Testimony of Deepak A Kapoor, MD

Re: H.R. 2557, Prostate Cancer Misdiagnosis Elimination Act of 2017

Contact Information:

Deepak A. Kapoor, MD
Chairman and CEO
Integrated Medical Professionals, PLLC
532 Broadhollow Road, Suite 142
Melville, NY 11747
Phone: (516) 342-8170
Fax: (516) 822-1686
Email: dkapoor@imppllc.com

Chairman Burgess and Ranking Member Green, thank you for inviting me to testify on the Prostate Cancer Misdiagnosis Elimination Act.

My name is Deepak Kapoor, and I am a practicing urologist specializing in the care of genitourinary malignancies, including prostate cancer. I also am Chairman and CEO of Integrated Medical Professionals (the largest independent urological practice in the country) as well as Clinical Associate Professor of Urology at the Icahn School of Medicine at Mount Sinai Hospital in New York. One out of every 80 men nationwide with prostate cancer are diagnosed and treated by our physicians in my practice.[1]

About one man in seven will be diagnosed with prostate cancer during his lifetime. Prostate cancer is usually diagnosed via needle biopsy of the prostate. As physicians who treat cancer, we rely on the results of the biopsy to counsel our patients on what treatment options are available to them – as such, the accuracy of the biopsy is of paramount importance. Recently, the clinical literature has revealed a troubling persistence of specimen complications where a relatively high number of biopsies had been switched or contaminated with tissue from another patient. This can result in invasive and expensive treatment of patients who do not have cancer and no treatment of some who have potentially life-threatening disease.

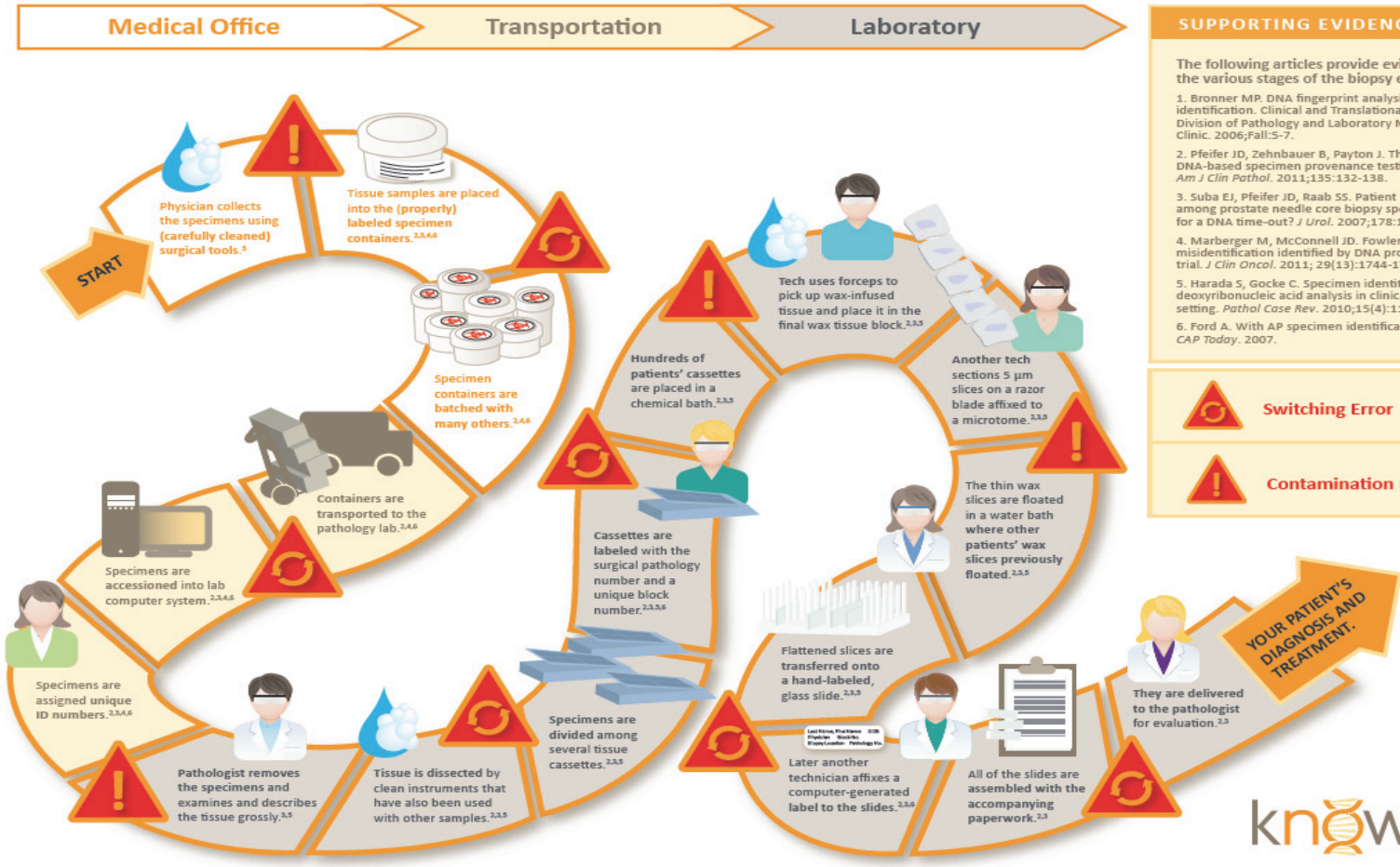
The promise of precision medicine and targeted therapy requires complete diagnostic accuracy and the elimination of diagnostic errors due to specimen switches and contamination. To improve diagnostic accuracy and eliminate medical mistakes, our practice changed our treatment protocol to require a DNA test for *all* positive biopsies to ensure that the right patient receives the right treatment - or no treatment at all. Importantly, this service is performed by an outside laboratory and not billed by my practice – there is no financial incentive for doctors to order this test.

Despite the best laboratory practices including (1) specimen bar coding, (2) rigorous chain of custody, and (3) detailed specimen handling protocols, recent studies document a persistently high rate of specimen provenance complications among prostate biopsy specimens. Specimen complications occur when a specimen from one patient is transposed with, or contaminated by, that of another patient.

Biopsy workflow is complex. This chart shows ten different places within the diagnostic testing cycle where a patient sample can be transposed with or contaminated by another patient's sample. These errors can result in the wrong patient getting the wrong diagnosis and tragically, the wrong or unnecessary treatment.

[1] American Cancer Society. *Cancer Facts and Figures 2017*. Atlanta: American Cancer Society; 2017.

Complications within the Diagnostic Testing Cycle[1]



SUPPORTING EVIDENCE OF ERRORS

The following articles provide evidence of errors in the various stages of the biopsy evaluation process.

1. Bronner MP. DNA fingerprint analysis for specimen identification. Clinical and Translational Pathology Research. Division of Pathology and Laboratory Medicine, Cleveland Clinic. 2006;Fall:5-7.

2. Pfeifer JD, Zehnbauer B, Payton J. The changing spectrum of DNA-based specimen provenance testing in surgical pathology. *Am J Clin Pathol*. 2011;135:132-138.

3. Suba EJ, Pfeifer JD, Raab SS. Patient identification error among prostate needle core biopsy specimens--are we ready for a DNA time-out? *J Urol*. 2007;178:1245-1248.

4. Marberger M, McConnell JD. Fowler J, et al. Biopsy misidentification identified by DNA profiling in multicenter trial. *J Clin Oncol*. 2011; 29(13):1744-1749.

5. Harada S, Gocke C. Specimen identity testing using deoxyribonucleic acid analysis in clinical and surgical pathology setting. *Pathol Case Rev*. 2010;15(4):116-120.

6. Ford A. With AP specimen identification, the hero is zero. *CAP Today*. 2007.

Switching Error

Contamination Error

The literature shows these errors are frighteningly common. A 2015 study documented that over 2.5%[2] of prostate biopsy patients are subject to specimen complications. Among patients newly diagnosed with prostate cancer, the study concluded that at least 1.28% are actually cancer free.

As noted in a June 26, 2017 New York Times article, these medical errors can have traumatic consequences on patients, with many being told they have prostate cancer when they do not and others inaccurately being told they are cancer free.[3] Patients inaccurately told they have prostate cancer are subject to expensive, invasive treatments such as surgery and radiation therapy. Patients inaccurately told they do not have cancer, defer or delay treatment because the cancer is not diagnosed at the earliest opportunity, with potentially fatal consequences.

There is a very simple way to eliminate these errors entirely: DNA fingerprinting with a DNA Specimen Provenance Assignment (DSPA) test, which definitively rules out switching and contamination errors that could otherwise lead to prostate cancer misdiagnosis. This process is as follows:

- A patient's reference DNA profile is established by a pre-biopsy cheek swab
- Biopsy tissue samples are placed in bar-coded specimen containers.
- DNA from the tissue a pathologist reads as malignant is compared to the reference DNA from the cheek swab.
- DSPA concordance ensures assignment of the positive diagnosis to the proper patient

Not only do these tests assuredly improve patient care, but they will certainly lead to savings to Medicare. According to an April 2016 Milliman study,[4] potential savings to the Medicare program from eliminating these medical errors would be at least $539 million over the next 10 years from eliminating:

- Unnecessary treatment for the 1.28% of patients newly diagnosed with prostate cancer that do not actually have cancer, and
- Over-treatment of the 0.19% of newly diagnosed patients that are misdirected to active therapy when their low grade cancer should be monitored through active surveillance.

This estimate was based on a rigorous analysis of MedPAR fee-for-service data based on the weighted average cost of treating prostate cancer. It is a conservative

---

[2] Wojno, Kirk, et al. "The Clinical and Economic Implications of Specimen Provenance Complications in Diagnostic Prostate Biopsies." *The Journal of Urology*, Vol. 193, Issue 4 (2014): 1170-1177.

[3] Kolata, Gina. "The Lab Says It's Cancer. But Sometimes the Lab Is Wrong." *New York Times* June 26, 2017.

[4] Milliman, Inc. "Prostate Cancer Treatment Utilization and Cost Analysis." April 12, 2016.

estimate because it excludes Part D drugs costs, assumes zero patient volume and price growth, and limits the treatment window to three years, though prostate cancer treatments often result in chronic, lifetime conditions.

DSPA is widely used today: Physicians rely on DSPA to accurately diagnose more than 60,000 prostate cancer patients per year and offered by many labs: Cleveland Clinic, Mayo Clinic, Labcorp, Strand Diagnostics. Yet Medicare asserts it does not have the authority to pay for DSPA testing because it does not explicitly diagnosis or treat disease. This interpretation of the Medicare statute is harmful to patients, wasteful of Medicare resources, and is in direct conflict with Medicare's own acknowledgement that "…DSPA testing is very useful as a tool for avoiding error and misidentification of a patient with cancer…"[5]

Congress can solve this problem by enacting the Prostate Cancer Misdiagnosis Elimination Act, which would require Medicare coverage of the DSPA test for positive biopsies where treatment is recommended by the treating physician. The bill has the full support of the entire prostate cancer patient and provider community, including ZERO – The End of Prostate cancer, American Urological Association, the Men's Health Network , Prostate Health Education Network, the Vietnam Veterans of America, and the Alliance for Aging Research. I urge Congress to seize the opportunity eliminate literally eliminate thousands of preventable medical errors, improve health care and reduce costs by enacting this bill.

[5] Strand Analytical Labs, Decision of Medicare Appeals Council, M-13-160 at 8 (Feb. 19, 2013). Available at https://www.q2a.com/Portals/0/MAC%20Referrals/PDF%2004012013/1-921456878%20Appeals%20Council%20DNA%20matching_Redacted.pdf