GERALD M. CROSS, MD, FAAFP, ACTING UNDER SECRETARY FOR HEALTH, DEPARTMENT OF VETERANS AFFAIRS

STATEMENT OF
GERALD M. CROSS, MD, FAAFP
ACTING UNDER SECRETARY FOR HEALTH
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BEFORE THE
SENATE COMMITTEE ON VETERANS' AFFAIRS
JUNE 29, 2009

Good morning, Senator Specter and Congressman Adler. Thank you for the opportunity to discuss the Philadelphia Veterans Affairs Medical Center's (VAMC) treatment of Veterans with prostate cancer through brachytherapy. I am accompanied today by Mr. Michael E. Moreland, Director, VISN 4; Mr. Richard Citron, Director, Philadelphia VA Medical Center; Dr. Michael Hagan, National Director for Radiation Oncology in the Veterans Health Administration; and Dr. Richard Whittington, Physician in Radiation Therapy at the Philadelphia VAMC. The staff at the Philadelphia VAMC discovered the problem of possible under-dosing and incorrect dosage of patients in May 2008, and the VA medical center director did not hesitate to immediately suspend the program and convene an Administrative Board of Investigation to uncover the facts. We informed and treated all affected Veterans and promptly suspended the program. The VA National Director of Radiation Oncology is continuing to investigate the reasons why these problems were not detected earlier. My testimony today will briefly describe brachytherapy, explain what happened as we currently understand the facts, and describe VA's response. Please let me begin by saying I am disappointed my fellow Veterans did not always receive the quality health care they deserve.

Brachytherapy for prostate cancer is a form of nuclear radiotherapy where small radioactive seeds are implanted in the prostate to destroy cancerous cells. Although risk to healthy tissues in the body is minimal, side effects may occur.

On May 5, 2008, a radiation oncologist performed a permanent implant prostate brachytherapy procedure using seeds of a lower apparent activity than intended. A physicist discovered this under-dosage ten days after the initial procedure. The physicist notified the facility's Radiation Safety Officer, who immediately reported the problem to VA's National Health Physics Program. On May 16, 2008, VA's National Health Physics Program also notified the Nuclear Regulatory Commission (NRC). VA convened a Clinical Risk Assessment Advisory Board, which recommended that all prior treatments be reviewed and that all patients who received inadequate radiation dosages be notified. Independent, external physicians and physicists with no involvement with the Philadelphia VAMC's brachytherapy program conducted these examinations of patient scans, dosages, and medical records. During this review, it was discovered that 92 events involving under-dosing or doses to organs or tissues other than the treatment site were found that met the definition of a medical event according to the NRC. VA

has regularly informed the NRC of any updates. It is important to highlight for these additional cases that the definition of "medical event" does not necessarily mean Veterans were harmed, and experts still debate the long-term impact of this treatment. Nonetheless, VA took the conservative approach of notifying these Veterans because we did not deliver a treatment as promised.

On July 2, 2008, the Philadelphia VAMC issued a press release and notified local members of Congress and Veterans Service Organizations. The facility also took proactive steps to contact each of the 114 Veterans who underwent brachytherapy at the VAMC from 2002 (when the program started) to 2008, whether they experienced a medical event or not. VA sent each Veteran a certified letter and called each Veteran or the Veteran's family directly. We also established a toll-free telephone number to answer questions. VA is covering all costs associated with additional tests and continuing to monitor their care at other VA and private facilities.
We regret this problem went undetected for nearly six years. VA, as other health systems, relies on complementary systems of accountability to identify quality problems like these on the system and individual levels. We use multiple internal and external survey and inspection processes (e.g., Joint Commission, American College of Radiology Oncology, American College of Radiology, Nuclear Regulatory Commission, and others); review of public databases such as the National Practitioner Databank; patient satisfaction and complaints; and individual peer review. Many of these systems failed to detect the aberrant care at Philadelphia, and, in fact, it was only the recognition of potential problems by VA staff that eventually led to more in-depth investigation, review, and subsequent disclosure to patients and the public.

The Philadelphia VAMC's brachytherapy program has been suspended since June 2008 and will not be reopened until the NRC's concerns have been satisfied and until requirements of the VA Radiation Oncology Program are met. VA also temporarily suspended programs at facilities in Washington, D.C., Cincinnati, Ohio, and Jackson, Mississippi. Based upon these reviews, the Cincinnati program was found satisfactory and is in the process of fulfilling national VA requirements for resuming prostate brachytherapy. Complete reviews of the Jackson and Washington programs continue. VA will also notify any additional Veterans if we determine they experienced a medical event.

VA currently offers brachytherapy at nine other facilities, and we are working with the NRC on regulatory issues related to prostate brachytherapy. Currently, the NRC is refining the definition of "medical event" as it pertains to these procedures. VA has developed criteria for suspending and restarting prostate brachytherapy programs. VA's National Health Physics Program will be conducting periodic site inspections at all facilities where prostate brachytherapy is performed and whenever a possible medical event is reported. VA clinical standards and procedures are now among the most rigorous in the health care industry.

Secretary Shinseki and VA's senior leadership are conducting a top-to-bottom review of the Department and are implementing aggressive actions to ensure the right policies and procedures are in place to protect our Veterans while providing them the highest quality health care possible.

Let me again emphasize our regret that this incident occurred, and add how proud I am of the work our staff at the Philadelphia VAMC does on behalf of America's Veterans. Nearly 60,000 Veterans receive world-class health care at this facility every year and these events are uncharacteristic of the level of care we provide. While we recognize the seriousness of the situation, it is important that our Veterans and their loved ones have faith and confidence in our medical system and in our system of care. Thank you once again for the opportunity to testify.