Prostate Cancer Roundtable

P.O. Box 77476 : Washington, DC 20013
www.prostatecancerroundtable.net
Email: www.prostatecancerroundtable.net/contact-us

March 22, 2012

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Letter to Director Collins on the Prostate, Lung, Colorectal, and Ovarian study

Dear Secretary Sebelius,

We would like to call your attention to a request we have made of Director Collins of NIH. We have requested that a quality review be performed of the PLCO (Prostate, Lung, Colorectal, and Ovarian) study's prostate cancer screening data, and that the use of this data for policy decisions be embargoed until this review is complete.

As explained in the enclosed letter, the effectiveness of the PSA test is a central focus of the study. Yet by year 6 of the study, 53% of the control (non-screened) group received the PSA test one or more times as part of their routine care, while 15% of the screening group never attended a screening. To put it simply, by year 6, 53% of the non-screened group were screened while 15% of the screened group was never screened. In our opinion the quality of the PLCO study is highly questionable.

We are concerned that the USPSTF draft "D" Recommendation on PSA screening for prostate cancer relies heavily on this data, and on the numerous journal articles that have referenced this data. It is for this reason that we have requested the embargo.

We would further request that the USPSTF review process be reopened and that a new review of the effectiveness of the PSA be initiated, with a prohibition of use of the PLCO and any journal articles that relied on PLCO data.

The need to reopen the process is illustrated by encouraging news from the European Randomized Study of Screening for Prostate Cancer (ERSCP) which has followed 182,000 men for 11 years. The latest data from ERSCP demonstrate a compliance-adjusted reduction in prostate cancer-specific mortality of 29% at 11 years of follow-up. ERSCP is a much larger study than PLCO and compliance has been greater from the beginning of the study.

The Prostate Cancer Roundtable recognizes that a better test for the early detection of prostate cancer is needed, however, the PSA test is all that is available today. In addition we are very concerned that private insurers will no longer cover the PSA test for early detection screening with a "D" recommendation. We believe that this will be detrimental for all men but will put men at high risk for prostate cancer at even greater risk of being diagnosed with late stage (non-curable) disease. Also please know that

African American men (the highest risk group) were poorly represented (approximately 4%) in the PLCO study; another of the major shortcomings of the study.

Thank you for consideration of this request.

The following members of the Prostate Cancer Roundtable endorse this letter:

• Ed Randall's Fans for the Cure (www.edrandallsfansforthecure.org)

• Malecare Prostate Cancer Support (www.malecare.org)

• Men's Health Network (www.menshealthnetwork.org)

• National Alliance of State Prostate Cancer Coalitions (www.naspcc.org)

• Prostate Cancer International (pcainternational.org)

• Prostate Conditions Education Council (www.prostateconditions.org)

• Prostate Health Education Network (www.prostatehealthed.org)

• The Prostate Net (www.prostatenet.org)

• Us TOO International Prostate Cancer Education and Support Network (www.ustoo.org)

• Women Against Prostate Cancer (www.womenagainstprostatecancer.org)

About the Prostate Cancer Roundtable : www.prostatecancerroundtable.net
The Prostate Cancer Roundtable, representing America's prostate cancer community, is a group of independent, patient-centric, not-for-profit organizations that cooperate to foster the development of policies supporting high quality prostate cancer research, the prevention and early detection of clinically significant prostate cancer, the appropriate care and effective treatment of men with prostate cancer, and the appropriate education of all men at risk for this disease.

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January 24, 2012

Francis S. Collins, M.D., Ph.D.
Director
National Institutes of Health
Building 1 Room 126
1 Center Drive
Bethesda, MD 20814

RE: PLCO and the USPSTF

Dear Dr. Collins,

The Prostate Cancer Roundtable members listed below are requesting that NIH take actions to perform a quality review of the PLCO (Prostate, Lung, Colorectal, and Ovarian) study's prostate cancer screening data, and to embargo the use of this data for policy decisions until this review is complete.

The initial release of the PSA screening data in 2009 created uproar within the medical/scientific community about the quality of the results because of contamination between the study and control groups. Comments following a recent release of updated PLCO study data, reported online in the Journal of the National Cancer Institute on January 6, 2012, greatly increased the Roundtable's concern about the quality and usefulness of the data for important policy decisions.

The effectiveness of the PSA test is a central focus of the study**;** however by year 6 of the study, 53% of the control (non-screened) group received the PSA test one or more times as part of their routine care. Meanwhile, 15% of the screening group never attended a screening. The study's senior author Philip Prorok, PhD, from the National Institutes of Health was quoted in an interview with Medscape Medical News that "maybe there is a benefit. The lack of a reduction in mortality could be explained, in part, by screening in the control arm." Dr. Prorok also indicated that the level of contamination, after the first 6 years, would be reviewed and updated.

The PLCO study is the only randomized controlled PSA screening study in the United States and the U. S. Preventive Services Task Force (USPSTF) is using it as primary scientific evidence in formulating a recommendation on PSA screening. On October 7th, the USPSTF released a draft recommendation which would downgrade the PSA test grade to "D." A final recommendation at the grade "D" level would result in a major change in the detection of prostate cancer after 20 years of a focus on early detection, during which time the prostate cancer mortality rate has declined by 40%.

The Prostate Cancer Roundtable members listed below are of the strong opinion that any policy change of the magnitude that will result from a USPSTF grade "D" recommendation should be based on sound and indisputable scientific evidence. The

PLCO PSA screening data is highly disputed. We are of the opinion that it is the responsibility of NIH to resolve these disputes through a rigorous review of the data in question.

Dr. Collins we appreciate your consideration of this request to review the PLCO PSA screening data and to embargo its use until this review is completed. We believe this will be in the best interest of the American public and the credibility of the USPSTF.

We would also welcome the opportunity to meet with you at your convenience to discuss this further.

Sincerely,

Scott Williams on behalf of the Prostate Cancer Roundtable

The following members of the Prostate Cancer Roundtable endorse this letter:

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cc: Secretary Kathleen Sebelius, Department of Health and Human Services
Dr. Carolyn Clancy, Director, Agency for Healthcare Research and Quality