

# Prostate Cancer Roundtable

P.O. Box 77476 : Washington, DC 20013

[www.prostatecancerroundtable.net](http://www.prostatecancerroundtable.net)

Email: [www.prostatecancerroundtable.net/contact-us](http://www.prostatecancerroundtable.net/contact-us)

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:*

- Ed Randall's Fans for the Cure ([www.edrandallsfansforthecure.org](http://www.edrandallsfansforthecure.org))
- Malecare Prostate Cancer Support ([www.malecare.org](http://www.malecare.org))
- Men's Health Network ([www.menshealthnetwork.org](http://www.menshealthnetwork.org))
- National Alliance of State Prostate Cancer Coalitions ([www.nasppcc.org](http://www.nasppcc.org))
- Prostate Cancer International ([pcainternational.org](http://pcainternational.org))
- Prostate Conditions Education Council ([www.prostateconditions.org](http://www.prostateconditions.org))
- Prostate Health Education Network ([www.prostatehealthed.org](http://www.prostatehealthed.org))
- The Prostate Net ([www.prostatenet.org](http://www.prostatenet.org))
- Us TOO International Prostate Cancer Education and Support Network ([www.ustoo.org](http://www.ustoo.org))
- Women Against Prostate Cancer ([www.womenagainstprostatecancer.org](http://www.womenagainstprostatecancer.org))

*About the Prostate Cancer Roundtable : [www.prostatecancerroundtable.net](http://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.

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