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September 4, 2014

Peter Wozniak
Chief Executive Officer
Venice Regional Bayfront Health
540 The Rialto
Venice, FL 34285

Dear Mr. Wozniak:

Public Citizen, a consumer advocacy group with more than 350,000 members and supporters nationwide, is writing in follow-up to its June 19 letter urging you to immediately terminate Venice Regional Bayfront Health's sponsorship of, and affiliation with, HealthFair.¹ We requested such action because the company's heavily promoted direct-to-consumer (DTC), nonselective, community-wide cardiovascular disease screening programs are (a) not consistent with evidence-based guidelines issued by major medical professional organizations; (b) unethical; and (c) much more likely to cause harm than to provide benefit.

We would like to call your attention to several important developments relevant to this issue since our June letter:

- (1) On June 19, Patrick T. O'Gara, M.D., President of the American College of Cardiology, a 47,000-member professional organization of cardiologists, issued the following statement supportive of Public Citizen's assessment of HealthFair's cardiovascular disease screening programs:²

The questions raised [by Public Citizen] about screening have some merit. The American College of Cardiology and American Heart Association have joint guidelines that offer recommendations to guide physicians in making decisions with individual patients about their risk for heart attack and stroke. Other than assessing blood pressure and serum cholesterol, being attentive to diabetes and promoting a healthy weight with regular exercise, we do not recommend broad and untargeted screening. Decisions about the need for additional testing should be based on each patient's circumstances.

The American College of Cardiology participates in the Choosing Wisely campaign, which encourages physicians and patients to discuss the costs and benefits of often overused tests and procedures.”

¹ Public Citizen. Letter to Peter Wozniak, Venice Regional Bayfront Health. June 19, 2014. <http://www.citizen.org/documents/2206FL4.pdf>. Accessed September 1, 2014.

² American College of Cardiology Press Office. ACC President comments on Public Citizen's criticism of cardiac screening programs. June 19, 2014.

- (2) On June 19, a spokeswoman for Dignity Health told the *Los Angeles Times* that Dignity Health-California Hospital Medical Center and Dignity Health-St. Bernardine Medical Center — two other institutions that had partnered with HealthFair — no longer had contracts with HealthFair.³
- (3) On June 24, Kimarie R. Stratos, Senior Vice President and General Counsel for Memorial Healthcare System, Hollywood, Florida — another institution that had partnered with HealthFair — notified Public Citizen that “Memorial Healthcare System has provided HealthFair with its notice of intent to terminate.”⁴
- (4) On June 29, Steven Weinberger, M.D., Executive Vice President and Chief Executive Officer of the American College of Physicians (ACP), the preeminent national organization of internists, stated that “the ACP supports the stance that Public Citizen has taken regarding DTC cardiovascular screening offered by HealthFair.”⁵
- (5) On June 30, Public Citizen wrote to The Joint Commission asking the organization to (a) investigate whether HealthFair or any of its partnered hospitals had ever misled consumers about the company being accredited by the Commission at a time when it was not; (b) reject any application for accreditation from the company; and (c) suspend the accreditation of any health care organization still partnered with HealthFair.⁶

In response to our letter, Mark R. Chassin, M.D., President and Chief Executive Officer of The Joint Commission, stated to the media that the Commission would contact all hospitals and health care organization partnered with HealthFair, inform them that HealthFair is no longer accredited, and request that they revise their promotional materials accordingly. The Joint Commission also announced that HealthFair previously had been accredited, but that status had expired in December 2013 and the company’s leadership had been informed it could no longer be accredited.⁷

- (6) On June 24, the U.S. Preventive Services Task Force (USPSTF) issued updated recommendations regarding screening for abdominal aortic aneurysms (AAA), based on an updated systematic review of the available evidence published between January 2004

³ Terhune C. Consumer group urges hospitals to stop ‘unethical’ health screenings. *Los Angeles Times*. June 19, 2014. <http://touch.latimes.com/#section/-1/article/p2p-80548581/>. Accessed August 28, 2014.

⁴ Stratos KR. Letter to Public Citizen from Memorial Healthcare System’s Legal Department regarding HealthFair. June 24, 2014. http://www.citizen.org/documents/2206_June%2024,%202014%20response_FL-Memorial%20Healthcare%20System.pdf. Accessed August 27, 2014.

⁵ Personal e-mail communication.

⁶ Public Citizen. Letter to Mark R. Chassin, The Joint Commission, regarding HealthFair. June 30, 2014. <http://www.citizen.org/documents/2207.pdf>. Accessed August 27, 2014.

⁷ Rice S. Public Citizen questions mobile health screenings. July 6, 2014. *Modern Healthcare*. <http://www.modernhealthcare.com/article/20140706/NEWS/140709989/public-citizen-questions-mobile-health-screenings>. Accessed August 27, 2014.

and January 2013.⁸ The updated recommendations differ slightly from the task force's 2005 recommendations and included the following:⁹

- (a) A recommendation for one-time screening for AAA with ultrasonography in men ages 65 to 75 who have ever smoked (no change from 2005). In making this recommendation, the USPSTF concluded with high certainty that that screening for AAA with ultrasonography in men ages 65 to 75 who have ever smoked has a moderate net benefit.
 - (b) A 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. In determining whether this service is appropriate in individual cases, the USPSTF recommended that 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. In making this recommendation, the USPSTF concluded that there is adequate evidence showing that one-time screening with ultrasonography results in a small benefit in men ages 65 to 75 who have never smoked.
 - (c) A 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 who have ever smoked.
- (7) On July 8, the USPSTF issued an updated recommendation against screening for asymptomatic carotid artery stenosis in the general population.¹⁰ Based on a systematic review of the existing scientific evidence, the USPSTF concluded with moderate certainty that the harms of screening for asymptomatic carotid artery stenosis outweigh the benefits.
- (8) On August 11, the *Journal of the American Medical Association* published a Viewpoint article critical of hospital relationships with DTC screening companies, citing HealthFair as a specific example.¹¹ The article — co-authored by Erik Wallace, M.D., Associate Dean for the Colorado Springs Branch of the University of Colorado School of Medicine; John Shumann, M.D., Associate Professor of Internal Medicine and Director of the

⁸ 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.

⁹ 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.

¹⁰ LeFevre ML 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 July 8, 2014, doi: 10.7326/M14-1333.

¹¹ Wallace EA, Schumann JH, Weinberger SE. Hospital relationships with direct-to-consumer screening companies. *JAMA.* Published online August 11, 2014. doi:10.1001/jama.2014.9500. <http://jama.jamanetwork.com/article.aspx?articleid=1896955>. Accessed August 27, 2014.

Internal Medicine Residency Program, University of Oklahoma School of Community Medicine-Tulsa; and the ACP's Dr. Weinberger — concluded as follows:

Direct-to-consumer screening companies should fully disclose the risks and benefits of their test offerings, including the potential financial and health-related complications of additional testing and treatment. They should do so based on the most recently published data and guidelines from peer-reviewed research, nationally recognized organizations like the American College of Cardiology, or both. However, DTC screening companies likely may not do so, because disclosing evidence that shows a lack of benefit, and indeed possible harm, is not in their financial interest.

If the primary goal of hospitals and DTC screening companies is to improve the health of the populations they serve, then both entities should provide clear and convincing evidence of net benefit with the tests and treatments they offer. Given the controversy over the values and ethics of DTC screening companies and the services they offer, hospitals should clearly and publicly explain their relationships with DTC screening companies, given the lack of evidence to support mass vascular screenings. Hospitals also should justify such relationships transparently or, as Public Citizen suggests, sever such relationships.

- (9) Today, Public Citizen requested that the Federal Trade Commission investigate the advertising and promotional activities of HealthFair. 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.

The most recent USPSTF guidelines add to the overwhelming body of data demonstrating that the DTC nonselective, community-wide cardiovascular disease screening programs heavily promoted by HealthFair are inappropriate and inconsistent with evidence-based medical practice. Furthermore, a growing chorus of medical experts and leaders of prominent professional medical organizations are voicing strong opposition to these screening programs, and some hospitals that have partnered with HealthFair have signaled that they have ended or will be ending their relationship with the company.

We therefore renew our call for your institution to sever its relationship with HealthFair and stop endorsing the company's heavily promoted, nonselective, community-wide cardiovascular disease screening programs, if it has not already done so.

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

Please notify us when you end your relationship with HealthFair.

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