strokes and heart attacks, HealthFair appears to rely on testimonials and anecdotal reports from a small subset of people who were screened by the company, were found to have purportedly critical cardiovascular abnormalities, subsequently underwent some type of medical intervention, and survived without experiencing a heart attack or stroke (see testimonials at <http://healthfair.com/healthfair-stories/testimonials>, including, for example, those at <http://healthfair.com/healthfair-has-life-saving-services> and <http://healthfair.com/the-scan-found-the-beginnings-of-plaque-in-the-arteries-in-my-neck>, accessed September 2, 2014; copies enclosed). Such testimonials and reports from screened individuals fall far short of the level of evidence necessary to demonstrate that these cardiovascular screening tests are life-saving.

Substantiation of claims that disease screening tests save lives and prevent heart attacks and strokes requires well-designed, prospective, randomized controlled clinical trials comparing

long-term mortality, heart attack, and stroke rates in people who are screened with those in people who are not screened. With respect to HealthFair's claims about its nonselective cardiovascular disease screening tests, such evidence does not exist. And without that evidence, the efficacy claims made by HealthFair are misleading because they state as fact propositions that have not been proven.

Examples of other types of misleading statements found on HealthFair's current website and in its online promotional materials are presented in Appendix C.

In addition, HealthFair's advertising and promotional materials are further misleading because they omit important information material to consumers about (a) the type of individuals for whom particular cardiovascular screening tests are clinically indicated; (b) evidence-based guidelines describing if and when such tests should be performed; and (c) the risks of cardiovascular disease screening — particularly indiscriminate screening, as promoted by HealthFair — including the risks of adverse health-related outcomes and financial harms that can result from false-positive test results and from overdiagnosis (see Appendices A and B).

### **Requested Action**

In summary, the inclusion of unsubstantiated medical-benefit efficacy claims about HealthFair's cardiovascular disease screening tests, combined with omissions of material information regarding the risks of these tests and the evidence-based guidelines describing their appropriate use, makes the company's advertising and promotional materials deceptive. The company has relied on such materials to successfully dupe large numbers of consumers across the country into undergoing unnecessary and inappropriate cardiovascular disease screening tests, exposing them to risks of adverse health-related outcomes and financial harms.

We therefore urge the FTC to investigate HealthFair's advertising practices over the past 15 years and demand that the company provide rigorous scientific evidence from well-controlled clinical tests to substantiate its numerous medical-benefit efficacy claims. The Commission should also assess other affirmative statements, such as those identified in Appendix C, and the omissions of material information discussed above that further contribute to HealthFair's advertising and promotional materials being misleading. If your investigation finds these materials to be deceptive, we urge you to require that the company reimburse the hundreds of thousands of consumers who have purchased unnecessary HealthFair cardiovascular disease screenings because of those materials.

Please note that this letter is posted on Public Citizen's website, and you may publicly identify us as complainants in this matter to HealthFair or to any other parties.

Thank you for your prompt attention to this important patient safety and public health issue.

Sincerely,

Michael A. Carome, M.D.  
Director  
Public Citizen's Health Research Group

Sidney M. Wolfe, M.D.  
Founder and Senior Adviser  
Public Citizen's Health Research Group

Enclosures: HealthFair-INOVA print solicitation materials  
Referenced HealthFair webpages

## Appendix A

### Key Problems With the Cardiovascular Disease Screening Offered by HealthFair and its Partners

- (1) There is widespread consensus among medical experts that the basic package of six cardiovascular disease screening tests advertised by HealthFair<sup>13</sup> is not appropriate for unselected, asymptomatic individuals in the general population and is more likely to cause harm than to provide benefit.**

None of the current evidence-based guidelines issued by major medical professional organizations for the appropriate use of these six tests supports the type of widespread screening of asymptomatic individuals promoted and provided by HealthFair for any one of these tests individually, let alone together as a package (see Appendix B for further elaboration).

- (2) The promotion of this screening relies on fearmongering — scaring healthy individuals about their future health.**

HealthFair, like many other companies offering health screening tests directly to consumers, seeks to prompt asymptomatic individuals for whom screening for asymptomatic cardiovascular disease is *not clinically indicated* to undergo screening by using inappropriate direct-to-consumer advertisements and solicitations that target consumer fear about having undetected, potentially life-threatening disease.<sup>14</sup> Examples of such statements found on HealthFair’s website include the following:

- “HealthFair offers a range of appropriately-targeted health screening tests to identify **potential threats to your health**. Our health screening tests help **identify abnormalities that may lead to a heart attack, stroke, aneurysm and cancer**.”<sup>15</sup> [Emphasis added]
- “We offer more than 30 preventive tests that can help **identify hidden health abnormalities** and convey these discoveries to the consumers and their physicians for follow-up care.”<sup>16</sup> [Emphasis added]
- “Most abdominal aortic aneurysms are asymptomatic, not detectable on physical examination, and **silent until discovered during a screening test. The danger lies in the risk of the aneurysm rupturing; ruptured abdominal aortic aneurysms have a greater than 90 percent mortality rate**.”<sup>17</sup> [Emphasis added]

<sup>13</sup> HealthFair. Basic package. <http://healthfair.com/health-screenings/packages/basic-package>. Accessed September 2, 2014.

<sup>14</sup> Lovett KM, Liang BA. Direct-to-consumer cardiac screening and suspect risk evaluation. *JAMA*. 2011;305(24):2567-2568.

<sup>15</sup> HealthFair. Homepage. <http://healthfair.com/>. Accessed September 2, 2014.

<sup>16</sup> HealthFair. Letter from the president: Who is HealthFair? <http://healthfair.com/letter-from-the-president-who-is-healthfair>. Accessed September 2, 2014.

<sup>17</sup> HealthFair. Abdominal aortic aneurysm [sic]. <http://healthfair.com/health-screenings/screenings/abdominal-aortic-aneurysm>. Accessed September 2, 2014.

- “A carotid ultrasound can detect a blockage or narrowing of your carotid arteries so you can seek the required medical intervention **to prevent a stroke from occurring, saving you devastating, irreversible affects [sic] to your quality of living.**”<sup>18</sup>  
[Emphasis added]

**(3) For many people, false-positive test results from this screening lead to unfounded anxiety and additional unnecessary, risky, and costly diagnostic procedures and treatment interventions.**<sup>19,20</sup>

Because this screening is performed broadly on *unselected, predominantly asymptomatic populations* (i.e., those not at significant risk), many people will have false-positive test results. False-positive results can cause unfounded anxiety and lead to additional diagnostic procedures and treatments, exposing screened individuals to additional risk of physical harm, without providing offsetting benefits.

In addition to physical and psychological harms, false-positive results from medically inappropriate screening tests also cause financial harms to the people screened and others. Unnecessary costs are borne *directly* by the screened patients/consumers for the initial screening and for some of the unnecessary follow-up testing and treatment interventions. Additionally, *indirect* cost to the broader insured population results from insurance companies passing on the costs of superfluous follow-up testing and treatment via increased premiums.

**(4) Screening unselected, asymptomatic people will lead to *overdiagnosis*, which occurs when individuals are diagnosed with conditions that will never cause symptoms or death.**

Some individuals undergoing inappropriate screening will have certain true-positive abnormal results, leading to the diagnosis of conditions that will never cause symptoms or death, a problem known as overdiagnosis.<sup>21</sup> As with false-positive test results, overdiagnosis leads to unnecessary anxiety and unnecessary medical interventions. For example, imaging tests, such as the ultrasound cardiovascular disease screening tests offered by HealthFair, can detect abnormalities that for many people are minor and not destined to ever progress to causing symptoms or death; these people cannot benefit from treatment. In fact, they can only be harmed. When healthy people are systematically encouraged to get screened, overdiagnosis and the problems caused by it are made worse.<sup>22</sup>

<sup>18</sup> HealthFair. Carotid artery ultrasound. <http://healthfair.com/health-screenings/screenings/carotid-artery>. Accessed September 2, 2014.

<sup>19</sup> Lovett KM, Liang BA. Direct-to-consumer cardiac screening and suspect risk evaluation. *JAMA*. 2011;305(24):2567-2568.

<sup>20</sup> Perry S. Buyer beware on ‘direct-to-consumer’ health screenings. March 21, 2012. *MinnPost*. <http://www.minnpost.com/second-opinion/2012/03/buyer-beware-direct-consumer-health-screenings>. Accessed August 21, 2014.

<sup>21</sup> Welch HG, Schwartz LM, Woloshin S. *Overdiagnosed: Making People Sick in the Pursuit of Health*. 1st ed. Boston, MA: Beacon Press; 2011: at *xiv*.

<sup>22</sup> *Ibid*: page 44.



**(5) The promotion and provision of this screening is *unethical*.**

First, it is exploitative for HealthFair and its hospital partners to profit from the promotion of medically nonbeneficial testing through the use of misleading advertisements and solicitations that play on people's fear. Second, this screening violates the ethical principles of beneficence (the duty to promote good and act in the best interest of the patient and the health of society) and nonmaleficence (the duty to do no harm to patients).<sup>23,24</sup> Finally, direct-to-consumer promotional materials for screening tests that fail to disclose published guidelines on recommended indications for these tests, as well as the risks of harm, violate the ethical principle of respect for persons and patient autonomy (the duty to protect and foster a patient's free, uncoerced choices).<sup>25,26</sup>

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<sup>23</sup> Wallace EA, Schumann JH, Weinberger SE. Ethics of commercial screening tests. *Ann Intern Med.* 2012;157(10):747-748.

<sup>24</sup> Snyder L, American College of Physicians Ethics, Professionalism, and Human Rights Committee. American College of Physicians Ethics Manual: sixth edition. *Ann Intern Med.* 2012;156(1):73-104.

<sup>25</sup> Wallace EA, Schumann JH, Weinberger SE. Ethics of commercial screening tests. *Ann Intern Med.* 2012;157(10):747-748.

<sup>26</sup> Snyder L, American College of Physicians Ethics, Professionalism, and Human Rights Committee. American College of Physicians Ethics Manual: sixth edition. *Ann Intern Med.* 2012;156(1):73-104.

## Appendix B

### Assessment of Cardiovascular Disease Screening Tests Offered by HealthFair

HealthFair offers four cardiovascular disease screening packages, all of which include the following six tests: echocardiogram, electrocardiogram, carotid artery ultrasound, abdominal aortic aneurysm ultrasound, hardening of the arteries test, and peripheral arterial disease test.<sup>27</sup> An advertisement on the HealthFair website describing these screening packages misleadingly notes the following:<sup>28</sup>

Preventive health screenings are very useful in early detection of all types of illnesses and risk factors. HealthFair mobile health clinics offer a variety of comprehensive health screening tests that are **simple to understand, convenient and save you money.**

Along with individual health screening tests, HealthFair offers 4 health screening packages. Packaging our screenings together not only provides you with a more **comprehensive** understanding of your health, but also **saves you money.**

[Emphasis in original]

Print solicitation materials promoting HealthFair’s cardiovascular disease screening tests that are mailed directly to consumers homes mischaracterize these tests as “life-saving.”

The basic package, which includes only the six screening tests noted above, has previously been “valued at \$2,300” but offered at what is put forth as a bargain basement price of \$179.<sup>29</sup>

As discussed below, a review of current evidence-based guidelines and relevant scientific literature fails to provide support for use of these six tests — individually or together as a package — for widespread screening of asymptomatic individuals in the general population. For many individuals, the risks of harm outweigh the benefits of the testing. Moreover, since the tests are not clinically indicated for most people being screened, and since many people will undergo additional unnecessary testing, these screening packages will not likely save money.

Although the following screening tests sound appealing, each one either: (a) clinically benefits only appropriately selected high-risk groups of patients (rather than *all* adults); or (b) has not been scientifically proven to provide any clinically meaningful benefit to anyone. Widespread and indiscriminate use of these tests is likely to be harmful to large numbers of individuals in the general, asymptomatic population by yielding a significant number of false-positive test results, leading to subsequent unnecessary diagnostic procedures and treatments, associated adverse effects of those procedures and treatments, and unwarranted anxiety in tested individuals. In addition, some individuals undergoing inappropriate screening will have true-positive abnormal results, but the abnormalities found will never cause symptoms or death, leading to overdiagnosis.

<sup>27</sup> HealthFair. Screening packages. <http://healthfair.com/health-screenings/packages>. Accessed September 2, 2014.

<sup>28</sup> *Ibid.*

<sup>29</sup> HealthFair. Basic package. <http://healthfair.com/health-screenings/packages/basic-package>. Accessed September 2, 2014.

## A. Echocardiogram:

The HealthFair online promotional advertisement states:

**Echocardiogram (ECHO):** Echocardiograms are considered to be one of the most accurate, non-invasive screening tests to obtain information about heart disease prevention, including: size and strength of contractions, valve function, and fluid around the heart.<sup>30</sup>

However, several major medical professional organizations affirmatively recommend *against* indiscriminate screening with echocardiograms in low-risk, asymptomatic individuals, and we are not aware of any major medical professional organization that endorses such screening.

In 2010, the American College of Cardiology Foundation (ACCF) and American Heart Association (AHA) issued evidence-based practice guidelines on the use of echocardiograms to assess apparently healthy, asymptomatic adults for risk of developing cardiovascular events associated with atherosclerotic vascular disease.<sup>31</sup> The guidelines were developed in collaboration with the American Society of Echocardiography, American Society of Nuclear Cardiology, Society of Atherosclerosis Imaging and Prevention, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance. The ACCF/AHA practice guidelines state that echocardiography is not recommended for cardiovascular risk assessment of coronary heart disease in asymptomatic adults without hypertension because such testing provides no benefit. The ACCF/AHA guidelines separately note that echocardiography to detect left ventricular hypertrophy (enlargement of the left ventricle) may be considered in asymptomatic adults with hypertension, but additional studies are needed.

In 2011, the ACCF, American Society of Echocardiography, AHA, American Society of Nuclear Cardiology, Heart Failure Society of America, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Critical Care Medicine, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance issued evidence-based appropriate use criteria for using echocardiograms for a variety of possible indications.<sup>32</sup> For each indication, these organizations classified the use of echocardiograms into one of the following three categories:

- **Appropriate:** The test is one in which the expected incremental information, combined with clinical judgment, exceeds the expected negative consequences — including the risks of the procedure itself and the downstream impact of poor test performance such as delay in diagnosis (false-negatives) or inappropriate diagnosis (false-positives) — by a

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<sup>30</sup> HealthFair. Basic package. <http://healthfair.com/health-screenings/packages/basic-package>. Accessed September 2, 2014.

<sup>31</sup> Greenland P, Alpert JS, Beller GA, et al. 2010 ACCF/AHA guideline for assessment of cardiovascular risk in asymptomatic adults: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2010;122(25):2748-2764.

<sup>32</sup> Douglas PS, Garcia MJ, Haines DE, et al. ACCF/ASE/AHA/ASNC/HFSA/HRS/SCAI/SCCM/SCCT/SCMR 2011 Appropriate Use Criteria for Echocardiography. A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force. *J Am Soc Echocardiogr*. 2011;24(3):229-267.

sufficiently wide margin for the specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication.

- **Uncertain:** The test *may* be generally acceptable and *may* be a reasonable approach for the specific indication; uncertainty also implies that more research and/or patient information is needed to classify the indication definitively.
- **Inappropriate:** The test *is not* generally acceptable and *is not* a reasonable approach for the specific indication.

These organizations classify use of echocardiograms as *inappropriate* for the following indications:

- Initial evaluation of ventricular function (for example, screening) with no symptoms or signs of cardiovascular disease.
- Routine evaluation of systemic hypertension without symptoms or signs of hypertensive heart disease.

The appropriate use criteria for use of echocardiograms are mostly based on expert consensus and observational data, because data from randomized clinical trials testing the usefulness of echocardiography-guided management compared with non-echocardiography-guided management are unavailable for most indications.<sup>33</sup>

Results of a randomized clinical trial published in 2013 provide additional evidence that strongly bolsters the 2011 appropriate use criteria classification of echocardiograms as inappropriate for evaluating asymptomatic individuals. As part of a large prospective cohort study of cardiovascular disease conducted in Norway, 6,861 adults age 55 to 74 were randomly assigned to a screening group (n = 3,272) that underwent echocardiograms or to a control group (n = 3,589) that did not undergo screening echocardiograms. Both groups received usual medical follow-up and care.<sup>34</sup> Approximately 60 percent of subjects in each group had hypertension. During 15 years of follow-up, there was no significant difference between the two groups in all-cause mortality, the primary outcome measure (26.9 percent in the screening group and 27.6 percent in the control group). Furthermore, no significant differences were observed for various secondary outcomes, including the incidence of sudden death, death from any heart disease, myocardial infarction (heart attack), and stroke.

Thus, screening for structural or valvular heart disease with echocardiograms in the general, asymptomatic population has *not* been shown to significantly improve clinical outcomes, and numerous medical professional organizations strongly recommend against such screening.

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<sup>33</sup> Michos ED, Abraham TP. Echoing the appropriate use criteria: the role of echocardiography for cardiovascular risk assessment of the asymptomatic individual. *JAMA Intern Med.* 2013;173(17):1598-1599.

<sup>34</sup> Lindekleiv H, Løchen ML, Mathiesen EB, et al. Echocardiographic screening of the general population and long-term survival: a randomized clinical study. *JAMA Intern Med.* 2013;173(17):1592-8.

## B. Electrocardiogram:

The HealthFair online promotional advertisement states:

**Electrocardiogram (ECG or EKG):** An EKG provides a picture of the electrical activity responsible for the heart's cycle of contraction and relaxation. It provides doctors with information such as heartbeat irregularity and heart enlargement.<sup>35</sup>

HealthFair advertises elsewhere online that ECG testing can “predict a pending heart attack.”<sup>36</sup>

However, the U.S. Preventive Services Task Force (USPSTF) and American Academy of Family Physicians (AAFP) recommend *against* indiscriminate screening with ECG in low-risk, asymptomatic individuals, and we are not aware of any major medical professional organization that endorses such screening. This is true whether the screening is for arrhythmia, as suggested above, or for coronary artery disease to assess an increased risk of heart attack.

In 2012, the USPSTF issued an evidence-based grade D recommendation *against* screening with resting (or exercise) ECG for the prediction of coronary heart disease events in asymptomatic adults at low risk for such events. A grade D recommendation means the USPSTF recommends against the screening test based on a conclusion that there is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefit. In making its grade D recommendation against ECG screening in asymptomatic, low-risk adults, the USPSTF concluded with moderate certainty that the potential harms of screening for coronary heart disease with resting (or exercise) ECG equal or exceed the potential benefits in asymptomatic adults at low risk for coronary heart disease events.<sup>37</sup> It noted, in particular, the following:

For asymptomatic adults at low risk for [coronary heart disease] events, a resting or exercise ECG is unlikely to provide additional information about [coronary heart disease risk] beyond that obtained with conventional [coronary heart disease] risk factors (that is, Framingham risk factors) and result in changes in risk stratification that would prompt interventions and ultimately reduce [coronary heart disease]-related events. False-positive results may cause harms in low-risk asymptomatic adults...

### Potential Harms

In all risk groups, an ECG abnormality (as a result of a true- or false-positive result) can lead to invasive confirmatory testing and treatments that have the potential for serious harm, including unnecessary radiation exposure and the associated risk for cancer. Studies report that up to 3% of asymptomatic patients with an abnormal exercise ECG result receive angiography and up to 0.5% undergo revascularization, even though revascularization has not been shown to reduce [coronary heart disease] events in asymptomatic persons. Angiography and revascularization are associated with risks,

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<sup>35</sup> HealthFair. Basic package. <http://healthfair.com/health-screenings/packages/basic-package>. Accessed September 2, 2014.

<sup>36</sup> HealthFair. Electrocardiogram. <http://healthfair.com/health-screenings/screenings/electrocardiogram>. Accessed September 2, 2014.

<sup>37</sup> Moyer VA; U.S. Preventive Services Task Force. Screening for coronary heart disease with electrocardiography: U.S. Preventive Services Task Force recommendations statement. *Ann Intern Med.* 2012;157(7):512-518.

including bleeding, contrast-induced nephropathy, and allergic reactions to the contrast agent.

### **Current Practice**

Screening with resting or exercise ECG in low-risk patients is not recommended by any organization. ...

### **Costs**

Although the cost of resting ECG may be low, the downstream costs of resulting diagnostic testing and treatments can be substantial.

In 2012, the USPSTF also concluded that the current evidence is insufficient to assess the balance of benefits and harms of screening with resting (or exercise) ECG for the prediction of coronary heart disease events in asymptomatic adults at intermediate or high risk for coronary heart disease events.<sup>38</sup>

In 2012, the AAFP, following the lead of the USPSTF, issued a grade D recommendation *against* screening with resting (or exercise) electrocardiography for the prediction of coronary heart disease events in asymptomatic adults at low risk for such events.<sup>39</sup> The AAFP likewise concluded that the current evidence is insufficient to assess the balance of benefits and harms of screening with resting (or exercise) ECG for the prediction of coronary heart disease events in asymptomatic adults at intermediate or high risk for coronary heart disease events.<sup>40</sup>

In 2010, the ACCF and AHA issued evidence-based practice guidelines on the use of resting ECGs to assess cardiovascular disease risk in asymptomatic adults.<sup>41</sup> The guidelines were developed in collaboration with the American Society of Echocardiography, American Society of Nuclear Cardiology, Society of Atherosclerosis Imaging and Prevention, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance. The ACCF/AHA practice guidelines state that a resting ECG is reasonable for cardiovascular risk assessment in asymptomatic adults with hypertension or diabetes, although this was assigned level C, the lowest estimate of certainty of a treatment effect. The ACCF/AHA practice guidelines also state that a resting ECG *may be considered* for cardiovascular risk assessment in asymptomatic adults without hypertension, a guideline that was also assigned a level C for the estimate of certainty of treatment effect. This falls far short of recommending the type of widespread screening of asymptomatic individuals promoted by HealthFair.

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<sup>38</sup> *Ibid.*

<sup>39</sup> American Academy of Family Physicians. Clinical preventive service recommendation:coronary heart disease. 2012. <http://www.aafp.org/patient-care/clinical-recommendations/all/coronary-heart-disease.html>. Accessed June 7, 2014.

<sup>40</sup> *Ibid.*

<sup>41</sup> Greenland P, Alpert JS, Beller GA, et al. 2010 ACCF/AHA guideline for assessment of cardiovascular risk in asymptomatic adults: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2010;122(25):2748-2764.

In conclusion, performance of screening ECGs in asymptomatic individuals has *not* been shown to significantly improve clinical outcomes, key medical professional organizations recommend against such screening, and no organizations endorse indiscriminate widespread screening.

### C. Stroke/Carotid Artery Ultrasound:

The HealthFair online promotional advertisement states:

**Stroke/Carotid Artery Ultrasound:** A carotid artery ultrasound is a painless test that uses high-frequency sound waves to generate images of the interior of your carotid arteries. An accumulation of plaque in your carotid arteries is a good indicator of a risk of stroke.<sup>42</sup>

This screening test looks for stenosis (narrowing) of the carotid arteries, which can be a risk factor for stroke.

However, several major medical professional organizations affirmatively recommend *against* indiscriminate screening with carotid artery ultrasounds in low-risk, asymptomatic individuals, and we are not aware of any major medical professional organization that endorses such screening.

Good evidence indicates that although stroke is a leading cause of death and disability in the United States, a relatively small proportion of all disabling, unheralded strokes are due to carotid artery disease. Studies also suggest that only about 1% of the general population older than 65 has severe carotid artery stenosis (60% to 90% narrowing).<sup>43</sup> Carotid artery stenosis is more prevalent in older adults, smokers, those with hypertension, and those with heart disease; unfortunately, research has not found any single risk factor or clinically useful risk stratification tool that can reliably and accurately distinguish people who have clinically important carotid artery stenosis from those who do not.<sup>44</sup>

In 2006, the AHA and the American Stroke Association issued a series of evidence-based guidelines for the primary prevention of ischemic stroke.<sup>45</sup> The value of the guidelines was affirmed by the American Academy of Neurology. Although the guidelines did not include a specific recommendation about screening the general population for asymptomatic carotid stenosis, they did state the following:

Although highly selected patients may benefit, screening of general populations for asymptomatic carotid stenosis is unlikely to be cost-effective. The cost-effectiveness of even a one-time screening approach would be highly dependent on the ability to identify a group of persons with a high pretest likelihood of having high-grade asymptomatic

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<sup>42</sup> HealthFair. Basic package. <http://healthfair.com/health-screenings/packages/basic-package>. Accessed September 2, 2014.

<sup>43</sup> U.S. Preventive Services Task Force. Screening for carotid artery stenosis: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med.* 2007;147(12):854-859.

<sup>44</sup> *Ibid.*

<sup>45</sup> Goldstein LB, Adams R, Alberts MJ, et al. Primary prevention of ischemic stroke: a guideline from the American Heart Association/American Stroke Association Stroke Council. *Stroke.* 2006;37(6):1583-633.

disease, the availability of a screening test with a very high sensitivity and specificity when used on a side-scale basis, and very low perioperative complication rates.

As discussed below, these conditions for cost-effective screening are not met for carotid artery ultrasound screening of asymptomatic individuals in the general population.

In 2007, the USPSTF issued an evidence-based grade D recommendation, *against* screening for asymptomatic carotid artery stenosis in the general population.<sup>46</sup> In making this a grade D recommendation, the USPSTF concluded with moderate certainty that for individuals with asymptomatic carotid artery stenosis, the benefits of screening do not outweigh the harms. It noted, in particular, the following:

### **Importance**

Good evidence indicates that although stroke is a leading cause of death and disability in the United States, a relatively small proportion of all disabling, unheralded strokes is due to [carotid artery stenosis].

### **Detection**

The most feasible screening test for severe [carotid artery stenosis] (for example, 60% to 99% stenosis) is duplex ultrasonography. Good evidence indicates that this test has moderate sensitivity and specificity and yields many false-positive results. A positive result on duplex ultrasonography is often confirmed by digital subtraction angiography, which is more accurate but can cause serious adverse events. Noninvasive confirmatory tests, such as magnetic resonance angiography, involve some inaccuracy. Given these facts, some people with false-positive test results may receive unnecessary invasive carotid endarterectomy surgery.

### **Benefits of Detection and Early Intervention**

Good evidence indicates that in selected, high-risk trial participants with asymptomatic severe [carotid artery stenosis], carotid endarterectomy by selected surgeons reduces the 5-year absolute incidence of all strokes or perioperative death by approximately 5%. These benefits would be less among asymptomatic people in the general population. For the general primary care population, the benefits are judged to be no greater than small.

### **Harms of Detection and Early Intervention**

Good evidence indicates that both the testing strategy and the treatment with carotid endarterectomy can cause harms. A testing strategy that includes angiography will itself cause some strokes. A testing strategy that does not include angiography will cause some strokes by leading to carotid endarterectomy in people who do not have severe [carotid artery stenosis]. In excellent centers, carotid endarterectomy is associated with a 30-day stroke or mortality rate of about 3%; some areas have higher rates. These harms are judged to be no less than small.

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<sup>46</sup> U.S. Preventive Services Task Force. Screening for carotid artery stenosis: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med.* 2007;147(12):854-9.



In July 2014, the USPSTF issued an updated recommendation against screening for asymptomatic carotid artery stenosis in the general population.<sup>47</sup> In reaffirming its prior recommendation, the USPSTF concluded with moderate certainty that the harms of screening for asymptomatic carotid artery stenosis outweigh the benefits. The USPSTF presented the following updated rationale:<sup>48</sup>

**Importance**

Stroke is a leading cause of death and disability in the United States. Although asymptomatic carotid artery stenosis is a risk factor for stroke, it causes a relatively small proportion of strokes.

**Detection**

The most feasible screening test for carotid artery stenosis (defined as 60% to 99% stenosis) is ultrasonography. Although adequate evidence indicates that this test has high sensitivity and specificity, in practice, ultrasonography yields many false-positive results in the general population, which has a low prevalence of carotid artery stenosis (approximately 0.5% to 1%). There are no externally validated, reliable tools that can determine who is at increased risk for carotid artery stenosis or for stroke when carotid artery stenosis is present. Adequate evidence indicates that the accuracy of screening by auscultation of the neck is poor.

**Benefits of Detection and Early Intervention**

There is no direct evidence on the benefits of screening for carotid artery stenosis. Adequate evidence indicates that in selected trial participants with asymptomatic carotid artery stenosis, carotid endarterectomy (CEA) performed by selected surgeons reduces the absolute incidence of all strokes or perioperative death by approximately 3.5% compared with (outdated) medical management. However, this difference is probably smaller with current optimal medical management. The magnitude of these benefits would be smaller in asymptomatic persons in the general population. For the general primary care population, the magnitude of benefit is small to none. There is no evidence that identification of asymptomatic carotid artery stenosis leads to any benefit from adding or increasing medication doses (beyond current standard medical therapy for cardiovascular disease prevention).

**Harms of Detection and Early Intervention**

Adequate evidence indicates that both the testing strategy for carotid artery stenosis and treatment with CEA can cause harms. Although screening with ultrasonography has few direct harms, all screening strategies, including those with or without confirmatory tests (that is, digital subtraction or magnetic resonance angiography), have imperfect sensitivity and specificity and could lead to unnecessary interventions and result in serious harms. In selected centers similar to those in the trials, CEA is associated with a 30-day stroke or mortality rate of approximately 2.4%; reported rates are as high as approximately 5% in low-volume centers and 6% in certain states. Myocardial infarctions

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<sup>47</sup> LeFevre on behalf of the U.S. Preventive Services Task Force. Screening for asymptomatic carotid artery stenosis: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med*. Published online 8 July 2014. doi:10.7326/M14-1333.

<sup>48</sup> *Ibid.*

are reported in 0.8% to 2.2% of patients after CEA. The 30-day stroke or mortality rate after carotid angioplasty and stenting (CAAS) is approximately 3.1% to 3.8%. The overall magnitude of harms of screening and subsequent treatment of asymptomatic carotid artery stenosis is small to moderate depending on patient population, surgeon, center volume, and geographic location.

In 2007, the American Society of Neuroimaging, with co-sponsorship by the Society of Vascular and Interventional Neurology, issued evidence-based recommendations on the screening of asymptomatic carotid artery disease in the general population and selected subsets of patients.<sup>49</sup> These societies issued a grade E recommendation *against* screening for carotid artery stenosis in the general population or in a selected population based on age, gender, or any other variable alone. The criteria for a grade E recommendation were that the prevalence of disease may be high or low but detection and treatment is documented to have no benefit, or prevalence of disease is low. They also issue a grade A recommendation that screening of selective subpopulation of adults age 65 or older with at least three cardiovascular risk factors (hypertension, coronary artery disease, current cigarette smoking, or hyperlipidemia) needs to be considered. The criteria of a grade A recommendation were that the prevalence of disease is high and detection and treatment is of documented benefit.

In 2011, the Society for Vascular Surgery, issued a position statement recommending ultrasound screening of carotid arteries only for high-risk individuals age 55 or older, taking into account cardiovascular risk factors, such as a history of hypertension, diabetes mellitus, smoking, hypercholesterolemia, or known cardiovascular disease.<sup>50</sup> The position statement provided little substantive evidence to support this recommendation.

Thus, screening for carotid artery stenosis with ultrasound in the general, asymptomatic population has *not* been shown to significantly improve clinical outcome, and numerous medical professional organizations strongly recommend against such screening.

#### **D. Abdominal Aortic Aneurysm Ultrasound:**

The HealthFair online promotional advertisement states:

**Abdominal Aortic Aneurysm (AAA) Ultrasound:** This ultrasound test is used to visualize the presence of an aneurysm, i.e., an abnormal swelling or dilation of a blood vessel. The danger lies in the risk of the aneurysm bursting or rupturing. Ruptured abdominal aortic aneurysms have a greater than 90 percent mortality rate.<sup>51</sup>

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<sup>49</sup> Qureshi AI, Alexandrov AV, Tegeler CH, et al. Guidelines for screening of extracranial carotid artery disease: a statement for healthcare professionals from the multidisciplinary practice guidelines committee of the American Society of Neuroimaging; cosponsored by the Society of Vascular and Interventional Neurology. *J Neuroimaging*. 2007;17(1):19-47.

<sup>50</sup> Society for Vascular Surgery. SVS position statement on vascular screenings. January 2011. <http://www.vascularweb.org/about/positionstatements/Pages/svs-position-statement-on-vascular-screening.aspx>. Accessed June 7, 2014.

<sup>51</sup> HealthFair. Basic package. <http://healthfair.com/health-screenings/packages/basic-package>. Accessed September 2, 2014.

By definition, an AAA is present when aortic diameter equals or exceeds 3.0 cm (slightly more than one inch).<sup>52</sup> Most people who have an AAA show no signs or symptoms until it ruptures. The strongest risk factor for *rupture* of an AAA is the aortic diameter.<sup>53</sup> Thus, risk of AAA rupture rises with increasing size of the aneurysm. AAAs with a diameter between 3.0 and 3.9 cm have an essentially 0% annual rupture risk; those with between 4.0 and 4.9 cm have a 1% risk; and those between 5.0 and 5.99 cm have a 11% annual rupture risk.<sup>54</sup>

In a study of an unselected general population in the U.K., the prevalence of AAA was six times greater in men than women for all age groups.<sup>55</sup> For men not screened for AAA, almost all deaths from ruptured AAAs occurred after age 65, with more than half occurring before age 80.<sup>56</sup> For women not screened for AAA, the majority of AAA-related deaths occurred after age 80.<sup>57</sup>

Several major medical professional organizations affirmatively recommend one-time ultrasound screening for AAAs *only in certain high-risk individuals* given the epidemiology of AAAs described above, and we are not aware of any major medical professional organization that endorses indiscriminate ultrasound screening for AAAs in low-risk, asymptomatic individuals.

In 2005, the USPSTF issued the following evidence-based recommendations for AAA screening:<sup>58</sup>

- (1) A grade B recommendation for one-time screening for AAA by ultrasonography in men age 65 to 75 who have ever smoked. In making this a grade B recommendation, the USPSTF offered the following rationale:

The USPSTF found good evidence that screening for AAA and surgical repair of large AAAs ( $\geq 5.5$  cm) in men age 65 to 75 years who have ever smoked (current and former smokers) leads to decreased AAA-specific mortality. There is good evidence that abdominal ultrasonography, performed in a setting with adequate quality assurance (that is, in an accredited facility with credentialed technologists), is an accurate screening test for AAA. There is also good evidence of important harms of screening and early treatment, including an increased number of surgeries with associated clinically significant morbidity and mortality, and short-term psychological harms. On the basis of the moderate magnitude of

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<sup>52</sup> Fleming C, Whitlock EP, Beil TL, Lederle FA. Screening for abdominal aortic aneurysm: a best-evidence systematic review for the U.S. Preventive Services Task Force. *Ann Intern Med.* 2005;142(3):203-211.

<sup>53</sup> Lederle FA, Johnson GR, Wilson SE, et al. Rupture rate of large abdominal aortic aneurysms in patients refusing or unfit for elective repair. *JAMA.* 2002;287(22):2968-2972.

<sup>54</sup> LeFevre ML on behalf of the U.S. Preventive Services Task Force. Screening for abdominal aortic aneurysm: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med.* Online June 24, 2014. doi: 10.7326/M14-1204.

<sup>55</sup> Scott RA, Bridgewater SG, Ashton HA. Randomized clinical trial of screening for abdominal aortic aneurysm in women. *Br J Surg.* 2002;89(3):283-285.

<sup>56</sup> *Ibid.*

<sup>57</sup> *Ibid.*

<sup>58</sup> U.S. Preventive Services Task Force. Screening for abdominal aortic aneurysm: recommendation statement. *Ann Intern Med.* 2005;142(3):198-202.

net benefit, the USPSTF concluded that the benefits of screening for AAA in men age 65 to 75 years who have ever smoked outweigh the harms.

- (2) No recommendation for or against screening for AAA in men age 65 to 75 who have *never* smoked. In making this grade C recommendation, the USPSTF offered the following rationale:

The USPSTF found good evidence that screening for AAA in men age 65 to 75 years who have never smoked leads to decreased AAA-specific mortality. There is, however, a lower prevalence of large AAAs in men who have never smoked compared with men who have ever smoked; thus, the potential benefit from screening men who have never smoked is small. There is good evidence that screening and early treatment lead to important harms, including an increased number of surgeries with associated clinically significant morbidity and mortality, and short-term psychological harms. The USPSTF concluded that the balance between the benefits and harms of screening for AAA is too close to make a general recommendation in this population.

- (3) A grade D recommendation *against* routine screening for AAA in women. In making this a grade D recommendation, the USPSTF offered the following rationale:

Because of the low prevalence of large AAAs in women, the number of AAA-related deaths that can be prevented by screening this population is small. There is good evidence that screening and early treatment result in important harms, including an increased number of surgeries with associated morbidity and mortality, and psychological harms. The USPSTF concluded that the harms of screening women for AAA therefore outweigh the benefits.

In June 2014, the USPSTF issued a revised recommendation statement, based on an updated review of the available evidence published between January 2004 and January 2013.<sup>59</sup> The updated recommendations differ slightly from the 2005 recommendations and include the following:<sup>60</sup>

- (1) A grade B recommendation for one-time screening for AAA with ultrasonography in men ages 65 to 75 who have ever smoked (no change from 2005). The USPSTF provided the following updated rationale for this unchanged recommendation:

Four large, population-based, randomized, controlled trials (RCTs) show that invitation to 1-time screening for AAA is associated with reduced AAA-specific mortality in men. This benefit begins 3 years after testing and persists up to 15

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<sup>59</sup> Guirguis-Blake JM, Beil TL, Senger CA, Whitlock EP. Ultrasonography screening for abdominal aortic aneurysms: a systematic review for the U.S. Preventive Services Task Force. *Ann Intern Med.* 2014;160(5):321-329.

<sup>60</sup> LeFevre ML on behalf of the U.S. Preventive Services Task Force. Screening for abdominal aortic aneurysm: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med.* 2014;161(4):281-290. Published online June 24, 2014: doi: 10.7326/M14-1204.

years. In addition, risk reduction for AAA rupture and emergency surgery persists up to 10 to 13 years.

In the 2 highest-quality trials, the relative reduction in AAA-specific mortality after 13 years was 42% to 66%. In the largest trial, where prevalence of AAA was approximately 5% in the screened group, screening was associated with an absolute risk reduction in death of 1.4 per 1000 men.

Abdominal aortic aneurysms are most prevalent in men who have ever smoked, occurring in approximately 6% to 7% of this population. This prevalence increases the importance of screening in these men because it maximizes the absolute benefit that could be achieved (that is, it improves the likelihood that men in this group will benefit from screening). Convincing evidence shows that 1-time screening with ultrasonography results in a moderate benefit in men aged 65 to 75 years who have ever smoked.

The USPSTF concluded with high certainty that that screening for AAA with ultrasonography in men aged 65 to 75 years who have ever smoked has a moderate net benefit.

- (2) A grade C recommendation that clinicians *selectively* offer screening for AAA in men ages 65 to 75 who have never smoked rather than routinely screening all men in this group. Evidence indicates that the net benefit of screening all men ages 65 to 75 years who have never smoked is small. In determining whether this service is appropriate in individual cases, patients and clinicians should consider the balance of benefits and harms on the basis of evidence relevant to the patient's medical history, family history, other risk factors, and personal values. The USPSTF offered the following rationale for this new recommendation:

Screening men overall reduces AAA-specific death, rupture, and emergency surgery. However, the lower prevalence of AAA in men who have never smoked (approximately 2%) substantially reduces the absolute benefit (that is, it greatly lowers the probability that men in this group will benefit from screening). Adequate evidence shows that 1-time screening for AAA with ultrasonography results in a small benefit in men aged 65 to 75 years who have never smoked.

The USPSTF also suggested the following clinical considerations with respect to this new recommendation:

Despite the demonstrated benefits of screening for AAA in men overall, the lower prevalence of AAA in male never-smokers versus male ever-smokers suggests that clinicians should consider a patient's risk factors and the potential for harm before screening for AAA rather than routinely offering screening to all male never-smokers. Important risk factors for AAA include older age and a first-degree relative with an AAA; other risk factors include a history of other vascular aneurysms, coronary artery disease, cerebrovascular disease, atherosclerosis, hypercholesterolemia, obesity, and hypertension. Factors associated with a

reduced risk for AAA include African American race, Hispanic ethnicity, and diabetes.

- (3) An I statement concluding that the current evidence is insufficient to assess the balance of benefits and harms of screening for AAA in women ages 65 to 75 years who have ever smoked (An I statement means the USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence may be lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.) The USPSTF offered the following rationale for this draft statement:

*Potential Preventable Burden.* A screening study in Sweden found that the prevalence of AAA in women aged 70 years was low (0.8%) for ever-smokers but increased to 2.0% for current smokers. A meta-analysis of individual-patient data found that women have a higher risk than men for AAA rupture at the same diameter (hazard ratio [HR], 3.76 [95% CI, 2.58 to 5.47]). However, AAA-associated deaths occur at an older age in women (at a time of increased competing causes of death and a declining benefit–risk ratio for operative interventions), with 70% of deaths occurring after age 80 years in women compared with fewer than 50% in men. In the only screening RCT that included women, most screen-detected AAAs in women were small (3.0 to 3.9 cm) and AAA-specific mortality was low in screened and unscreened women (<0.2%) after 10 years.

*Potential Harms.* Four RCTs (primarily done in men) showed that screening for AAA doubled the rate of AAA-associated surgeries, largely driven by an increase in elective surgeries. Most screen-detected AAAs were below the 5.5-cm threshold for immediate repair. This finding generally results in long-term or lifelong surveillance and is probably associated with some amount of overtreatment, although the magnitude of this burden is difficult to quantify.

Most screening trials reported an associated decrease in emergency AAA repairs and a reduced 30-day mortality rate associated with emergency surgery in populations invited to screen, although mortality associated with elective surgery was not reduced. Operative mortality associated with AAAs is higher in women than in men (7% vs. 5% for open repair and 2% vs. 1% for endovascular repair, respectively).

*Costs.* In addition to the cost of ultrasonography screening (approximately \$100), the estimated potential associated cost of elective surgery to repair a screen-detected AAA ranges from \$37 000 to \$43 000. Potential opportunity costs also may arise, because screening may take the place of other preventive activities that may be more beneficial to the patient.

*Current Practice.* Screening for AAA is provided as part of the “welcome-to-Medicare visit” for women who have a family history of AAA. However, the evidence is insufficient to accurately characterize current practice patterns related to screening for AAA in women.

A retrospective analysis from 2000 to 2010 used the National Inpatient Sample, a database that has a stratified 20% random sample of all nonfederal inpatient hospital admissions in the United States. This analysis found that women are more likely than men to have open surgery versus endovascular aneurysm repair (EVAR) for unruptured AAA (24% vs. 17%, respectively), potentially because of issues with access to the iliac artery (that is, smaller artery size) that may preclude endovascular management.

A retrospective review of 4026 AAA repairs in the Vascular Study Group of New England database (a voluntary registry from 30 academic and community hospitals in the 6 New England states) reported that women were more likely than men to have open surgery versus EVAR and to be older and have smaller aortic diameters at the time of repair. Postoperative complications were higher in women than in men after elective EVAR or open repair, including emergency reoperations, dysrhythmias, leg ischemia or emboli, bowel ischemia, or need for discharge to another medical facility rather than home.

- (4) A grade D recommendation *against* routine screening for AAA in women who have never smoked. The USPSTF offered the following rationale for this draft updated recommendation:

The prevalence of AAA in women who have never smoked is low (0.03% to 0.60% in women aged 50 to 79 years). The evidence also shows no apparent benefit of screening for AAA in women. The USPSTF therefore concludes that adequate evidence shows that the absolute benefit of 1-time screening for AAA with ultrasonography in women who have never smoked can effectively be bounded at none or almost none.

In discussing the harms of detection and early treatment of AAAs, the USPSTF noted the following:<sup>61</sup>

In the available trials, groups invited to screening were approximately twice as likely as control groups to have any AAA surgery within 3 to 5 years, predominantly driven by an increase in elective surgeries. More than 90% of AAAs identified by screening were below the 5.5-cm threshold for immediate repair. Detecting smaller AAAs generally leads to long-term (potentially lifelong) surveillance.

A person's risk for death related to elective surgery for AAA is lower than that for death related to emergency surgery for rupture. However, the increase in the overall rates of detection and surgery in the screening groups still potentially represents a harm. A proportion of AAAs will never rupture because they do not advance or because a person dies of a competing cause.

The exact extent of overdiagnosis and overtreatment is difficult to estimate. One study from Massachusetts General Hospital reviewed 24 000 consecutive autopsies between

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<sup>61</sup> *Ibid.*

1952 and 1975 and found that 75% of the 473 patients who died with an undetected or unoperated AAA had a cause of death not related to the AAA (41% were >5.1 cm in diameter). Given that even elective treatment is associated with some risk for perioperative mortality, overtreatment is an important issue to consider when deciding whether to screen for this condition. ...

Convincing evidence shows that the harms associated with 1-time screening for AAA with ultrasonography are at least small in all populations and potentially higher in women because of their higher risk for operative mortality.

In 2011, the Society for Vascular Surgery issued a position statement on vascular screening recommending a one-time ultrasound screening for AAA for all men age 65 or older and screening men as early as age 55 who have a family history of AAA.<sup>62</sup> The society also recommended one-time ultrasound screening for AAA for all women age 65 or older who have a family history of AAA or have smoked.

In 2012, the ACCF, American College of Radiology, American Institute of Ultrasound in Medicine, American Society of Echocardiography, American Society of Nephrology, Intersocietal Commission for the Accreditation of Vascular Laboratories, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Interventional Radiology, Society for Vascular Medicine, and Society for Vascular Surgery jointly issued evidence-based appropriate use criteria for noninvasive vascular testing (ultrasound and physiological testing) for a variety of possible indications.<sup>63</sup> For each indication, these organizations classified the use of noninvasive vascular testing into one of the following three categories: appropriate, uncertain, or inappropriate (see section A above for definitions of these designations).

These organizations classify screening for AAA as *inappropriate* for anyone under age 65 with no history of smoking, except as noted below. They also classify such screening as *uncertain* for anyone 65 or older with no history of smoking.

These organizations did classify screening for AAA as *appropriate* for the following subgroups:

- Adults older than age 60 with a first-degree relative with an AAA.
- Adults age 65 or older who are current or former smokers.

In summary, the USPSTF and many other major medical professional organizations recommended against routine screening for AAA, or designate such screening as inappropriate for those individuals who are not at high risk for developing AAA. Screening for AAA in the general, asymptomatic population has *not* been shown to significantly improve clinical outcome and is likely to do cause more harm than benefit.

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<sup>62</sup> Society for Vascular Surgery. SVS Position Statement on Vascular Screenings. January 2011. <http://www.vascularweb.org/about/positionstatements/Pages/svs-position-statement-on-vascular-screening.aspx>. Accessed August 21, 2014.

<sup>63</sup> Mohler ER, Gornik HL, Gerhard-Herman M, et al. ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/SVM/SVS 2012 appropriate use criteria for peripheral vascular ultrasound and physiological testing part I: arterial ultrasound and physiological testing. *J Am Coll Cardiol*. 2012;60(3):242-276.



### **E. Hardening of the Arteries Test (Arterial Stiffness Index):**

The HealthFair online promotional advertisement states:

**Hardening of the Arteries Test (ASI):** The ASI test measures the hardening of the arteries, which narrow and stiffen with age and the accumulation of plaque. Blockages starve tissue of blood and oxygen, which can result in damage or tissue death. This is a common cause of heart attack and stroke.<sup>64</sup>

The ASI is determined with a device (e.g., VitalVision) that calculates ASI in the upper arm using computerized oscillometry (a technique that measures how elastic or stiff arteries are by assessing changes in pressure and volume in arteries each time the heart beats).<sup>65</sup> HealthFair uses this technology for its screening packages.<sup>66</sup>

The presence of arterial stiffness is proposed as a predictor of cardiovascular disease. However, there is a lack of rigorous scientific evidence supporting ASI screening in clinical practice.

In 2010, the ACCF and AHA issued an evidence-based practice guideline on the use of specific measures of arterial stiffness to assess apparently healthy, asymptomatic adults for risk of developing cardiovascular events associated with atherosclerotic vascular disease.<sup>67</sup> The guidelines were developed in collaboration with the American Society of Echocardiography, American Society of Nuclear Cardiology, Society of Atherosclerosis Imaging and Prevention, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance. The ACCF/AHA practice guideline states that measures of arterial stiffness outside of research settings are not recommended for cardiovascular risk assessment in asymptomatic adults because such testing provides no benefit.

Thus, while inclusion of the ASI in the package of screening tests provided by HealthFair provides a nice promotional gimmick, screening the asymptomatic population with this test has *not* been shown to significantly improve clinical outcome and is not recommended by any major medical professional organizations for use in clinical practice.

### **F. Peripheral Arterial Disease Test:**

The HealthFair online promotional advertisement states:

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<sup>64</sup> HealthFair. Basic package. <http://healthfair.com/health-screenings/packages/basic-package>. Accessed September 2, 2014.

<sup>65</sup> Altunkan S, Oztas K, Seref B. Arterial stiffness index as a screening test for cardiovascular risk: a comparative study between coronary artery calcification determined by electron beam tomography and arterial stiffness index determined by a VitalVision device in asymptomatic subjects. *Eur J Intern Med.* 2005;16(8):580-584.

<sup>66</sup> Accessed at HealthFair. Arterial stiffness index. <http://healthfair.com/health-screenings/screenings/arterial-stiffness-index>. Accessed June 8, 2014.

<sup>67</sup> Greenland P, Alpert JS, Beller GA, et al. 2010 ACCF/AHA guideline for assessment of cardiovascular risk in asymptomatic adults: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation.* 2010;122(25):2748-2764.

**Peripheral Arterial Disease Test (PAD):** Peripheral arterial disease is a common circulatory problem in which narrowed arteries reduce blood flow to your limbs. Plaque can also build up in the arteries supplying blood to your heart and brain, which can cause a stroke or heart attack.<sup>68</sup>

The test that HealthFair uses to evaluate peripheral arterial disease is the ankle-brachial index, or ABI.<sup>69</sup>

In 2012, the ACCF, American College of Radiology, American Institute of Ultrasound in Medicine, American Society of Echocardiography, American Society of Nephrology, Intersocietal Commission for the Accreditation of Vascular Laboratories, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Interventional Radiology, Society for Vascular Medicine, and Society for Vascular Surgery jointly issued evidence-based appropriate use criteria for noninvasive vascular testing (ultrasound and physiological testing) for a variety of possible indications. These appropriate use criteria identify the following as the only appropriate indications for lower extremity artery testing with ABI: patients with diminished pulses, femoral bruit, age greater than 50 with diabetes or smoking, or age greater than 70, which is consistent with ACC/AHA peripheral artery disease (PAD) guidelines. The evaluation with ABI for those younger than 50 and those with diabetes was classified as uncertain.<sup>70</sup>

In 2013, the USPSTF, based on a systematic review of the scientific literature,<sup>71</sup> issued a grade I statement on ABI testing, concluding that the current evidence is *insufficient* to assess the balance of benefits and harms of screening for peripheral artery disease and cardiovascular disease risk assessment with the ABI in adults.<sup>72</sup> In making this statement, the USPSTF noted the following regarding its assessment of the possible benefits and harms of ABI screening:

#### **Benefits of Detection and Early Treatment**

The USPSTF found no evidence that screening for and treatment of PAD in asymptomatic patients leads to clinically important benefits. It also reviewed the potential benefits of adding the ABI to the Framingham Risk Score (FRS) and found evidence that this results in some patient risk reclassification; however, how often the reclassification is appropriate or whether it results in improved clinical outcomes is not known.

Determining the overall benefit of ABI testing requires not only evidence on appropriate risk reclassification but also evidence that this reclassification leads to

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<sup>68</sup> HealthFair. Basic package. <http://healthfair.com/health-screenings/packages/basic-package>. Accessed September 2, 2014.

<sup>69</sup> HealthFair. Ankle Brachial Index. <http://healthfair.com/health-screenings/screenings/ankle-brachial-index>. Accessed September 2, 2014.

<sup>70</sup> Mohler ER, Gornik HL, Gerhard-herman M, et al. ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/SVM/SVS 2012 appropriate use criteria for peripheral vascular ultrasound and physiological testing part I: arterial ultrasound and physiological testing. *J Am Coll Cardiol*. 2012;60(3):242-276.

<sup>71</sup> Lin JS, Olson CM, Johnson ES, Whitlock EP. The ankle-brachial index for peripheral artery disease screening and cardiovascular disease prediction among asymptomatic adults: a systematic evidence review for the U.S. Preventive Services Task Force. *Ann Intern Med*. 2013;159(5):333-341.

<sup>72</sup> Moyer VA, U.S. Preventive Services Task Force. Screening for peripheral artery disease and cardiovascular disease risk assessment with the ankle-brachial index in adults: U.S. Preventive Service Task Force recommendation statement. *Ann Intern Med*. 2013;159(5):342-348.

treatments shown to improve clinical outcomes. One randomized trial found that aspirin did not reduce [cardiovascular disease] events in patients with a low ABI. No studies assessed the effect of lipid-lowering therapy or other cardiovascular risk reduction interventions in patients with asymptomatic PAD and no known diagnosis of [cardiovascular disease] or diabetes. The USPSTF found inadequate evidence that early treatment of screen-detected PAD leads to improvement in clinical outcomes.

### **Harms of Detection and Early Treatment**

The USPSTF found no studies addressing the magnitude of harms of screening for PAD with the ABI; however, the direct harms to the patient of screening itself, beyond the time needed for the test, are probably minimal. Other harms resulting from testing may include false-positive results, exposure to gadolinium or contrast dye if magnetic resonance angiography (MRA) or computed tomography angiography (CTA) is used to confirm diagnosis, anxiety, labeling, and opportunity costs.

The USPSTF found inadequate evidence on the harms of early treatment of screen-detected PAD. One study showed that low-dose aspirin treatment in asymptomatic patients with a low ABI may increase bleeding. Additional harms associated with treatment include use of unnecessary medications (or higher doses) and their resulting adverse effects and discontinuation of medications known to be effective in patients with established coronary artery disease (CAD) if the patient is reclassified to a lower risk category on the basis of a normal ABI.

We are not aware of any major medical professional organization that endorses such screening for peripheral vascular disease with ABI in the general asymptomatic population.

Moreover, treatment benefits for asymptomatic individuals with screen-detected PAD are not well established, and there appear to be no studies that directly assess the impact of screening unselected adults (or generally asymptomatic adults) with ABI on cardiovascular disease or PAD health outcomes.<sup>73</sup>

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<sup>73</sup> Lin JS, Olson CM, Johnson ES, et al. *The Ankle Brachial Index for Peripheral Artery Disease Screening and Cardiovascular Disease Prediction in Asymptomatic Adults: A Systematic Evidence Review for the U.S. Preventive Services Task Force*. Rockville, MD: Agency for Healthcare Research and Quality; 2013. <http://www.ncbi.nlm.nih.gov/books/NBK164524>. Accessed June 9, 2014.

## Appendix C

### Examples of Misleading Statements in HealthFair Promotional Materials

HealthFair statements are presented below in italics, followed by Public Citizen’s assessment of each.

- *HealthFair offers a range of appropriately-targeted health screening tests to identify potential threats to your health.* (<http://healthfair.com>, accessed September 2, 2014; copy enclosed)

This statement is misleading because the range of tests offered by HealthFair includes the company’s heavily promoted basic cardiovascular disease screening package — which is comprised of an echocardiogram, electrocardiogram, carotid artery ultrasound, abdominal aorta ultrasound, arterial stiffness index, and ankle-brachial plexus. These tests are not being “appropriately targeted” by HealthFair. The package is advertised and promoted widely and indiscriminately to asymptomatic individuals in the general population age 45 or older. As discussed in Appendices A and B, it is not appropriate to screen all asymptomatic adults over age 45 with the six tests that make up the basic cardiovascular screening package, either together or individually. Moreover, for some of the individual tests, such as an echocardiogram, it is not appropriate to screen any asymptomatic individual in the absence of prior evidence of cardiac disease. For other tests, such as ultrasound screening for abdominal aortic aneurysm, appropriately targeted screening would involve screening only certain high-risk individuals based on factors such as age, sex, and smoking history (see Appendix B at pages 18-24 and footnotes 51-63).

- *Health screenings are essential to a healthy lifestyle because the sooner a threat is detected, the higher the success of treatment and the lower the risk of complications.* (<http://healthfair.com>, accessed September 2, 2014; copy enclosed)

The first part of this statement is misleading because it implies that the cardiovascular disease screening tests offered by HealthFair are “essential to a healthy lifestyle” for asymptomatic adults in the general population. Because the risks of such screening in asymptomatic adults over age 45 outweigh the potential benefits, as discussed in Appendices A and B, the opposite is true: Undergoing the cardiovascular screening packages offered by HealthFair would be part of an *unhealthy* lifestyle.

The second part of the statement is also misleading because it implies that for all the types of cardiovascular problems screened for by HealthFair’s basic cardiovascular disease screening package, the sooner an abnormality is detected, the higher the success of treatment and the lower the risk of complications. Again, as discussed in Appendices A and B, the available scientific evidence does not support this broad implication, even for the individual tests.

- *Preventive health screenings are very useful in early detection of all types of illnesses and risk factors.* (<http://healthfair.com/health-screenings/packages>, accessed September 2, 2014; copy enclosed)

The available evidence refutes the broad assertion that preventive screenings are very useful for the early detection of “all types of illnesses and risk factors.” Indeed, for many types of illness that HealthFair screens for, the available evidence demonstrates that preventive health screenings are not useful.

- *HealthFair mobile health clinics offer a variety of comprehensive health screening tests that are **simple to understand, convenient and save you money**. ... Packaging our screenings together not only provides you with a more **comprehensive** understanding of your health, but also **saves you money**.* [Bold in original] (<http://healthfair.com/health-screenings/packages>, accessed September 2, 2014; copy enclosed)

The statement that HealthFair screenings, either individually or in packages, save people money is misleading. For most people being screened, the tests are not clinically indicated. For such people, any expenditure on such testing is a waste, not a saving, of money.

For the minority of people for whom, because of age, symptoms, or other characteristics, one of the individual cardiovascular disease screening tests offered by HealthFair is clinically indicated, their health insurance likely would cover some or all of the costs of the testing when performed by another health care provider. For insured individuals, any out-of-pocket expense would likely be less than the fees that must be paid in advance to HealthFair when the screening tests are scheduled.

- *Why can't my physician do these health screenings as part of my routine physical? Due to the typically high cost of these preventive tests, many physicians will only order them when a patient is showing apparent symptoms.* (<http://healthfair.com/resources/faq>, accessed September 2, 2014; copy enclosed)

HealthFair's answer to the frequently asked question above is false and misleading. The reason many physicians do not order the screening tests offered by HealthFair has nothing to do with cost. Well-trained physicians practicing evidence-based medicine do not order these tests as a general practice because the currently available scientific evidence and evidence-based guidelines issued by major medical professional organizations do not support such testing and for most of these tests indicate that the risks outweigh the benefits for most asymptomatic people, as discussed in Appendices A and B. Physicians will order a test, such as an abdominal aortic ultrasound to screen for an aneurysm, in appropriately selected, high-risk asymptomatic individuals for whom the available evidence indicates that the benefits outweigh the risks. And when the test is clinically indicated, health insurance will typically cover much of the cost for such preventive services in insured patients.<sup>74</sup>

- *What is the Arterial Stiffness Index? The Arterial Stiffness Index (ASI) is a measure of the loss of elasticity in the arteries that occurs with onset of vascular disease and advancing age. ... ASI screenings are pain-free, highly effective and may determine whether you have risk of heart disease.* (<http://healthfair.com/health-screenings/screenings/arterial-stiffness-index>, accessed September 2, 2014; copy enclosed)

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<sup>74</sup> Healthcare.gov. Preventive care benefits: Preventive health services for adults. <https://www.healthcare.gov/what-are-my-preventive-care-benefits>. Accessed August 26, 2014.

HealthFair's statement that the ASI screening is "highly effective" is misleading. Evidence-based guidelines indicate that such measures of arterial stiffness outside of research settings are not recommended for cardiovascular risk assessment in asymptomatic adults because such testing provides no benefit.<sup>75</sup>

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<sup>75</sup> Greenland P, Alpert JS, Beller GA, et al. 2010 ACCF/AHA guideline for assessment of cardiovascular risk in asymptomatic adults: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2010;122(25):2748-2764.