

## **Response of Partnership for Prevention and its Council on Aspirin for Health and Prevention to the FDA’s Rejection of Aspirin Use for Primary Prevention**

The Food and Drug Administration (FDA) recently declined [Bayer HealthCare’s petition](#) to allow aspirin to be approved for the primary prevention of heart attack and stroke among those at moderate risk for heart disease (i.e., with a 10-year risk of  $\geq 10\%$ ). The FDA reviewed the scientific evidence to weigh the benefits of taking aspirin against the risks associated with it and determined that there was insufficient evidence to warrant the use of aspirin for primary prevention, even among higher-risk individuals.

Partnership for Prevention and its Council on Aspirin for Health and Prevention (CAHP) respect the FDA’s process and interpretation of the evidence for making regulatory decisions, but believe the benefits of taking aspirin outweigh the risk for bleeding in many people at moderate-to high-risk for a first heart attack or stroke. Partnership for Prevention, through its National Commission on Prevention Priorities, found aspirin counseling to be among the highest-value preventive services clinicians can deliver. Each year, 45,000 lives could be saved if utilization increased to 90% among those who are eligible to take aspirin for primary prevention.<sup>1</sup> The CAHP supports those findings, as well as clinical guidelines issued by the U.S. Preventive Services Task Force,<sup>2</sup> the American Heart Association,<sup>3</sup> the American Diabetes Association,<sup>4</sup> and the American Stroke Association<sup>5</sup> that recommend aspirin therapy for primary prevention among those at-risk for cardiovascular events when the benefits outweigh the harms.

Although the FDA’s decision keeps aspirin for primary prevention as an “off label” use, the agency recognizes that many people who have not had a cardiovascular event are already taking aspirin for primary prevention. The FDA stated “We encourage patients to talk to their healthcare provider about the best treatment for their individual situation. The kinds of evidence FDA uses to make regulatory decisions, which have broad public health implications, may be different from those used by a physician treating a specific patient.” Partnership for Prevention

and the CAHP agree fully that the decision to start or stop aspirin therapy should be made in consultation with a health care provider. The CAHP urges providers to discuss aspirin use for primary prevention with patients to determine when it is appropriate, and for consumers to ask their providers about whether preventive aspirin is right for them. Guidance for doing so can be found at [aspirinproject.org](http://aspirinproject.org), an educational website developed by Partnership for Prevention and the CAHP that provides consumers and health care providers with information and resources to help them decide together if aspirin is the right choice.

The Council on Aspirin for Health and Prevention is a volunteer group of healthcare professionals with expertise in cardiovascular disease prevention and aspirin. It is convened by Partnership for Prevention to identify, discuss, and vet ideas and opportunities for broadening the appropriate use of aspirin. The CAHP's efforts focus on the provider-patient relationship and the interventions, policies, educational strategies, and systems that influence this relationship.



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<sup>1</sup> Partnership for Prevention. Preventive Care: A National Profile on Use, Disparities, and Health Benefits. Washington, DC: Partnership for Prevention; 2007.

<sup>2</sup> Aspirin for the Prevention of Cardiovascular Disease. U.S. Preventive Services Task Force. Available at: <http://www.uspreventiveservicestaskforce.org/uspstf/uspasm.htm>. Accessed May 14, 2014.

<sup>3</sup> Mosca L, Benjamin EJ, Berra K, et al. Effectiveness-Based Guidelines for the Prevention of Cardiovascular Disease in Women – 2011 Update: A Guidelines from the American Heart Association. *Circulation*. 2011;123:1243-1262.

<sup>4</sup> Pignone M, Alberts MJ, Colwell JA, et al. Aspirin for Primary Prevention of Cardiovascular Events in People with Diabetes. A position statement of the American Diabetes Association, a scientific statement of the American Heart Association, and an expert consensus document of the American College of Cardiology Foundation. *Diabetes Care*. 2010;33(6):1395-1402.

<sup>5</sup> Goldstein LB, Bushnell CD, Adams RJ, et al. Guidelines for the Primary Prevention of Stroke: A Guideline for Healthcare Professionals from the American Heart Association/American Stroke Association. *Stroke*. 2011;42:517-584.