PHILADELPHIA VA TERMINATED CANCER TREATMENT PROGRAM

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MONDAY, JUNE 29, 2008

United States Senate,
Committee on Veterans' Affairs,
Philadelphia, PA

The Committee met, pursuant to notice, at 10:00 a.m., in Multipurpose Room 1, Philadelphia VA Medical Center, Hon. Arlen Specter, presiding.

Present: Senator Specter, Representatives Adler and Fattah.

OPENING STATEMENT OF SENATOR SPECTER

Senator Specter. Good morning, ladies and gentlemen. The hour of 10:00 having arrived, we will proceed with this hearing of the Veterans' Committee of the United States Senate.

One of the constitutional responsibilities of the Senate is to conduct oversight on activities of the Federal Government. We all know the tremendous debt which is owed by our society to the veterans of America who have fought in wars to establish and maintain our liberty, and one of the responses by a grateful government has been to provide medical care for the veterans. This is a subject which is very near and dear to my heart, because the first veteran I knew was my own father, Harry Specter.

My story is a typical American story, both parents were immigrants. My father came to this country from Russia in 1911 at the age of 18 and spoke about the privilege of being an American and serving with the American expeditionary force in France in 1918 to make the world safe for democracy. He was wounded in action. The government promised World War I veterans a $500 bonus--you could say they made him a $500 promise, too, and that promise was broken, as so many promises are broken by the Federal Government.

After my election in 1980, I immediately joined the Veterans' Affairs Committee in the United States Senate because of my concern for fair and equitable treatment for veterans, and had the honor to serve for six years as Chairman of the Veterans' Affairs Committee.

This hearing has been convened as a result of widespread publicity about problems in the Veterans Administration here in the city of Philadelphia. A week ago yesterday, there were extensive Sunday stories by both the Philadelphia Inquirer and the New York Times. Those stories reported that there was a systematic problem on the treatment of prostate cancer at the Philadelphia VA Medical Center, causing 82 veterans to receive incorrect doses of radiation. There was a procedure undertaken where there were seeds implanted to kill the cancer cells, but the seeds

were planted, in some cases, in the bladder or elsewhere. The New York Times characterized the procedures here as a "rogue cancer unit."

One factor which we will inquire into today is why these errors were not detected for a period of some six years, and why the oversight was done by the operative physicians themselves as opposed to some independent agency, and a major question exists as to what can be done to correct whatever problem existed, and what assurances can be given to the veterans and the public generally that the procedures here will be maintained and corrected so that appropriate service will be given to the veterans who are served here.

We now turn to our first witness, who is the Reverend Ricardo Flippin, a patient who was mentioned in the articles that I referred to. Reverend Flippin is a 21-year veteran of the United States Air Force, received his treatment here, he is a native of Philadelphia but currently resides in Charleston, West Virginia.

In accordance with the standard procedures, we will have testimony limited to five minutes, and then there will be questioning.

I expect to be joined by Congressman John Adler from New Jersey of the House of Representatives Veterans' Committee, and we will ask all witnesses to observe the time

limit, and there is a clock in front of each witness.

Reverend Flippin, we thank you for coming from West Virginia. We understand that you had been a native of Pennsylvania, Philadelphia, and we look forward to your testimony. You may proceed.

STATEMENT OF REVEREND RICARDO FLIPPIN, UNITED STATES AIR FORCE

Mr. Flippin. Thank you. Dear Senator Specter, I would like to thank you for your interest in this situation at the Philadelphia VA, and for inviting me here today.

Although I was born and raised in Philadelphia, I had been absent from the Philadelphia area from the time that I left to join the Air Force. I returned to Philadelphia in 2004 to take care of my mother, whose health was failing. As I did not have a private physician in this area, I decided that I would try to take advantage of my benefits as a veteran and I sought medical care from the Philadelphia VA. This was my first contact with the VA health care system.

On April 15, 2004, I made my first trip to the Philadelphia VA, because my family doctor in Charleston had told me that my PSA was increasing and that I should make a point of following up with the doctor, when I got to Philadelphia. A PSA test was performed on my first visit, which showed a level of 7.04. It took the VA until May 9, 2005 to actually treat my prostate.

On June 3, 2004, I returned to the Philadelphia VA and was given a referral for urology consult. This consult took place on June 29, 2004. I was scheduled for a biopsy which took place on August 26, 2004.

On September 23, 2004, I was advised that I had cancer. In December of 2004, I met with a physician to discuss my opinions.

In January 2005, I believe that I met with the radiation oncologist. He was quite convincing that brachytherapy was the best option for my situation and that he had received good results from this procedure in the past and had performed hundreds of them. Let me say at this point that that is what impressed me, was that this physician had told me, looking me eyeball to eyeball, that he had actually performed over 600 brachytherapy procedures. My procedure was not scheduled until May 9, 2005. By then, my mother had passed away, and I had returned to Charleston, West Virginia to be with my wife, my granddaughter, and my niece.

During the time after my procedure, I had medical problems that required me to return to the VA on several occasions for additional medical care. Eventually, the VA sent me to the Ohio State University for an additional procedure with a specialist. Until I received notification from the VA in Philadelphia that they were investigating my medical care as well as the medical care of other veterans, no one had ever told me that there had been any problem with the procedure that was performed at the Philadelphia VA. To date, no one from the Philadelphia VA has specifically told

me what went wrong with my procedure, nor have I been advised to what went wrong with my procedure, nor have I been advised to what the effects of this procedure has been and will be on me.

On July 2, 2008, they sent me a letter saying, "Our review of your treatment program has indicated that there is a possibility that you received the radiation to your prostate gland that was less than your physician intended," which led me to believe that there was something wrong with the seeds or perhaps the equipment. The letter never mentioned that other parts of my body apparently got a radiation dose greater than my physician intended.

On August 15, 2008, they sent me a letter saying that the treatment did not meet the VA standard of care. The results of a CT scan indicate that the treatment that you receive did not meet the VA's high standard of care. "You recently were notified by telephone of this result, and this letter is being sent to confirm that conversation. We have also advised your VA primary care physician of this fact, and we will send him/her a copy of this letter."

They sent me some forms for filing a claim, which was nice of them, but not one person in the VA told me what the effects of the surgery that I received were, no one from the Philadelphia VA, no one from the West Virginia VA has written me or called me and said that I am more likely to

get a reoccurrence. No has said--

Senator Specter. Reverend Flippin, before your time expires, would you tell us what injuries, if any, you sustained.

Mr. Flippin. I sustained a radiation burn to my rectum which caused me to be laid up for five months, 24 hours a day, bedridden.

Senator Specter. You may proceed.

Mr. Flippin. For the last several years, I have worked with a program designed to help veterans deal with the issues that they face. My biggest concern is that there may be veterans out there who have had this happen to them and they have not gotten the message from the VA. As someone who has spent 20 years on active duty in the Air Force and as someone who regularly works with veterans to see that they get the services that they need, I know that there are probably some veterans out there who received letters but did not open them because they were from the VA. They also may have received phone calls they did not return because they were from the VA and my hope is that the attention that this is creating will make those guys or, more likely, their spouses or family members, go back and open those letters and get the follow-up treatment that they need.

Finally, I really cannot add anything to the discussion about Dr. Kao. I have never met the gentleman. He was not

the doctor who I met with to decide the type of therapy to select. I was surprised to learn this week that he was a contractor. No one told me that my surgery was going to be done by someone who did not work for the VA. Thank you for your concern about the medical care that veterans are receiving from the Department of Veterans' Affairs.

Respectfully submitted, Reverend Ricardo C. Flippin.

[The prepared statement of Mr. Flippin follows:]

Senator Specter. Thank you, Reverend Flippin.

Without objection, I will put into the record a statement from Representative Schwartz.

[The statement of Ms. Schwartz follows:]

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Senator Specter. I would like to turn now to Congressman John Adler, House of Representatives, who is a member of the Veterans' Affairs Committee and who, early on, spoke out about this issue.

Welcome, Congressman Adler, and would you care to make an opening statement?

OPENING STATEMENT OF MR. ADLER

Mr. Adler. Senator, thank you very much, and thank you as well on behalf of the veterans of America and the people of America for your calling this field hearing here today. You acted promptly when you learned about the troubles we have had with the brachytherapy program here at this VA hospital. Your concern for veterans has been noted for a number of years, but the fact that you would have such a prompt hearing, I think the country thanks you for that.

Our first President, George Washington, once said, "The willingness with which our young people are likely to serve in any war, no matter how justified, shall be directly proportional as to how they perceive the veterans of earlier wars were treated and appreciated by their country."

The veterans like Reverend Flippin who sought treatment for their prostate cancer at the Philadelphia VA Hospital did not receive the quality healthcare their selfless service to our country earned them.

The people responsible for administering the

substandard care in brachytherapy let our veterans down and sent the wrong message to young men and women thinking about joining our all-volunteer armed forces. We must do better for him.

So, in my sense, this hearing today, and the hearing we will have in Washington next week are about evaluating what happened, not to cast blame, although there is certainly some blame to go around, but to reassure our veterans and those considering volunteering for our armed forces in the future, that we will keep faith with the commitment we have made to them as they have kept faith with us by keeping us safe and keeping us free and keeping us the strongest country in the world.

Reverend Flippin, I thank you for your 20 years of active duty service; that would have been enough. But I thank you as well for coming forward to share with us in this room, with newspapers, with America, the substandard care you received. It would have been enough if you had just soldiered on as you had while on active duty and suffered quietly, but the fact that you would share your experience, share your physical pain and your emotional trauma so that we can learn from it, so that we can set in place a new standard of care to meet the needs of our veterans, like yourself, going forward, is greatly to your credit. It is part of your ongoing service to your country,

and I appreciate it, I am sure Senator Specter appreciates it, Representative Schwartz appreciates it, all the people from our region and from the whole country should join us in thanking you for what is going on.

I wonder at what point you first decided we were letting you down as a country. At what point did you think, during your process, during your treatment, that the VA Hospital was not giving you the standard of care you deserved.

Mr. Flippin. I think--

Senator Specter. Congressman Adler, we are going to hold the questions for the first round of questioning.

Mr. Adler. I am sorry. Fine. I apologize.

Senator Specter. It is okay.

We will turn now to Congressman Chaka Fattah for an opening statement.

Thank you for joining us, Congressman Fattah.

OPENING STATEMENT MR. FATTAH

Mr. Fattah. Well, Senator, I rearranged my schedule so that I could be here. I want to thank you for holding this hearing. It is very timely. This is a great facility that has provided a lot of care for our veterans over many years, but this incident raises an extraordinary level of concern, and I want to thank you for convening us today, and I am here to get some answers.

So, rather than giving a major opening statement, I want to thank the Reverend for his service to the country. My brother also served in the Air Force, and I think it also says a great deal about you that you returned to Philadelphia to care for, at that time, your ailing mother, and that you are leading a faith community. You are a service to our country in every respect, and we want to get to the bottom of what happened, and in incidents where mistakes happened, we are all human beings, but the question becomes, what was done once the mistake was realized, and whether or not, in this instance, all of our veterans were best served.

And I thank the Senator for using the weight of his office to convene us so that we could begin to get to the answers to this question. So, thank you, Senator Specter for your leadership on this subject. Thank you.

Senator Specter. Thank you, Congressman Fattah.

Before turning to questions, we are going to hear from other witnesses.

I would like to call now Dr. Gary Kao to the witness stand, if Dr. Kao would step forward.

Dr. Kao has a bachelor's degree from John Hopkins, an M.D. from John Hopkins, and a Ph.D. from the University of Pennsylvania. He was board certified in 1994 by the American Board of Radiology, and was contracted by the VA in

2002.

We are calling on Dr. Kao early because he has been identified in the news accounts as having performed a number of the operative procedures in question.

I note that you are accompanied Dr. Kao, and if those who have accompanied you would identify themselves, I would appreciate it.

Mr. Vaira. Good morning, Senator Specter, Congressmen. I am Peter Vaira of the Law Firm of Vaira & Riley, and my associate is William Murray, from my law firm.

Senator Specter. Thank you very much, Mr. Vaira.

Dr. Kao, the floor is yours and you may proceed.

STATEMENT OF GARY KAO, M.D., PH.D., ASSOCIATE PROFESSOR, RADIATION ONCOLOGY, UNIVERSITY OF PENNSYLVANIA

Dr. Kao. Thank you, Senator Specter and Congressmen, for the opportunity to voluntarily appear before you so that I may be heard on this very important subject matter and correct some very serious false allegations contained in recent publications about me, most notably the New York Times.

I have worked very hard in my life to best serve the field of radiation oncology and my patients in over 15 years of clinical practice. My dedication to my work is reflected in my educational achievements, earning a bachelor's degree and a medical doctorate degree from Johns Hopkins University and its School of Medicine, followed by medical internship and residency and radiation oncology residency. This culminated in board certification in radiation oncology.

I am especially proud that, in 15 years of continuous medical practice, there has not been a single malpractice claim against me. My impeccable background and commitment to the care of my patients make the false accusations against me particularly devastating and misguided.

Let me first express my sincere sadness to the plight of Reverend Flippin. I would have welcomed the opportunity to do anything I could to help him, but I have never been

contacted by Reverend Flippin or anyone on his behalf after the procedure, and therefore do not know about his complaints and symptoms which arose about a year after his procedure.

I was first notified about Reverend Flippin from the New York Times article published the previous Sunday, and because I have not had access to any of his records since leaving the VA, I am unable to further comment on his medical treatment or condition.

What I can truthfully report is that I, along with others at the Philadelphia VA, implemented the program for brachytherapy to serve the best interest of veterans. Contrary to allegations that I was a "rogue physician," there were precise standard operating procedures formulated and followed and a system of monitoring and oversight. We formulated the first algorithm of any radiation oncology procedure at the VA to define those standard operating procedures. As with any program, it is not without incidents or challenges; however, I have always acted in the best interests of the patients in delivering this important treatment. I have never, nor would I ever, falsify documents, cover up results, or act in a manner detrimental to the interest of any patient.

What has become clear is that a misunderstanding of elementary principles or concepts have led some to

inappropriately and incorrectly conclude that deficient care was routinely rendered; it was not the case. It is important that these issues be clearly understood. A fundamental issue which I want to directly address and which has been misunderstood is the subject of what the NRC defines as a reportable medical event and its applicability to our work at the VA.

Here are the facts:

Fact one, the standard definition of a reportable medical event to the NRC was not in existence when the brachytherapy program started at the VA. The definition was specifically never mentioned in my training in brachytherapy at the Northwest Hospital in Seattle, nor was it clarified by NRC personnel in their investigations in 2003 or 2005 when they were on site at the Philadelphia VA. This definition was not the subject of any training provided to us by the NRC or the VA.

Fact two, the definition of a reportable medical event to the NRC does not define a standard of effectiveness of medical treatment either scientifically or medically.

A patient whose treatment results in a reportable medical event may still have received effective treatment and be within the appropriate standard of medical care.

Fact three, the appropriate standard of medical care for brachytherapy should not be determined by the NRC

definition of a reportable medical event. There are many more significant factors that determine appropriate treatment, such as the number of seeds, the location of seeds in the prostate, location of seeds outside the prostate, the concentration of seeds in the affected area of the prostate, the size, shape of the prostate, the stage, grade, extent, and location of the cancer, and the clinical follow-up of the PSA test results, all of which are not addressed in the NRC defined standards.

The field of brachytherapy during the period of 2002 to 2008 was and still is an evolving field. While certain conditions and circumstances at the Philadelphia VA could have been improved, I am confident, based on my knowledge of the field and the nature of the patients treated at the VA that, during my tenure, the patients received appropriate medical care, and which was effective in addressing their cancer.

In considering my experience at the VA and experience in the brachytherapy program, however, there are certainly issues which need to be addressed and implemented the care provided to our veterans. These include the following:

One, a system should be established so that a treating VA physician is notified when his or her patient presents for treatment at any other VA medical center. This should be accomplished with appropriate confidentiality and privacy

safeguards, but which would enable a VA physician to have access to the patient's electronic medical records at any other VA medical center.

For complex medical procedures such as brachytherapy, two, there should be a uniform set of standard operating procedures established through a collaboration of the involved healthcare professionals and administrative personnel. Once defined, these standard operating procedures should be applied throughout the entire VA system with appropriate treatment.

Three, there should be a method of categorizing systemic problems by level of urgency, so that serious problems such as those involving failures of medical equipment or transfer of patient-related data will receive immediate attention from the proper personnel being quickly resolved.

Four, there should be a formal system by which the NRC and other national regulatory bodies would be required to continually train doctors and other personnel in the latest defined standards.

Five, the respective medical disciplines of separate VA hospitals should have a formal system of continuous dialogue, together about difficulties encountered during practice and possible suggested solutions. This could be accomplished with the aid of a videoconferencing system to

which all VA physicians have access.

Six, for every complex medical procedure, there should be sufficient funds for the VA to provide timely and complete care to veterans. Relating to my own experience, having a full-time medical physicist dedicated to brachytherapy would have enabled us to transition earlier to a real-time system of brachytherapy.

Thank you, Senator and Congressmen.

[The prepared statement of Dr. Kao follows:]

Senator Specter. Thank you, Dr. Kao.

We are now going to turn to Panel 3 before any of the questioning so we can have a factual basis for the questioning beyond what has appeared in the press.

So, I would like to call at this time Dr. Gerald Cross, Dr. Richard Whittington, Director Michael Moreland, Director Richard Citron, Dr. Michael Hagan, and Director Steve Reynolds.

Our first witness on this panel will be Dr. Gerald Cross, who has an M.D. from Loma Linda University. He is the Veteran Administration's top doctor, and is the Principal Deputy under the Secretary of Veterans' Affairs for Health. Dr. Cross appeared at a hearing of the Veterans' Committee last week and graciously consented to come to this hearing, although it caused a change to his plans. So, we appreciate your being available, but we did want to proceed at the earliest date practical.

Dr. Cross, the floor is yours for five minutes.

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

Dr. Cross. Good morning, Senator and Congressmen. Thank you for the opportunity to discuss the treatment of veterans with prostate cancer through brachytherapy.

VA has a well-documented record of quality care, but when there are exceptions, whatever the cause may be, we apologize and express our deep regret to the patient, as I do now.

Indeed, we go beyond that. We work with the individual patient to provide them the care that they need. We further analyze what went wrong, we take corrective actions, and we look at the lessons learned that can be applied throughout our national healthcare system. VA is not afraid to admit when we make a mistake, and we strive to make as few mistakes as possible.

The staff at the Philadelphia VAMC discovered the problem, a possible underdosing and incorrect dosage of patients in May 2008, and the VA Medical Center Director immediately suspended the program and convened the Administrative Board of Investigation to uncover the facts.

We informed and treated all affected veterans. The VA National Director of Radiation Oncology continues 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.

In brachytherapy for prostate cancer, small radioactive seeds are implanted in the prostate to destroy cancerous cells. Although the risk to healthy tissues to the body is minimal, side effects may occur.

So, what has been learned? A lot. We value our relationships with universities, but the responsibilities for care and oversight must be well defined at the outset, even when, as in this case, there is a contract with a university, despite those facts, at the end of the day, VA must oversee the quality of care for veterans.

External oversight is also important, but not sufficient. Noteworthy is the fact that the VA program is accredited while about 85 percent of the programs outside the VA are not.

We will continue to ensure that all stakeholders are made aware of all-important developments, positive and negative, concerning veterans' healthcare.

Now, I will describe the details. On May 5, 2008, a radiation oncologist performed a brachytherapy procedure using seeds of a lower apparent activity than intended. A physicist discovered this underdosing 10 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. VA convened a clinical risk assessment advisory board which recommended that all prior treatments be reviewed and notification of all patients who received inadequate radiation dosages.

External physicians and physicists with no involvement with the Philadelphia VAMC brachytherapy program conducted these examinations of patient scans, dosages, and medical records. During this review, we found up to 92 potential events involving underdosing or imprecise placement. 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 the treatment. Nonetheless, VA took the conservative approach of notifying these veterans.

On July 2, 2008, the Philadelphia VAMC issued a press release and notified local members of Congress and veteran service organizations; that was in 2008. The facility also took the proactive steps to contact each of the 114 veterans who underwent brachytherapy at 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. VA, as with other health systems, relies on complimentary systems of accountability to identify quality problems. Many of these systems failed to detect the less-than-optimal care in this case, 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 to the public.

The Philadelphia VAMC brachytherapy program has been suspended since June 2008, and will not reopen until the NRC's concerns have been satisfied and until requirements of the VA radiation oncology program are met.

Senator Specter. Did you say suspended in June 2008?

Dr. Cross. Yes, sir. This notice was sent out in June 2008.

VA currently offers brachytherapy at nine other facilities, and we are working to ensure the highest quality of care for 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 program. VA's National Health Physics Program will continue to conduct the site inspections at all facilities where prostate brachytherapy is conducted.

VA clinical standards and procedures are now among the most rigorous in the healthcare industry.

Secretary Shinseki in VA--

Senator Specter. Dr. Cross, how much more time will you need?

Dr. Cross. Thirty seconds.

Senator Specter. Thank you.

Dr. Cross. Thank you, sir.

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

Let me again emphasize our regret that this incident occurred and how proud I am of the work our staff at the Philadelphia VAMC does on behalf of America's veterans. While we recognize the seriousness of this situation, it is important that our veterans and their loved ones have faith

and confidence in our medical system.

Thank you once again for the opportunity to testify, Senator.

[The prepared statement of Dr. Cross follows:]

Senator Specter. Thank you very much, Dr. Cross.

Our next witness is Dr. Richard Whittington. Dr. Whittington is the physician on radiation therapy at the Philadelphia VA Medical Center, former head of radiation oncology here, doctorate degree and M.D. from Rice University.

Thank you for joining us, Dr. Whittington, and we look forward to your testimony.

STATEMENT OF RICHARD WHITTINGTON, M.D., CHIEF OF RADIATION ONCOLOGY, PHILADELPHIA VA MEDICAL CENTER

Dr. Whittington. I do not have a formal opening statement, Senator. I am sorry.

All I would like to say that I have been around the Veterans' Administration for most of my life. My father recently retired from the Veteran's Administration after working with the VA for 52 years. My sister has worked for the VA for 33 years. My brother worked for the Veterans' Administration until the day he died. I am a veteran myself, and I have to say that these incidents that are described are the low point in my professional career, because it happened on my watch.

[The prepared statement of Dr. Whittington follows:]

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Senator Specter. We will turn next to Dr. Steve Reynolds, the Director of Nuclear Materials Safety from the Nuclear Regulatory Commission, bachelor of science in engineering from Florida Institute of Technology, and the Director of the Nuclear Materials Safety Center since 2005.

Thank you for joining us, Director Reynolds, and the floor is yours for five minutes.

STATEMENT OF STEVE REYNOLDS, DIRECTOR, NUCLEAR MATERIALS SAFETY, UNITED STATES NUCLEAR REGULATORY COMMISSION

Mr. Reynolds. Thank you. Senator Specter, Congressman Adler, and Congressman Fattah, I am honored to represent the U.S. Nuclear Regulatory Commission at today's hearing.

The NRC is very concerned about this issue, and an important part of our mission as a regulator for the civilian use of nuclear material is to protect public health and safety, including medical uses; therefore, we are concerned about all patients receiving medical care, including our veterans.

The NRC does not regulate the practice of medicine. We do, however, set the rules under which licensees such as the VA use radioactive material. As a holder of the NRC license, it is the responsibility of the VA to identify problems in medical treatments and report those problems to the NRC.

The NRC, once notified of the apparent problems, began increasingly intensive inspections of the brachytherapy program at VA Philadelphia and at the 12 other VA facilities that conduct this medical procedure. We are concerned about what we have found to date.

The VA has suspended this procedure at five sites, including the VA Philadelphia, and they will not restart

until we, the NRC, are satisfied they have addressed all the problems. Our inspections are continuing, and once we complete these later this summer, the Agency will determine if enforcement action is necessary.

We are also looking at NRC procedures to see if there are improvements we can make in our oversight system. We will continue to look critically at our inspection and licensing programs as well as to consider proposed regulatory changes.

In closing, the NRC takes these medical events very seriously, and continues to be actively engaged on these issues. Thank you.

[The prepared statement of Mr. Reynolds follows:]

Senator Specter. Thank you very much, Director Reynolds.

The other individuals who are here are for the purpose of answering questions. So, at this time, I would like Reverend Flippin and Dr. Kao to return to the witness table, and Dr. Cross and Director Reynolds to stay, and the other prospective witnesses to step back and we may call on you as the occasion presents itself.

We will now turn to the opening rounds of questions of the witnesses, and they will be also five minutes in duration.

Dr. Cross, according to the media accounts, there were 92 veterans at the Philadelphia VA Medical Center who received incorrect doses of radiation. They received substantially less than the radioactive seeds and other patients received excessive radiation to nearby tissue, including bladder and other organs. The incorrect doses were performed, according to media reports, at the University of Pennsylvania by a doctor under contract to the VA, and that doctor has been identified as Dr. Gary Kao.

According to the press reports, it took more than six years to catch the mistakes, and the checks were made by those who were in the program, that the quality assurance aspects of the program were conducted by the contracted doctors themselves and were not independent enough to assure

getting an unbiased report.

What has your investigation disclosed with respect to those allegations?

Dr. Cross. We have indeed found on our own investigation after we discovered this problem ourselves that up to 92 individuals could have been underdosed--and that is potentially underdosed. Some investigation still continues into that area.

It is important to understand--and I am a family physician, so this is not my area of specialty--but as I have learned more about this in the recent days, I have been impressed that this is both an art and a science. The art is in how the patient is addressed, how the seeds are actually lined up and planted.

We did not rely just on internal review, Senator, and that is important for you to know. And I want to read one 10-second statement. We also had external review. We were accredited whereas most programs are non-accredited, and we received a statement in 2007 from the American Radiation Oncology--that specifically mentions brachytherapy, and in summary states the following of the review: "In summary, your PVMC practice, as noted above, is a well organized and operated radiation oncology practice that not only meets but in many aspects exceeds the ACRO standards for practice accreditation, and we are pleased to inform you that the

PVAMC has been awarded a three-year accreditation."

They go on to complement the quality assurance program and so forth. Now, this is an external review organization that came in to review our program.

Senator Specter. Dr. Cross, you have stated in your opening statement that it is up to the Veterans Administration to do the oversight.

Dr. Cross. Yes, sir.

Senator Specter. What is your response to the allegation that the quality assurance aspects of the program were conducted by the contracted doctors themselves and were not independent enough to assure that there was an unbiased report?

Dr. Cross. I think that is a valid statement.

Senator Specter. Why, Dr. Cross, did it take six years to find out what was going on?

Dr. Cross. For two reasons.

The first is that any complication or underdosing is not immediately apparent unless specifically measured.

Number two, the measures that were put in place to check on the quality, like the one that I just read to you, suggested that things were not only good, but better than the national average.

Senator Specter. Dr. Cross, with respect to the VA procedure generally, is this aberrational what went on here

at the veterans' hospital or is this, with respect to two items, something that could be occurring other places, and that is, number one, the failure of having objective observers to make a determination, and secondly a failure to find a problem for such a long period of time?

We are obviously concerned about what happened here, but we are also very concerned about what the practices are by the VA nationally.

My time is up and the red light is on. I am going to shift and have ten-minute questioning rounds by each of the panelists to give you a chance to respond, Dr. Cross.

Dr. Cross. There is, in fact, something unique in this situation at Philadelphia that I think is more so than we would find at other locations, and that is the nature of the contract and the nature of the relationship with the University.

In my review of this program, it is almost indistinguishable as to where the University ends and the VA begins. In fact, the radiation oncology reviewer--

Senator Specter. Well, that may be indistinguishable, but you are saying that the Veterans' Administration has the responsibility for oversight.

Dr. Cross. That is exactly my point. That arrangement, I think, was part of the problem. We value tremendously our relationship with our university

affiliates, but in this case there was a contract, and the contract had some rather, in my experience, unusual language, to the point that when the reviewers reviewed the program from the American College of Radiation Oncology, they made the following statement: "This VA radiation oncology department is under the control of the University of Pennsylvania."

I think that we, regardless of any such relationships, regardless of any such contracts, we, the VA, must prevail in having our oversight of this program and other programs.

Senator Specter. Well, what are you doing to correct this kind of problem here and nationally?

Dr. Cross. It is quite a long list of things, Senator, but let me highlight just a couple of them.

Number one, we hired a highly regarded radiation oncologist to review our programs.

Number two, we invested in training--mandatory training. In fact, in January of this year, we brought all of the individuals involved in these programs, the key individuals, to Washington, D.C. for additional review and training of current procedures and policies.

Number three, when we found the problem here at Philadelphia, we did not stop there. We mandated that we review all of our other programs, as well, and we did that ourselves.

Senator Specter. When you suspended the program in June 2008, as you testified, did you know about these failures at that time?

Dr. Cross. When we curtailed the program here at Philadelphia in 2008, we notified the VSOs, we notified the congressional offices, we notified the media, then we took further action--

Senator Specter. The answer to my question is, yes, you did know about the problem?

Dr. Cross. No, sir, we decided to start an investigation at that time of all of our other sites, as well.

Senator Specter. And did you later find out about the problems?

Dr. Cross. We did find some other problems, as well.

Senator Specter. And what action did you take at that time to notify congressional oversight?

Dr. Cross. We notified the Committee members.

Senator Specter. Notified?

Dr. Cross. Committee staffers.

Senator Specter. I did not hear that.

Dr. Cross. We notified Committee staffers.

Senator Specter. Let me turn to you, Dr. Kao. You have counsel with you, but nonetheless let me say that, as you have noted, you are appearing here voluntarily and you

are under no obligation to respond to questions, but we do appreciate your being here.

The allegations, as you have already heard, are very serious. You have been identified as the individual who performed these procedures on most of the 92 veterans. The allegation has been made that the seeds were not planted in the prostate where they should have been, but they were instead lodged in the bladder and other organs that there were insufficient seeds planted. Did you plant seeds that went into the bladder and other organs?

Dr. Kao. Senator, let me first correct something that has been incorrectly stated--

Senator Specter. Why don't you do that, but answer my question first.

Dr. Kao. Sir, yes, there have been occasions where seeds have been implanted in the bladder or outside the prostate.

Senator Specter. What action did you take on that to notify the patients?

Dr. Kao. The chance of seeds in the bladder or outside of the prostate is a recognized risk of the procedure and--

Senator Specter. Well, it is a recognized risk, but did you notify the patients?

Dr. Kao. No, sir.

Senator Specter. Why not?

Dr. Kao. Even when seeds are outside the prostate, they still contribute radiation dose to the cancer, so--

Senator Specter. The allegations are that you also had excessive radiation. Is that true?

Dr. Kao. I believe some of our cases had seeds and radiation outside the prostate which would constitute a medically reportable event.

Senator Specter. But did you have excessive radiation?

Dr. Kao. By that definition, sir, it would be yes.

Senator Specter. And did you notify those patients about the excessive radiation?

Dr. Kao. I did not.

Senator Specter. I am 35 seconds over.

Congressman Adler.

Mr. Vaira. Can he explain that--

Senator Specter. Oh, yes. Pardon me. You may proceed with explanation.

Mr. Vaira. He would just like to explain that. Yes or no sometimes has a--gives you a bad definition.

Would you please, in about a minute, explain that.

Senator Specter. Take whatever time you need, Dr. Kao. I wanted you to answer my questions, but you are privileged to say whatever you care to on that.

Dr. Kao. So, every step of the brachytherapy procedure was defined in the algorithm that we collaboratively wrote,

and at the time that the program was implemented, the definition of what is reportable to the NRC was not in existence and only came later on. If we had been aware of this definition, we would have acted to notify the NRC and the patient.

We were working very closely and continually supervised by the radiation safety of the VA and we trusted their advice as to what should be reported. In retrospect, I should have known that the definition of what is reportable has changed through the years.

Senator Specter. Thank you, Dr. Kao.

I will turn now to Congressman Adler.

Mr. Adler. Thank you, Senator.

Doctor, you seem to be the only person in this room except perhaps counsel that fails to recognize the statistics we have been dealing with. Colleagues at your table here have been acknowledging that we have, out of 116 procedures, 92 botched procedures.

You quarrel with the New York Times, you quarrel with the Philadelphia Inquirer, it seems you are quarreling with the panelists here who are acknowledging the VA has responsibility to 92 for inadequate medical care.

Do you care in any way to refine your testimony to talk about whether there was any substandard care on your part.

Dr. Kao. No, Congressman, I do not believe that our

procedures were botched.

I do recognize there were occasions where we could have done better. I still maintain that we rendered effective treatment, Senator.

Through the years of the program, we were continually improving our results, and yet, we recognize that we can still do better and we were in the process of transitioning to the real-time brachytherapy system, which would have also helped in improving the quality of our treatment, Congressman.

Mr. Adler. Doctor, I heard you earlier, I think, sort of blame a lack of training for the problems that this program encountered. I heard you sort of blame the Radiation Oncology Department and its lack of supervision of you and your coworkers. I heard you blame the Radiation Safety Office and the VA hospital administration, it is in your written testimony.

I am sort of baffled. We have these 92 people who got, by any fair measure, substandard care. I understand there are legal concerns you face right now. I am concerned about the medical concerns and the America-obligation concerns these 92 people--this is a good chance for you to say I am sorry--not to take all the blame. There may be other people that deserve blame. This would be your chance to say to Reverend Flippin, I am sorry for what you went through.

This would be a good chance. Why don't you do that right now, say, I am sorry for the pain you suffered, sir.

Dr. Kao. Congressman, I agree with you. I do accept a share of the blame. I do believe that we could have and should be doing better. I am saddened by the plight of the Reverend and wish that I had the chance to do anything, anything at all to help him.

Mr. Adler. Gosh, it seems to me you had a chance when you were performing the radiation procedure on him; that was the chance.

Dr. Cross, you told us a moment ago that after the revelation of this problem in June of 2008, you reviewed all programs. Can you go into a little bit more detail, because I guess what we need to hear, not just for patients coming to this VA hospital which, by and large, as Congressman Fattah suggests, has provided very good care in so many different fields for so many different veterans over the years, but why don't you reassure us that you in fact reviewed all of the programs so that this problem which was not isolated to one doctor, but this program occurred massively here at Philadelphia and, to a lesser extent, I guess, in Jackson, in Cincinnati, and in Washington, D.C., that this problem is unique and that, by and large, the VA program is delivering the quality of care that America owes its veterans.

Dr. Cross. Thank you, Congressman. Of course, VA does deliver good quality of care, but we are also a trusted organization, and the point here is, when we find something wrong, our policy, our ethics, is to acknowledge it, accept it, and do something about it, and that is what we did.

We found the problem; it was not the external reviewers, it was not all those accrediting groups that found it, it was our own staff who found it. And when they found it, they brought it forward, bravely, appropriately, and our leadership then said, let's disclose it, let's notify Congress, let's notify the media, let's notify the VSOs, and let's take action.

One of the things that we do when we find a problem is, well, that is one place. Could this problem be occurring elsewhere? And so, we mandated that all of our other facilities undergo a special review which our staff put together and conducted to see how they were doing.

We did find some problems, not to the level of concern that I had in Philadelphia, but when we find those problems, we work with the NRC who have been very collaborative and helpful with us as a partner in this to make sure that the corrective actions are taken. We are still working on that.

Mr. Adler. Doctor, I thank you for that answer.

I guess I am still stumped as to how this could have gone on for six years before it reached your level to be

addressed for this facility and nationally.

How could it have gone on for that long? It seems like a long time for the folks at the top not to know what the folks in the field are doing to rather than for our veterans.

Dr. Cross. I think the lesson learned here is we have to find a better way to monitor this kind of very highly, highly specialized, relatively unusual procedure that we deal with in hospitals nationwide. I do not think this is just an issue for the VA, I think this is an issue for the entire national health system, that we have to address this and do a better job of it.

As a result of that, that is why we are working with the NRC and the Joint Commission and others to make sure that we have the lessons learned from this and are better able to detect it more quickly.

Mr. Adler. I guess I am still not getting the answer I need to hear for my satisfaction and for the satisfaction of the people of America about why it took so long to catch it in the sense that this was six years from the first botched procedure to the closure of the program. Why six years? Why not, we caught it after 20 patients got substandard treatment? Why do we wait for 92 patients to get less than what they deserved, having served in uniform our country-- why did it take that long for us to catch a problem and

really stop it?

Dr. Cross. My impression, based on the reviews I have done is there was not adequate follow-up on the measurement done afterwards, number one.

Number two, all of the people that we brought in to do the external review said we were doing a great job.

Mr. Adler. Maybe I could turn to Mr. Reynolds.

We treat nuclear products, whether very small, like a radiation seed, or very large, like a nuclear power plant, very seriously. That is why we have a federal agency to keep America safe, the Nuclear Regulatory Commission. So, whether it is power plants around the country or whether it is a nuclear materials program, I have to think that it cannot be a good thing to put nuclear material in the wrong parts of somebody's body; am I wrong on that?

Mr. Reynolds. We expect, when people use--the medical professionals use radioactive material, that they put it in the right spot in the body, absolutely, sir.

Mr. Adler. Is it in any way problematic to you--to me, it is outrageous--but maybe just problematic, a lower threshold, that we are taking these seeds of nuclear radioactive material and putting them not where they are designed to fight a cancer, but in other body parts in that general region, but not actually the spot that has the cancer. Is that not at least problematic to you?

Mr. Reynolds. Right. We expect--in fact, the VA's license requires them to identify problems like this and report them to us.

Mr. Adler. Well, given the seriousness of putting nuclear material in somebody's body, how did it break down so badly here where--apparently just one doctor doing the procedures, but lots of people floating around in the hospital in the VA system, with the NRC--how do so many people not catch this and say, this is a pattern of substandard care? How did it wait so long before the NRC or the VA system shut this outrage down?

Mr. Reynolds. Let me try to answer that for you.

Again, I will go back. The VA is responsible for identifying their medical problems and reporting them to us. This means that the doctors involved, Dr. Kao and the other doctor, the medical physicist involved that, when the perform the procedures, if they identify a problem, they are supposed to report that. They are required to identify the problem and report that. This also includes the VA Philadelphia's radiation safety officer. She is responsible for the day-to-day oversight of the doctors and the medical physicists and the rest of the medical staff in their use of radioactive material. This also includes the VA Philadelphia's Radiation Safety Committee, who is responsible here in Philadelphia for reviewing medical

treatments and reviewing them critically and assessing if anything needs to happen and reporting to them. Also responsible is the VA National Health Physics Program. National Health Physics Program is responsible for performing inspections at the VA hospitals where they use radioactive material. Those people did not report--did not identify the problems and did not report them.

What we have seen and what we have documented in our inspection report is a lack of a strong safety culture here at the VA Philadelphia, and safety culture is one where people expect and are free to raise safety issues. Based on interviews we have had with some of the medical physicists and others, they were aware of substandard treatments, and for whatever reason that I do not understand, they did not raise that to their management or to the NRC.

Mr. Adler. Do other VA hospitals around the country that have brachytherapy programs have a different reporting standard, or did this VA hospital just fail to meet the standard that is nationwide?

Mr. Reynolds. The reporting standard is the same for all hospitals, VA or otherwise, that do this treatment.

Mr. Adler. My time is expired.

Senator Specter. Thank you Congressman Adler, Congressman Fattah.

Mr. Fattah. Thank you.

Mr. Reynolds, is it not true that these reporting standards for a medically reportable event was not in place at the time that these procedures were taking place?

Mr. Reynolds. No, sir. I believe Dr. Kao is mistaken. The requirements to report to NRC when there is adverse care to patients went into effect in 1979.

Mr. Fattah. Was this part of that doctrine in 1979, because we were not doing seeds in 1979, were we? We were implanting seeds in 1979?

Mr. Reynolds. I am not sure exactly when prostate brachytherapy started.

Mr. Fattah. Okay. Well, let me--I will come back to that.

Doctor--now, how do you pronounce your name?

Dr. Kao. Kao.

Mr. Fattah. Kao. Let me thank you. You are one of the most educated people in the country in terms of cancer and radiation; is that correct?

Dr. Kao. Thank you, Congressman, yes.

Mr. Fattah. And a journalist wrote a story and it said that you did certain things, and I wanted to give you a chance to get some things cleared up here.

When the allegation in the New York Times story said that seeds or overdoses of radiation in these seeds that were implanted in patients, did that relate to any of the

patients that you treated?

Dr. Kao. I believe, yes, Congressman.

Mr. Fattah. So, didn't you use a standardized seed strength?

Dr. Kao. Yes, Congressman.

Mr. Fattah. So, when there are references made to more strength than might have been desired, or weakened, what does that refer to?

Dr. Kao. I believe the allegation was that there was an incorrect number of seeds outside or inside the prostate, Congressman.

Mr. Fattah. Now, the prostate is a walnut-sized organ, right?

Dr. Kao. Yes, Congressman. I am sorry, it is difficult to see from your angle, but it is this little thing that sits below the prostate--I am sorry, below the bladder, in front of the rectum, and above the testicles.

Mr. Fattah. Is it a normal occurrence when you are implanting seeds that some seeds end up outside the prostate, across the breadth and width of this type of medical treatment?

Dr. Kao. It is almost unavoidable, Congressman. Brachytherapy is an inherently subjective procedure where seeds are put in by hand, and so that is a recognized risk and in every consent form, Congressman.

Mr. Fattah. So, if we looked at all these cases across the country, it would be an abnormality for seeds not to end up outside the prostate.

Dr. Kao. It would be very frequent.

Mr. Fattah. Okay. It would be very frequent for them to end up in the rectum or in the bladder.

Dr. Kao. Bladder or outside--and sometimes it migrates into other organs, such as the lung.

Mr. Fattah. Now, Dr. Reynolds, is it a reportable medical event if a seed ends up in the rectum, under the NRC, today, yesterday, any day?

Mr. Reynolds. Well, the requirements have not changed since Dr. Kao has been practicing and--

Mr. Fattah. No, no. I am not asking about--is it now, today, a reportable event if a seed ends up in the rectum?

Mr. Reynolds. It depends on the placement of the seed and the strength of that seed, but most likely, yes.

Mr. Fattah. It is not always reportable, but in some cases, it is.

Mr. Reynolds. Right. It depends on what the doctor has prescribed for the patient.

Mr. Fattah. Now, there is a Safety Committee at the NRC, and there was a meeting on May 7, 2009, and there were various quotes that were ascribed to the Doctor from that meeting. He says in his testimony, his voluntary testimony

before the Committee today, in his written testimony, that none of these quotes were made by him.

Dr. Cross, is there any way for us to figure out how that can be the case, that there are quotes in a report ascribed to the Doctor, that he asserts before this Committee that he did not make?

Dr. Cross. Sir, did you say that is the NRC Committee or--

Mr. Fattah. Yes, it is an NRC Committee, not a VA committee, but I am asking you--

Dr. Cross. I would not be able to comment.

Mr. Fattah. Okay. So, well, it was a VA procedure, so I just figured you may have had some input in this process.

Can you help us, Director Reynolds.

Mr. Reynolds. I am sorry. I am confused about what, specifically, you are talking about.

Mr. Fattah. Well on number 14 of page 8, the Doctor says that there are a number of quotes and he goes through them, in detail, from this safety report, and he says he did not make them, and the report says that he did.

Mr. Reynolds. Could you mention the doctor's name for me?

Mr. Fattah. Dr. Kao.

Mr. Reynolds. Oh, okay. I am sorry. I was thinking you were saying somebody else.

Mr. Fattah. Is there anyone accompanying you who can help us with this mystery?

Mr. Reynolds. I thought you were talking about somebody else. Please ask your question, again. I think I can answer it.

Mr. Fattah. There are some quotes in the report from May 7, 2009, the Safety Committee, and it ascribes specific quotes, extensive quotes to the doctor that he asserts in his written testimony to the Committee today that he did not make.

I am trying to figure out how we can determine how that could have happened.

Mr. Vaira. There are two statements that we handed out. One, a lengthy one, and I think that is the one you are quoting from, it is about 14 or 15 pages.

Mr. Fattah. Yes.

Mr. Vaira. I do not know if the Director--your examiner there--has that in front of him.

Mr. Fattah. Okay. Well, it is probably too much of a time constraint for us to try to get to it at this point, but it is of interest that you can have these extensive quotes--yes.

Mr. Reynolds. I am sorry. They handed me his statements right now. This is information that, when our inspectors talked to Dr. Kao, this is what he told our

inspectors.

It may not be verbatim what Dr. Kao told our inspectors, but this is our inspectors' words of what Dr. Kao said to our inspectors during our inspection.

Mr. Fattah. So, these are quotes that are not quotes.

Mr. Reynolds. No, these are quotes of what was said at the Advisory Committee for the use of medical isotopes.

Mr. Fattah. Okay. Well, thank you.

Dr. Cross, you said in your response to Senator Specter, that this is a problem--first of all, there are a number of VA programs in terms of prostate cancer that have been put on hold. How many are there that have been put on hold?

Dr. Cross. At the moment, I believe we have two that are still under investigation and several more that--

Mr. Fattah. Well, originally that were put on hold, based on this review.

Dr. Cross. I would have to--I do not have my experts at the table with me, so--

Mr. Fattah. The gentleman that is behind you is trying to tell you.

Dr. Cross. Four.

Mr. Fattah. Four, okay. So, this is not a Philadelphia VA issue, this is something that you were looking at across the board.

Dr. Cross. Exactly, and that is the routine procedure for us, when we find a problem in one place we look--

Mr. Fattah. And did you say that this problem exists in non-VA medical facilities, and perhaps even more so?

Dr. Cross. I think the issue of compliance with the standards, the oversight, the accreditation are all issues that apply not only to the VA but to the broader system, as well.

Mr. Fattah. Okay. Senator Specter, I also want to acknowledge the presences of--Congressman Brady has a staffer here and Councilwoman Jannie Blackwell, who represents this area--and I want to thank you again for holding this hearing.

Senator Specter. Thank you very much, Congressman Fattah.

We will proceed now with a second round of questioning, five minutes.

Reverend Flippin, what injuries did you sustain as a result of this procedure?

Mr. Flippin. I was informed by a doctor at Ohio State University that I had a radiation burn to my rectum.

Senator Specter. And what is the consequence of that?

Mr. Flippin. The consequence of that was loss of a job, approximately four-and-a-half months of 24/7--

Senator Specter. You earlier told me that there was

bleeding involved.

Mr. Flippin. Oh, yes, when I went to the bathroom.

Senator Specter. Indelicate as it is, it is important for the record. What specifically happened to you in that respect.

Mr. Flippin. Okay. That is what sent me back to the West Virginia VA hospital, was that I started experiencing bleeding in my stool, approximately ten--I started experiencing bleeding in my stool and--

Senator Specter. Reverend Flippin, you had testified earlier that no one ever informed you about what had happened from the VA, is that so?

Mr. Flippin. Right. I did not know anything about this until I receive the first letter.

Senator Specter. First letter from whom?

Mr. Flippin. From the VA.

Senator Specter. When did you get that?

Mr. Flippin. Last year. I think it was November 5--July 2, 2008 was when I received the letter stating about the brachytherapy and the care that I had received.

Senator Specter. Dr. Cross, the information is that there were similar problems in Jackson, Cincinnati, the District of Columbia, Philadelphia had 97, Jackson 8, Cincinnati 6, and D.C. 3. What action has the Veterans' Administration taken with respect to those other sites.

Dr. Cross. The one definitive action, I believe, in Cincinnati, is that they have been cleared. It turned out that they got a good review, and we go with the NRC, they can proceed to continue on.

The only two that are still being reviewed further is Washington and Jackson, as I recall.

Senator Specter. Dr. Cross, you testified that there needs to be some attention to this kind of issue, as you put it, by a national health system. Would you amplify what you think could be done? We are now considering comprehensive health reform. This could well be an issue to be included. What specifically would you like to see be done by the national health system?

Dr. Cross. Sir, I was not referring to health reform, I was referring to the oversight organizations that we work with every day. We work with a number of them.

Senator Specter. Well, what could be done better on the oversight, then?

Dr. Cross. I think that we have to put in place some better, clearer, more easily understood standards, perhaps. There is still debate on some of the issues as to whether or not these specific standards that are in place right now that we are trying vigorously to enforce are really relevant clinically in the long term, over time. That has to be clarified, and I think we would like to work with the

organizations that do that to be useful in that regard.

Senator Specter. Director Reynolds, Dr. Kao has stated that there was not a sufficient definition of a reportable medical standard.

Do you think there is any substance to that position?

Mr. Reynolds. The entire medical community across the Nation has been subject to that standard for many years and has used it successfully.

Senator Specter. You think there is a sufficient definition of a reportable incident?

Mr. Reynolds. Yes, sir.

Senator Specter. So, you think that if there was excessive radiation or seeds went into the bladder that would clearly be something that ought to be reported, at least to the patient.

Mr. Reynolds. Yes, sir. In fact--

Senator Specter. What corrective action do you anticipate from your Nuclear Regulatory Commission?

Mr. Reynolds. Well, first, we expect the VA address all their problems to ensure this problem will not happen again, and that includes developing nationwide standards and procedures, it includes training of all the staff that Dr. Cross already talked about. And then, we are also looking at our inspection procedures to see if we can enhance them, and would we want the VA's National Health Physics Program

to do inspections more often, and then, do we need to do more inspections on the VA and the VA's National Health Physics Program?

Senator Specter. Congressman Adler, would you like a second round of five minutes?

Mr. Adler. Reverend Flippin, Let us just imagine that over the course of six years you performed 116 sermons, and out of those 116 sermons, 92 of them were lousy, don't you think you would get booed out of your church?

Mr. Flippin. Yes, sir.

Mr. Adler. Aren't you, as I am, surprised that Dr. Kao still has a medical license after botching 92 of 116 procedures?

Mr. Flippin. I do not know anything about Dr. Kao. The only thing I would say is that when you mentioned, wouldn't it be nice to say something to Reverend Flippin and it was a very--I was moved, and I thought he might look at me and say something. Now, I have an impression of Dr. Kao that I had not before even coming in here.

Mr. Adler. I thought we both got the same impression, sir.

Dr. Cross, you heard Dr. Kao say that there might be grossly inadequate training for the physicians who perform brachytherapy procedures. Do you have any comment about the adequacy of training the doctors receive or standards that

the VA uses to evaluate doctors before allowing them to perform this procedure in Philadelphia or anywhere around the country over the last number of years.

Dr. Cross. I am not sure I heard the statement as you quoted it; however, training is always important, and when we find an issue like this, my natural inclination is to look at training and was it adequate. That is always the first place to look at.

We have good people, and if they are well trained and ready to go, we can usually avoid problems, and so I think naturally that is the first place to look, and then the accreditation and the oversight and all those kind of things that go along with it.

Mr. Adler. I kind of heard Dr. Kao pointing at you and the VA system and that is why he did not do such a good job.

I also heard Mr. Reynolds say the reason the NRC did not hear about problems is because people in the VA system failed to report to the NRC some of these problems.

Is that generally accurate, Mr. Reynolds?

Mr. Reynolds. Correct.

Mr. Adler. So, I guess I am asking you what you would have done differently over the years--not you, personally, but the system would have done differently over the years to report up to the NRC this inadequate use of radioactive materials in the bodies of veterans who are coming for good

care, and lots of cases, 80 percent of the time, did not get that good care.

Dr. Cross. First, I think it is important to note that we did report to the NRC at the time that this was uncovered in June of 2008, and in fact, I have the exact date right here and who was contacted.

We consider them to be important allies in this effort. The point is that you are making, we should have done that sooner and that should have been discovered sooner, and that is where we have to put the mechanisms in place within the VA and outside the VA that will ensure that this is more easily detected, more quickly detected.

Mr. Adler. Do you have a sense why peer review did not catch this problem here, right in the hospital, before it ever got to 20 patients and 40 patients and 60 patients--before it got to 82 patients.

Dr. Cross. I think I do, actually. There was a quality assurance program, but perhaps not as effective as it should have been.

Peer review really focuses more on finding things where there are complications that have occurred and then grading them and taking action as a result. In none of these situations would such an event have occurred, where there was a clear complication going.

Mr. Adler. Because I guess you are sitting next to a

clear complication. Poor Reverend Flippin had a--

Dr. Cross. I am pointing out that that was over a year later, and I think that is the point right there, that time lag and the lack of identifiable complications right them.

Mr. Adler. I guess I am hoping that you and Mr. Reynolds, the NRC, and the VA system can coordinate better. I am hearing some sort of blame, at least from the NRC towards the VA system. I think you have been much more respectful about owning up to responsibility in a shared way, but I guess I am hoping to leave this hearing and maybe a subsequent hearing in Washington with greater confidence than I had coming in here that you have now owned the problems, shared the responsibility with the NRC, and are defining a reporting schedule, a peer review system, a level of checks and balances throughout the system so we do not have to hear from the next Reverend Flippin, the next Air Force or Army, Marine, or Navy person who came getting good care--maybe not on prostate but on something else and it somehow slipped through in a different way, different than this one, but just as troubling as this one.

Can you give you me and this Committee the reassurance we need for America?

Dr. Cross. Absolutely, and I can do that because I view our colleagues who do oversight, whether it be the Joint Commission and the NCRO, the ACRO, or the Nuclear

Regulatory Commission as colleagues. I believe that they are allies. I see them as very important to this effort, and I engage them, pull them into our discussions, invite them to our meetings, invite them to our offices to work closely with us. That is the kind of relationship we are going to have, and that relationship is going to make this a success.

Mr. Adler. Well, Doctor, we certainly need that process and we certainly need better results.

Thank you.

Senator Specter. Congressman Fattah.

Mr. Fattah. Thank you, Senator.

Dr. Reynolds, I want to try to delve into this on a more general basis here.

Do you have a sense of how many of these procedures have been done, say, over the last five years, in our country.

Mr. Reynolds. At VA hospitals or across the board?

Mr. Fattah. No, across the board.

Mr. Reynolds. Thousands.

Mr. Fattah. Thousands. Can you tell us or give us a general understanding of how many medically reported events have occurred that have been reported to you?

Mr. Reynolds. Very few.

Mr. Fattah. Very few. That is what I want to try to

delve--I want to try to reconcile a couple of things.

The doctor who is one of the experts in this whole field says that it is a very frequent occurrence that, in planting these seeds, that this happens, and my colleague says that anyone who does this, this is a botched procedure and he is surprised that the doctor still has a medical license, but if this going on in thousands of cases and nobody is reporting it to you, then I am trying to figure out--because it gets to Senator Specter's real point, is if we are trying to fix healthcare nationwide we need to figure out how we deal with this on a systematic basis, because this is happening, it is going on--either it is not an event that can be avoided because of the proximity of the prostate to the rectum and the bladder, and therefore it is going to be visited upon almost anyone who gets this treatment or it is a botched procedure in which nobody who is performing them are reporting them to you anywhere across the country. Now, which one is it?

Mr. Reynolds. In addition to licensees, including the VA being required to report problems to us, we go out and do independent inspections, and based on our independent inspections of the other hospitals that do brachytherapy treatment, we have not seen this problem. The prostate is properly treated with seeds, we do not see medical events nowhere near the extent you see at VA Philadelphia.

Mr. Fattah. So, you are saying this is an aberration and that it is not the case that seeds end up outside the prostate on a normal occurrence.

Mr. Reynolds. You may have an occasional--

Mr. Fattah. I am going to give you a chance to review that before you comment.

Mr. Reynolds. Could you ask your question again, I lost my train of thought.

Mr. Fattah. Is this occurring in a great many of these procedures?

Mr. Reynolds. No. Medical events--

Mr. Fattah. No, not just the generality of medical events, but a reportable medical event having to do with seeds ending up outside the prostate.

Mr. Reynolds. Right. Medical events dealing with seeds outside the prostate happen very, very infrequently based on reports to us and based on our direct inspections.

Mr. Fattah. So, you get almost no reports.

Mr. Reynolds. That is correct.

Mr. Fattah. And therefore, you believe it almost never happens.

Mr. Reynolds. Based on the reporting to us and our inspections, that is correct--outside of VA Philadelphia.

Mr. Fattah. So, then the doctor is completely wrong that this is a frequent occurrence.

Doctor, go right ahead.

Dr. Kao. In the same transcript that, Congressman, you had referenced earlier, a physician advisor to the NRC has commented that if they were to audit all the programs that do brachytherapy in this country, there would be 20,000 reportable medical events. No program has undergone the level of scrutiny that this program has undergone, Congressman.

Mr. Fattah. So, there could be cases where the Reverend who got this treatment ended up with a situation and nobody told him about it. There could be a lot of people who are facing symptoms from seeds outside the prostate which may not be avoidable, but nonetheless, could--because, at the end of the procedure, the urologist is supposed to go in and get the seeds, right?

Dr. Kao. That is correct.

Mr. Fattah. And there are seeds that are unaccounted for. That is how this works, right?

Dr. Kao. That is correct.

Mr. Fattah. And those seeds are somewhere.

Dr. Kao. That is correct, Congressman.

Mr. Fattah. And they are probably somewhere close to the prostate, either in the rectum or the bladder.

Dr. Kao. Or in the tissue surrounding the prostate, Congressman.

Mr. Fattah. So, my point is that--I mean, I think there is a great deal of interest in this matter based on the way the New York Times wrote this story, but I think that the bigger story here is that this is not about this hospital or this doctor, this is about a procedure designed to help men with a very serious health problem in which part and parcel to that procedure is the real danger that these seeds can end up outside the prostate, and which almost no doctors are reporting this to doctors to anybody, including you, and you are the person that it should be reported to, both inside the VA and outside the VA, and I think that Senator Specter has brought this to our attention in a way that will impact national policy and that will be meaningful, and it is not part of any kind of witch hunt about a particular program or doctor here in Philadelphia.

Senator Specter. Thank you, Congressman Fattah.

Congressman Adler, do you care to make a final closing statement.

Mr. Adler. Let me first again thank Senator Specter for organizing this field hearing, and thank all the panelists for coming before us. I particularly thank Dr. Cross and folks from the VA hospital who have owned up to the seriousness of the problem that occurred here. For some of these procedures to have half the seeds be planted wrongly outside the prostate, that is not a near miss, that

is clearly a mistake, and I thank Dr. Cross and Dr. Whittington and other folks from the hospital and from the VA system who want to solve a problem, who acknowledge the seriousness of the problem, who know that we let down patients who came here to get high-quality care and did not get it, and I thank the VA system for shutting down this program until they get it right, and shutting down programs around the country until they get it right.

I understand a couple have been reopened. I hope this program is restored properly here. But until it is gotten right, we should not do it. This is not just an art, there is a science to it, and the science is to put these seeds in the right body part, and not kind of close, but right where they are needed to destroy the cancer rather than cause harm to patients who came here for good medical care.

Mr. Reynolds, I thank you for sharing your concerns about the reporting up to the NRC. I am hoping you will be more active in redefining what is a medical event so that you get more of the reporting that Congressman Fattah was talking about, because I think we need to have better communication, a better understanding of what is going right and what is going wrong. My sense is that this hospital does a lot of things right, but in this one program, was doing a lot of things wrong, and it is the aberration for this very good facility, but it is an aberration that lasted

for too long.

I hope we get to the bottom of this situation here. I hope it does not recur in this program, in this facility, or anywhere in the country, because I think our veterans deserve better care than they got in this particular situation here.

Thank you, Senator.

Senator Specter. Thank you, Congressman Adler.

Congressman Fattah, closing statement?

Mr. Fattah. No, I think I agree with my colleague when he says that our veterans deserve the very best care and that this is a great hospital. I definitely agree with that, since it is headquartered in my District.

I just think that, again, the real issue here is in our opportunity to impact national policy is the benefit of this hearing, and I want to thank Senator Specter for convening us.

Senator Specter. Thank you, Congressman Fattah.

One final point, Dr. Kao. Reverend Flippin raised the issue about your looking at him directly and saying something to him personally. You were not the doctor who attended Reverend Flippin, but you represent the whole process.

Would you care to look at him and say something to him?

Dr. Kao. Reverend Flippin, we should have, we can do

better. I hope we will have the chance to do better by you and your colleagues in the future.

Senator Specter. Well, that is great symbolism to conclude our hearing.

Mr. Vaira. Senator Specter.

Senator Specter. Sure.

Mr. Vaira. Congressman Fattah quoted from a not lengthy but about a 15-page statement that my client made to the--I do not know how accessible that is. It is damn good. It has got a lot of medical definitions and explanations in it.

If you want a copy, I know the staff has a copy--anybody here who wants a copy--we do not have enough with us--call my law firm and we will make it available to everybody. It is a good learning experience.

Thank you very much, Senator.

Senator Specter. Thank you, Mr. Vaira. Now that you have testified, I think you have to understand that you are subject to cross-examination.

Mr. Vaira. You and I go a long way back, Senator, a long, long, way.

Senator Specter. Peter Vaira is used to cross-examination, but customarily, he is doing it, but thank you.

Thank you, Dr. Kao, for being as candid as you have been, and thank you, Dr. Cross, for similarly giving your

vacation plans up and coming here today, and Director Reynolds and Reverend Flippin, the most important thing that needs to come out of this hearing--this is not the final chapter. The House Veterans' Affairs Committee will be having a hearing in Washington. I will be talking to the Chairman of the Senate Veterans' Affairs Commission, Senator Akaka, and we will be looking further, but we have identified some very, very serious problems, and we need to learn from our mistakes, and when Dr. Kao candidly said he planted seeds in the wrong organs and should have told people, candidly said there was excessive radiation and he should have told people, that should be a lesson for other doctors similarly situated.

The business of not having review and oversight by somebody who is outside the system is obvious, but that has to be done, and we have identified it as a national problem in Cincinnati and D.C. and a problem across the country. So, this is something which has to be attended to.

I want to thank my staff, Will Wagner and Trevor Benitone and others who have worked here on a short order, but I thought it was very important to have this initial oversight done very promptly because I hear a lot of street talk about what is going on and what is the care for veterans, and what great institutions like the Hospital of the University of Pennsylvania and the Philadelphia VA

Center has a problem like this it causes a lot of skepticism and doubt, but I think we have taken a significant step forward and very symbolic to have Dr. Kao and Reverend Flippin embrace, which is a great sign for America.

That concludes our hearing.

[Whereupon, at 11:35 a.m., the hearing was concluded.]