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June 19, 2014

Yousuf J. Ahmad  
Chief Executive Officer  
Mercy Health  
4600 McAuley Place  
Cincinnati, Ohio 45242

Dear Mr. Ahmad:

Public Citizen, a consumer advocacy group with more than 300,000 members and supporters nationwide, strongly urges you to immediately terminate The Heart Institute of Mercy Health's sponsorship of, and affiliation with, HealthFair — as evidenced by the websites for HealthFair<sup>1</sup> and your institution<sup>2</sup> — for the following reasons:

- (1) There is widespread consensus among medical experts that the basic package of six cardiovascular disease screening tests advertised by HealthFair<sup>3</sup> for unselected, asymptomatic individuals in the general population is not appropriate 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 for further elaboration).

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

HealthFair seeks to scare individuals for whom screening for asymptomatic cardiovascular disease is *not clinically indicated* into undergoing screening by using inappropriate direct-to-consumer advertisements and solicitations that target consumer fear about having undetected, potentially life-threatening disease.<sup>4</sup>

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<sup>1</sup> HealthFair website. <http://healthfair.com/>. Accessed June 17, 2014.

<sup>2</sup> Mercy Health. News articles: Mercy Health announces mobile heart screening dates in January. [http://e-mercy.com/news\\_show.aspx?mode=local&id=4313](http://e-mercy.com/news_show.aspx?mode=local&id=4313). Accessed June 18, 2014.

<sup>3</sup> HealthFair. Basic package. <http://healthfair.com/health-screenings/packages/basic-package/>. Accessed June 7, 2014.

<sup>4</sup> Lovett KM, Liang BA. Direct-to-consumer cardiac screening and suspect risk evaluation. *JAMA*. 2011;305(24):2567-2568.

**(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>5,6</sup>**

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

For example, according to the U.S. Preventive Services Task Force, screening for carotid artery stenosis in a low-prevalence population with noninvasive duplex ultrasonography results in a high number of false positives.<sup>7</sup> If all patients with a positive result underwent a confirmatory cerebral angiography, about 1 percent would suffer a nonfatal stroke due to the angiography.<sup>8</sup> If patients instead had follow-up testing with magnetic resonance angiography, a test that is less accurate than angiography, some people would end up undergoing an unnecessary carotid endarterectomy, which has a perioperative stroke or death rate of 2.4 to 3.7 percent.<sup>9</sup> Thus, some people inappropriately screened for carotid artery stenosis will suffer serious harm unnecessarily.

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 cost is borne *directly* by the screened patients/consumers for the initial screening and any 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) This screening 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 true-positive abnormal results, but the abnormalities found will never cause symptoms or death.<sup>10</sup> As with false-positive test results, overdiagnosis leads to unnecessary anxiety and medical interventions. Directly relevant to the screening offered by HealthFair, the use of imaging technologies, such as ultrasound, allows clinicians to detect abnormalities that for many people are minor and that are not destined to ever progress to causing symptoms; these people cannot benefit from treatment. In fact, they

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

<sup>6</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 June 7, 2014.

<sup>7</sup> Wolff T, Guirguis-blake J, Miller T, et al. Screening for carotid artery stenosis: an update of the evidence for the U.S. Preventive Services Task Force. *Ann Intern Med*. 2007;147(12):860-870.

<sup>8</sup> *Ibid.*

<sup>9</sup> *Ibid.*

<sup>10</sup> Welch HG, Schwartz LM, Woloshin S. *Overdiagnosed: Making People Sick in the Pursuit of Health*. 1st ed. Boston, MA: Beacon Press; 2011: page *xiv*.

can only be harmed. When healthy people are systematically encouraged to get screened, the problem of overdiagnosis is made worse.<sup>11</sup>

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

First, it is exploitative to promote and provide medically nonbeneficial testing through the use of misleading and fearmongering advertisements and solicitations in order to generate medically unnecessary but profitable referrals to your institution. 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>12,13</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>14,15</sup>

In conclusion, your institution's sponsorship of HealthFair and promotion of its screening programs directly to the public does a great disservice to the community that you serve and to public health more broadly. It is therefore imperative that your institution sever its relationship with HealthFair and stop endorsing the company's heavily promoted, nonselective, community-wide cardiovascular health screening programs.

Thank you for your prompt attention to this important patient safety and public health issue. Please contact us when you end your relationship with HealthFair.

Sincerely,

Christopher Gudas, M.D., M.P.H.  
Researcher  
Public Citizen's Health Research Group

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<sup>11</sup> *Ibid*: page 44.

<sup>12</sup> Wallace EA, Schumann JH, Weinberger SE. Ethics of commercial screening tests. *Ann Intern Med.* 2012;157(10):747-748.

<sup>13</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>14</sup> Wallace EA, Schumann JH, Weinberger SE. Ethics of commercial screening tests. *Ann Intern Med.* 2012;157(10):747-748.

<sup>15</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.

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## Appendix

### 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>16</sup> An advertisement on the HealthFair website describing these screening packages misleadingly notes the following:<sup>17</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, potentially life-saving 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]

The basic package, which includes only the six screening tests noted above, is “valued at \$2,300” but offered at what is put forth as a bargain basement price of \$179.<sup>18</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.

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<sup>16</sup> HealthFair. Screening packages. <http://healthfair.com/health-screenings/packages/>. Accessed June 7, 2014.

<sup>17</sup> *Ibid.*

<sup>18</sup> HealthFair. Basic package. <http://healthfair.com/health-screenings/packages/basic-package/>. Accessed June 7, 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>19</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>20</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>21</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>19</sup> *Ibid.*

<sup>20</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>21</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>22</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>23</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>22</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>23</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>24</sup>

HealthFair advertises elsewhere online that ECG testing can “predict a pending heart attack.”<sup>25</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>26</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

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<sup>24</sup> HealthFair. Basic package. <http://healthfair.com/health-screenings/packages/basic-package/>. Accessed June 7, 2014.

<sup>25</sup> HealthFair. Electrocardiogram. <http://healthfair.com/health-screenings/screenings/electrocardiogram/>. Accessed June 7, 2014.

<sup>26</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.



revascularization has not been shown to reduce [coronary heart disease] events in asymptomatic persons. Angiography and revascularization are associated with risks, 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>27</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>28</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>29</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>30</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>27</sup> *Ibid.*

<sup>28</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>29</sup> *Ibid.*

<sup>30</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>31</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>32</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>33</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>34</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

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<sup>31</sup> HealthFair. Basic package. <http://healthfair.com/health-screenings/packages/basic-package/>. Accessed June 7, 2014.

<sup>32</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>33</sup> *Ibid.*

<sup>34</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.

a group of persons with a high pretest likelihood of having high-grade asymptomatic 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>35</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

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<sup>35</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.

stroke or mortality rate of about 3%; some areas have higher rates. These harms are judged to be no less than small.

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>36</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>37</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>38</sup>

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<sup>36</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>37</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>38</sup> HealthFair. Basic package. <http://healthfair.com/health-screenings/packages/basic-package/>. Accessed June 7, 2014.

By definition, an AAA is present when aortic diameter exceeds 3.0 cm (slightly more than one inch).<sup>39</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>40</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>41</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>42</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>43</sup> For women not screened for AAA, the majority of AAA-related deaths occurred after age 80.<sup>44</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>45</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>39</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>40</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>41</sup> U.S. Preventive Service Task Force. Screening for abdominal aortic aneurysm: U.S. Preventive Services Task Force recommendation statement DRAFT. January 28, 2014.

<http://www.uspreventiveservicestaskforce.org/uspstf14/abdoman/abdomandraftrec.htm>. Accessed June 8, 2014.

<sup>42</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>43</sup> *Ibid.*

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

<sup>45</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 January 2014, the USPSTF released a draft updated recommendation statement, based on an updated review of the available evidence published between January 2004 and January 2013.<sup>46</sup> The updated draft recommendations differ slightly from the 2005 recommendations and include the following:<sup>47</sup>

- (1) A grade B recommendation for one-time screening for AAA by 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) demonstrate that invitation to one-time AAA screening is associated with a reduction in AAA-specific mortality in men beginning 3 years after testing; this benefit persists up to

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<sup>46</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>47</sup> U.S. Preventive Services Task Force. Screening for abdominal aortic aneurysm: U.S. Preventive Services Task Force Recommendation Statement DRAFT.

<http://www.uspreventiveservicestaskforce.org/uspstf14/abdoman/abdomandraftrec.htm>. Accessed June 8, 2014.

15 years. In the two highest-quality trials, there was a 42% to 66% relative reduction in AAA-specific mortality after 13 years. Risk for AAA rupture and emergent surgery are also reduced at up to 10 to 13 years. AAAs are most prevalent in men who have ever smoked, occurring in about 6% to 7% of this population. This increases the importance of screening in this population, as it maximizes the absolute benefit that could potentially be achieved (i.e., it improves the likelihood that an individual in this group will be helped by screening). There is convincing evidence that one-time screening for AAA with ultrasonography results in a moderate benefit in men ages 65 to 75 years who have ever smoked.

- (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. Existing 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 draft updated recommendation:

Despite reductions in AAA-specific death, rupture, and emergent surgery seen with screening in men overall, the much lower prevalence of disease among men who have never smoked (about 2%) substantially reduces the absolute benefit that could potentially be achieved (i.e., it greatly lowers the probability that an individual in this group will benefit from screening). There is adequate evidence that one-time screening for AAA with ultrasonography results in a small benefit in men ages 65 to 75 years who have never smoked.

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

Despite the demonstrated benefits of screening for AAA in men overall, the much lower prevalence of disease in male never-smokers than in male ever-smokers suggests that clinicians should consider the patient's risk factors as well as the potential for causing harm when making the decision whether to screen, instead of routinely offering screening to all men who have never smoked. Important risk factors that increase risk for developing an AAA include older age and a first-degree relative with AAA; other risk factors include a history of other vascular aneurysms, coronary artery disease, cerebrovascular disease, atherosclerosis, hypercholesterolemia, obesity, and hypertension. African American race, Hispanic ethnicity, and diabetes are associated with reduced risk for developing an AAA.

- (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:

A single [randomized controlled trial] of screening for AAA included women in its study population. The trial detected no difference in AAA rupture rate, AAA-specific mortality, or all-cause mortality between women invited for screening and the control group. However, the trial was ultimately underpowered to detect differences in health outcomes by sex, and as such, the results do not rule out the possibility of a small benefit of screening in this population. Women age 70 years who have ever smoked have a relatively low prevalence of AAA (approximately 0.8% overall and about 2% for current smokers). There is inadequate evidence to conclude whether one-time screening for AAA with ultrasonography produces any benefit in women ages 65 to 75 years who have ever smoked.

- (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:

Given the extremely low prevalence of AAA in women who have never smoked—0.03% to 0.6% of women ages 50 to 79 years—coupled with the available evidence showing no apparent benefit of screening for AAA in women, the USPSTF concludes there is adequate evidence that the absolute benefits of one-time screening for AAA with ultrasonography in women who have never smoked can effectively be bounded near zero.

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>48</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>49</sup> For each indication, these organizations classified the use of noninvasive vascular testing into one of

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<sup>48</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 8, 2014.

<sup>49</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.



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.

#### **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>50</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>51</sup> HealthFair uses this technology for its screening packages.<sup>52</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 ACFP 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

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<sup>50</sup> HealthFair. Basic package. <http://healthfair.com/health-screenings/packages/basic-package/>. Accessed June 7, 2014.

<sup>51</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>52</sup> Accessed at HealthFair. Arterial stiffness index. <http://healthfair.com/health-screenings/screenings/arterial-stiffness-index/>. Accessed June 8, 2014.

developing cardiovascular events associated with atherosclerotic vascular disease.<sup>53</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:

**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>54</sup>

The test that HealthFair uses to evaluate peripheral arterial disease is the ankle-brachial index, or ABI.<sup>55</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

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<sup>53</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>54</sup> HealthFair. Basic package. <http://healthfair.com/health-screenings/packages/basic-package/>. Accessed June 7, 2014.

<sup>55</sup> HealthFair. Ankle Brachial Index. <http://healthfair.com/health-screenings/screenings/ankle-brachial-index>. Accessed June 8, 2014.

peripheral artery disease (PAD) guidelines. The evaluation with ABI for those younger than 50 and those with diabetes was classified as uncertain.<sup>56</sup>

In 2013, the USPSTF, based on a systematic review of the scientific literature,<sup>57</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>58</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 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

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<sup>56</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>57</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>58</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.

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>59</sup>

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<sup>59</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.