May 3, 2012

The Honorable Kathleen Sebelius
Secretary
US Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW – Room 120F
Washington, DC 20201

Re: US Preventive Services Task Force Review of Lung Cancer Screening

Dear Madam Secretary:

On November 16, 2010, immediately after the termination of the National Lung Screening Trial (NLST), we wrote to Carolyn Clancy MD, urging that the United States Preventive Services Task Force (USPSTF) expedite review of its 2004 recommendation on lung cancer screening. This request was quite timely in view of the NLST's scientific validation of the mortality benefit of low dose CT scans in a high risk population, and in view of the fact that 225,000 people are projected to be diagnosed with lung cancer in 2012, primarily at late stage.

In a response dated November 24, 2010, Dr. Clancy said the USPSTF anticipated that their draft recommendation would be available for public comment by spring of 2012. Our concerns about a lack of a sense of urgency were not allayed.

We understand that the responsibility of the USPSTF is to make evidence-based recommendations about clinical preventive services such as screenings. We appreciate that the USPSTF invited Lung Cancer Alliance to participate in the Topic Working Group, which to date, has held one conference call on November 10, 2011.

Now we have been advised that the draft comments will not be available for public comment until spring of 2013. This means the new recommendation will not be finalized, at the earliest, until three years after the termination of the NLST, and long after states make final decisions on the "Essential Health Benefits" that would be covered by State Health Exchanges.

In this regard, we noted in our letter to you on January 31, 2012 that a substantial percentage of people who will rely on these exchanges will be lower income and currently uninsured. For a variety of reasons, these populations are at greater risk for lung cancer and will continue to present primarily at late stage, leading to more costly treatments, poorer outcomes and a significantly higher likelihood of death from lung cancer. According to a 2009 study published in *the Journal of Clinical Oncology*, the incidence of lung cancer will increase by 52 percent overall between 2012 and 2030, with increases of up to 171 percent in minority populations.

If USPSTF delays are allowed to exclude lung cancer screening from essential health benefits, the impact will fall disproportionately on the populations most in need and the cost of care and the number of lives lost will continue to escalate.

The NLST had to be terminated and participants in the control arm notified as soon as the CT screened arm showed a 20 percent mortality benefit over the x-ray screened arm. This occurred just six years out,

with only two post baseline screenings, with imaging equipment that has since become outdated and without strict adherence to a protocol based on best published practices for screening and early disease management. It must be emphasized that 20 percent was the endpoint of the trial, but not the ceiling on the potential benefit of screening which subsequent modeling analyses of the NLST and other national and international studies indicate could be two to three times higher.

There is no evidence that the risks of screening outweigh the benefits or that screening will increase smoking. Over 50 percent of those with lung cancer are former smokers and another 18 percent are people who never smoked. Tobacco cessation, even if universal, would not end lung cancer. For those still addicted, screening provides a teachable moment and a rigorous tobacco cessation program should be included in the protocol.

With lung cancer the cause of over one in every four cancer deaths, and with CT screening offering the greatest potential mortality benefit ever for this disease, the lethargic pace of the USPSTF is unconscionable. We urge you to intervene.

While we work to develop and implement quality standards and guidelines that will bring lung cancer screening safely, effectively and efficiently to those at greatest risk, we implore you to insist that the USPSTF move swiftly and responsibly in re-evaluating the lung cancer screening recommendation. This is a remarkable moment in our nation's war on cancer. We are committed to supporting your efforts and thank you for your prompt attention to this vital public health opportunity.

Sincerely,

Laurie Fenton Ambrose
President and CEO
Lung Cancer Alliance

Cheryl G. Healton, Dr.PH
President and CEO
Legacy Foundation

Carolyn R. Aldigé
President and CEO
Prevent Cancer Foundation