Honorable Greg Walden
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

July 12, 2017

Dear Mr. Chairman and Ranking Member,

Every 20 minutes another American man dies from prostate cancer. That is more than 75 deaths per day and over 26,700 per year, enough to fill a baseball stadium. The American Cancer Society estimates in its Cancer Facts & Figures 2017 report that 161,360 men will be told they have prostate cancer in 2017. Early detection is critical. The most recent research shows the five-year survival rate for all men with prostate cancer is nearly 100%.

The current method to diagnose prostate cancer is via needle biopsy of the prostate. Over 800,000 prostate biopsies are performed on men each year. However, despite the most rigorous protocols for obtaining and handling specimens, about 2.5% are subject to specimen provenance complications (SPCs), where a specimen from one patient is transposed with or contaminated by that of another patient.

This clearly poses an immense issue for the American public. Not only do patients receiving false- negatives lose the opportunity to treat their cancer at its earliest possible stage, but patients receiving false-positives – an estimated 1.3%, according to peer-reviewed literature -- are erroneously told they have prostate cancer when they do not. This results in extreme financial and emotional stress and unnecessary, expensive and invasive procedures, including radical prostatectomy and radiation therapy.

Misdiagnosis and this unnecessary medical care can be eliminated through the use of DNA Specimen Provenance Assay, or "DSPA." This method of testing has evolved over the last several years, and it is recognized as the highest standard of care among prostate biopsy procedures. DSPA simply matches each patient's unique genetic profile to that of the diagnostic tissue read by a pathologist or genetic counselor, in order to rule out the presence of undetected provenance complications prior to treatment. This ensures the proper patient is matched to his specimen.

Despite widespread adoption of DSPA as standard of care, the Centers for Medicare & Medicaid Services (CMS) has adopted the position that this critical testing does not fall within a permitted Medicare benefit category, and is, therefore, not reimbursed by Medicare. This interpretation poses a tremendous threat to hundreds of thousands of Medicare beneficiaries. To deprive

Medicare beneficiaries of access to an important test which eliminates medical errors is contrary to the best interests of patients.

The undersigned organizations support H.R. 2557, The Prostate Cancer Misdiagnosis Elimination Act of 2017, which would make DSPA testing available to Medicare beneficiaries for prostate biopsies. We urge members of Congress to protect patients from the devastating impact of misdiagnosis that can result from SPCs by enacting this legislation that provides Medicare reimbursement for the simple and cost-saving DNA test that can eradicate tragic medical errors.

Sincerely,

Alliance for Aging Research
American Association of Clinical Urologists
American Urological Association
Large Urology Group Practice Association
Malecare Cancer Support
Men's Health Network
Prostate Conditions Education Council
Prostate Health Education Network
Us TOO International Prostate Cancer Education & Support
The Veterans Health Council
Vietnam Veterans of America and
ZERO - The End of Prostate Cancer

CC: Honorable Larry Bucshon

Encl: Appendix.

Appendix.

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