STATEMENT OF GARY KAO, M.D., Ph.D.

SUBMITTED TO

THE HEARING OF THE SENATE COMMITTEE OF

VETERANS' AFFAIRS

PHILADELPHIA VA MEDICAL CENTER

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Introduction

I became a doctor because of my desire to help people. I am and always have considered myself to be a compassionate dedicated physician who prides himself in taking care of his patients. I have never knowingly hurt any of my patients and my record shows that to be true - I am proud that I have not had a single malpractice claim filed against me in fifteen years of continuous clinical practice. In 1984 I graduated from Johns Hopkins University with a Bachelor of Arts in Philosophy and graduated in 1988 as a Medical Doctor from the Johns Hopkins School of Medicine. I completed two years of Internal Medicine Residency followed by completion of a Residency in Radiation Oncology, all at the University of Pennsylvania School of Medicine ("Penn"). I have been Board Certified in Radiation Oncology since 1994, and an Attending Physician at Penn since that time. I am also a member of American Society for Therapeutic Radiation Oncology.

In order to gain additional expertise in anticancer treatment, I completed a doctoral dissertation at Penn in Molecular Biology, which I successfully defended in 1998 and was awarded a Ph.D. from Penn in Molecular Biology. While still on staff at Penn, I completed a Postdoctoral Fellowship at the Fox Chase Cancer Center in 2002. Shortly after completing my Fellowship, I was assigned to the Philadelphia Veterans Affairs Medical Center ("PVAMC") and then became a full-time staff member of the PVAMC. I was asked by the PVAMC to start a brachytherapy program at the PVAMC and was proud to have earned this honor. I accepted the responsibility and worked hard with others at the PVAMC to develop a top notch program in this evolving area of medicine. I remained a PVAMC staff physician in Radiation Oncology continuously until the beginning of 2008.

Given all that I have worked so hard to achieve and my commitment to patient care, I was devastated, personally and professionally, by the false allegations published in the New York Times on Father's Day, branding me as a "rogue doctor" who had covered up mistakes and operated in isolation and without supervision. Never in my career have I ever falsified any medical records and never have I participated in a cover-up.

On the contrary, what happened at the PVAMC in connection with the brachytherapy program is in no way what has been depicted by the New York Times article. The truth is that the Prostate Brachytherapy team at the PVAMC was a collaborative interdisciplinary effort that I led, but which was minutely supervised every step of the way by the Radiation Oncology Department, the Radiation Safety Office and ultimately by the Administration of the PVAMC. Under sometimes challenging circumstances, the Team tried to deliver quality care to veterans, who would otherwise not have access to treatment.

That is why the malicious allegations against me and the Program are so deeply hurtful. So too is the claim that I operated on my own, without supervision and without guidance. The falsity of that allegation is easily demonstrated because there was a standard operating procedure for the administration of brachytherapy. The procedure was codified in a Prostate Brachytherapy Algorithm that was jointly

created by Radiation Oncology, Medical Physics, Urology, Radiation Safety and Nursing and disseminated to and approved by all levels of the PVAMC Administration. This Algorithm was constantly reviewed and revised as our Team gained more expertise in delivering care to our patients. The Algorithm established a consensus, providing structure for a procedure that had no precedence or guiding standards at the PVAMC when I was asked to help start this Program. Each brachytherapy patient treated by me or any other physician at the PVAMC was cared for according to the SOP established by Algorithm.

The following points address specific aspects in greater detail:

1. The PVAMC Prostate Brachytherapy Program was a multidisciplinary collaboration.
   The members of the Brachytherapy Team consisted of:
   i. Radiation Oncology
   ii. Urology
   iii. Radiation Safety
   iv. Medical Physics
   v. Nursing/ Program Coordinator
   vi. Administration
   The program was supervised by Radiation Safety. I was not a member of the Radiation Safety Committee and was not invited to attend meetings of the Committee.
2. The PVAMC Brachytherapy Program team members received the necessary training for Prostate Brachytherapy.
   a. As a resident physician, I was taught prostate brachytherapy at Penn by senior attending physicians.
   b. I completed the same Prostate Brachytherapy course in Seattle, WA at the Northwest Hospital that others from the PVAMC also attended.
   c. We observed the Prostate Brachytherapy Program at the Mercer Hospital affiliate of the Department of Radiation Oncology in Trenton, NJ, a program that also utilized the preloaded method of brachytherapy.
   d. I was proctored in the performing of my first ten Brachytherapy cases at the PVAMC by experienced physicians.
   e. Other physicians were available for immediate consultation and additional mentoring.
   f. **The allegations in the NY Times of a lack of brachytherapy training or supervision are therefore untrue.**
3. I created the protocol for providing brachytherapy treatment (**"Algorithm"**) with collective multidisciplinary input, vetted through the PVAMC Administration.
   a. The absence of standard policy regarding Brachytherapy in the PVAMC prompted the need for written consensus when the Program was first created in February 2002.
   b. The first version was completed before the first patient was treated in February 2002, and continuously updated through the years of the Program.

c. The Algorithm was collaboratively written by all members of the Brachytherapy Team, and represented our collaborative expertise regarding the Standard Operating Procedure for providing brachytherapy.
d. The Algorithm describes those patients for whom brachytherapy was most suited as well as those for whom the procedure would not be effective. It also details the steps each patient undergoes through the Brachytherapy process beginning with the pre- procedure planning and following through with the actual procedure and the post-procedure follow up.
e. The Algorithm does not include any reference to reportable Medical Events as defined by the Nuclear Regulatory Commission ("NRC") because no such definitions existed at the start of the program.
f. Because the PVAMC served a wide geographical patient population, the Algorithm recognized that those patients living far from Philadelphia may have to receive post procedure care at their local hospitals.
g. **The NRC, in its investigation, and the NY Times failed to mention the existence and purpose of the VA Prostate Brachytherapy Algorithm.**

4. The Initial and Revised Written Directives serve different purposes.
   a. **The New York Times article falsely accuses me of altering the Written Directive.**
   b. The Written Directive is mandated by the NRC and VA's Office of Radiation Safety. The forms were designed by Radiation Safety, completed by both Medical Physics and Radiation Oncology, signed by the physicians, and processed by Radiation Safety.
   c. The Initial Written Directive (WD) specifies the number of seeds to be ordered by Radiation Safety, i.e. the prescription for number of seeds. It is completed by the Medical Physicist together with the Radiation Oncologist physician, who then signs the WD.
   d. A copy of the Initial WD is submitted to Radiation Safety, which places the order of the number of seeds, and then receives and secures the seeds. The original WD remains in the patient's medical chart.
   e. On the day of the Brachytherapy procedure, Radiation Safety brings the seeds to the procedure room (adjacent to the OR suite), remains in the room to supervise the procedure, and to store and safeguard any seeds that are retrieved by Urology from the bladder or found outside the patient.
   f. Integral to the procedure is the Urologist. Immediately after the implanting of the seeds, the Urologist, using a cystoscope, will retrieve any seeds that have either migrated to or been implanted in the bladder. This action by the Urologist is done in connection with every procedure since a recognized risk of the procedure is that seeds will come to rest in the bladder.
   g. After the seeds are retrieved by the Urologist, that physician and Radiation Safety inform the Radiation Oncologist of the number of seeds that do not remain in the patient. Through this collaborative process, the Team determines the actual number of seeds that remain in the patient.
   h. Under supervision by Radiation Safety, the Radiation Oncologist completes the Revised WD that states the actual number of seeds retained within the patient. The Revised WD is submitted to Radiation

Safety, and a copy is again placed in the patient's medical chart. Radiation Safety staff and Urology are present throughout the brachytherapy procedure.

i. The WD can be revised yet again prior to the discharge of the patient on the day following the procedure. This revision would reflect any seeds passed by the patient in his urine while recovering from the procedure. If there is a second revision, it too is submitted to Radiation Safety and a copy is retained in the patient's chart.

j. The procedure described above assures that there is an accurate count of the disposition of all of the seeds originally ordered by Radiation Safety for a particular procedure.

k. **Given the appropriateness and the different purposes of the Initial and Revised Written Directives, my handling of the Written Directives was entirely appropriate and legal. I did not falsify or erase any Written Directive at any time, contrary to the allegations of the New York Times, nor was it likely that any other member of the Team did so. It is for this reason that these allegations are not only false but scurrilously so.**

5. How the Brachytherapy Procedure is performed.
   a. The prostate is an organ the size of a walnut and is immediately adjacent to the bladder and rectum.
   b. The procedure performed at the PVAMC was via the Preplanned, Preloaded Method. This entailed a transrectal ultrasound sizing of the prostate completed at least two weeks prior to the actual implant of the seeds. This ultrasound serves as the basis for the treatment planning which includes determining the number of seeds and needles required to be ordered by Radiation Safety via the Initial Written Directive.
   c. Informed consent is obtained from the patient, who is counseled that seeds can migrate away from the prostate, and that up to 5% of patients may develop complications that include an inflammatory condition of the rectum known as radiation proctitis.
   d. The patient is taken into the procedure room and anesthesia is induced.
   e. Stabilizing needles are inserted.
   f. The Urologist places the ultrasound probe, and inserts the first needle containing seeds into the prostate, and deposits the seeds contained within the first needle. This establishes the base of the prostate, and the deepest extent that all subsequent needles will reach.
   g. The Radiation Oncologist then inserts the remaining needles following the lead of the Urologist and deposits the remainder of the seeds.
   h. The Urologist then performs the previously mentioned cystoscopy to scan for and remove any blood clots or seeds from the bladder.
   i. Radiation Safety uses a Geiger counter to scan the entire room and every person leaving the room, to retrieve and store any seeds not in the patient.
   j. Anesthesia is reversed, and patient is moved to recovery.

6. The brachytherapy incident of 2003 was reported to the NRC and resulted in a thorough investigation.
   a. A patient who was implanted on February 3, 2003, had a significant

number of seeds in his bladder. All such seeds were retrieved by the Urologist.

b. As per standard operating procedure and under the direction of Radiation Safety, the patient had an Initial WD that specified the numbers of seeds ordered, and then a revised WD to reflect the actual number of seeds that were retained within the patient. A copy of both the Initial and Revised directive was retained by Radiation Safety, and the original put in the patient's medical chart.
c. This event was promptly reported to the NRC, who then came to PVAMC to conduct a full multiday investigation. The NRC ultimately cleared the Program to resume treating patients.
d. Because the dose of radiation delivered to the prostate was considered inadequate, a repeat brachytherapy was performed on March 31, 2003. This was successful in increasing the radiation dose received by the prostate. There were subsequently no unusual or unexpected complications or toxicity reported.
e. **Contrary to what was alleged by the New York Times, at no time did I or anyone cover-up the patient's treatment by altering the Written Directive.**

7. <u>The brachytherapy incident of 2005 was reported to the NRC and resulted in a thorough investigation.</u>
   a. A patient was initially seen and accepted for Brachytherapy by another Radiation Oncologist. I performed the Brachytherapy on 5/19/05. Because of poor imaging quality (due to the patient's inability to complete the necessary bowel preparation), many seeds were inserted into the bladder.
   b. As per the standard operating procedure and under the direction of Radiation Safety, the patient had an Initial WD that specified the numbers of seeds ordered, and then a revised WD to reflect the actual number of seeds that were retained within the patient. A copy of both the Initial and Revised directive was retained by Radiation Safety, and the original put in the patient's medical chart.
   c. During the course of the cystoscopy that is performed after every brachytherapy, a large number of seeds was retrieved from the bladder. This fulfilled the definition of a reportable Medical Event as I understood that definition at that time, and the case was promptly reported to the NRC. The NRC then came to PVAMC to conduct a full multiday investigation, and ultimately cleared the Program to resume treating patients.
   d. On re-evaluation of the patient, the consensus among the Prostate Brachytherapy Team was not to reimplant this patient, as the patient's limited expected life span rendered the risks greater than the expected benefit.
   e. **Contrary to what was alleged by the New York Times, the NRC performed a thorough investigation of this case.**

8. <u>The NRC definition of a reportable Medical Event has evolved over time and continues to be a subject of debate.</u>
   a. There was no NRC definition of a reportable Medical Event when the

Brachytherapy Program was first started at the PVAMC in 2002.

b. The physicians and physicists never received NRC training on this issue throughout the years the Program was operational.
c. The instruction following the investigation by NRC of the 2003 prostate brachytherapy incident was that "if greater than 20% of the seeds prescribed were retrieved from the bladder", this would constitute a reportable Medical Event and would trigger a repeat NRC investigation.
d. The brachytherapy incident of 2005 was clearly therefore a reportable Medical Event and appropriately reported.
e. The Prostate Brachytherapy Team was never instructed regarding D90 (the % of the prescribed dose that 90% of the prostate receives) as a metric that constitutes a reportable Medical Event. This means that no one on the Team was advised that if the dose received by the prostate was 20% greater or 20% less than the optimal dose it would constitute a Medical Event and would have to be reported to the NRC.
f. **The definition of a medically reportable Medical Event that consists of a D90 that is either 20% above or below the prescribed dose was <u>not in existence</u> when the Prostate Brachytherapy Program was first started, nor was that ever an instruction provided to the Team.**
g. While achieving a D90 that is not over and below 20% of the prescribed radiation dose rule is an optimal standard to strive for under NRC guidelines, it does not constitute a clinical standard of care for brachytherapy treatment. Indeed, recent articles published in the medical literature suggest treatment may be appropriate even when the D90 is less than 80%. I am happy to provide copies of those articles to the Committee should it wish to review them.

9. <u>I have never ordered the wrong seed strength.</u>
   a. My cases have been standardized on the 0.509 mCi seed strength.
   b. The discrepancy between 0.380 mCi and 0.509 mCi seed strengths that are mentioned in the NRC Inspection Report of March 30, 2009 involved prostate brachytherapy cases at the PVAMC that did not involve my patients.
   c. The discrepancy between the seed strengths calculated and actually ordered was discovered by Radiation Safety and reported to the NRC.

10. <u>The dose to the rectum has not been defined as a reportable Medical Event by the NRC</u>.
   a. As already stated, and as counseled in every consent form, radiation proctitis is a known and recognized risk of brachytherapy.
   b. Given the close proximity of the rectum to the prostate, brachytherapy cannot be performed in a way that avoids dose to the rectum. In fact, every seed implanted in the prostate delivers radiation dose to the rectum, since the prostate is immediately adjacent to the rectum.
   c. The dose to the rectum was not a metric that either PVAMC Radiation Safety or the NRC requested that we measure.

11. Despite the lack of computer interface between the CT scanner and the Variseed treatment planning workstation during 2006-2007, I provided effective treatment to my patients.
    a. At the conclusion of a procedure, a CT scan is done to determine the location of the seeds.
    b. The images of the CT scan are then transferred to a workstation that contains the software program called Variseed and which calculates the dose actually received.
    c. In or around November 2006 a computer interface problem between the CT scanner and the workstation containing the Variseed software occurred that prevented the precise calculation of doses of radiation.
    d. I reported this issue on several occasions to the appropriate persons overseeing the Program, but the problem persisted.
    e. I offered to take the CT scans on disk or flash drive to Penn to perform the Variseed calculations. However this was refused by the PVAMC due to confidentiality/ privacy/ security concerns.
    f. CT images however were still viewable and showed the location of the seeds, all of which were concentrated in areas of the prostate that contained cancer.
    g. I had only two choices: to stop the Brachytherapy Program, or to continue to deliver medical care which the patients needed. Most of the patients treated for Brachytherapy did not have the option of alternative treatments such as surgery or external beam radiation. External beam radiation would have required the patients to be treated on a daily basis, five days a week, for eight weeks. Surgery also had serious drawbacks including incontinence and impotence. Without brachytherapy, the patients' cancers would have gone untreated.
    h. I elected to continue treatment based on concern for the patients' welfare.
    i. The treatment was effective and well within the standard of care and was effective. The proof of the effectiveness was demonstrated in follow up visits with the patients and evaluation of their PSA levels.

12. There were a number of systematic failures at the PVAMC that affected the Brachytherapy Program.
    a. Prior to the development of the PVAMC Prostate Brachytherapy Program, there were no guidelines or policies for the design and operation of a VA brachytherapy program. Consequently, the Brachytherapy Team had to design its own set of procedures and policies, which led to the creation of the Prostate Brachytherapy Algorithm.
    b. When the Brachytherapy Program was first started, there was no standard definition of what is a reportable Medical Event.
    c. There was no system to train key members of the Brachytherapy Program on what later became a definition of a reportable Medical Event.
    d. There was no full time medical physicist dedicated to the brachytherapy program. This impacted on the ability to timely calculate the dose received by the patients.
    e. The lack of a computer interface between the CT scanner and the Variseed dose calculation workstation prevented the precise calculation of

the doses of radiation received by the patient.

f. There was no mechanism by which concerns regarding key steps of the procedure could bypass the chain of command to solve problems, such as the computer interface problem.
g. Understandable concerns about patient confidentiality prevented the alternative transport of data from the CT scanner via memory storage media and devices.

13. To address some of these concerns, the Brachytherapy Program was in the process of moving from Preloaded to Real-time Treatment Systems.
    a. The members of the Brachytherapy Program recognized the drawbacks of the Preloaded Brachytherapy System, such as the inability to customize the placement of the seeds to match the patient's actual anatomy.
    b. Consequently, members of the Team were in the process of receiving training in the Real-time Treatment System, which does account for changes in the patient's anatomy and which includes continuous fluoroscopic verification of the location of the deposited seeds.
    c. Real-time treatment would allow for the seeds to be customized to the prostate on the day of the procedure.
    d. The Brachytherapy Program was halted before the change in Treatment approach could be implemented.

14. During a meeting of the Advisory Committee on the Medical Uses of Isotopes of the NRC, held in Rockville, Md. on May 7, 2009, it was falsely alleged that a key physician of the Brachytherapy Program had made certain statements and actions ("Committee Meeting Transcript"). Inflammatory statements and actions were falsely attributed to this member of the Prostate Brachytherapy Program, including:

    i. "The physician that did this particular implant, once again, he felt that the 24 Gray was clinically acceptable." Committee Meeting Transcript at page 192.

    ii. "And if he felt that 24 Gray was satisfactory, that is the way it was." Committee Meeting Transcript at page 192.

    iii. "Well, one of the things that we noticed was that the physician that was primarily involved in the brachytherapy program, he consistently did this. They didn't use fluoroscopy during seed placement. He refused to use fluoroscopy, said he didn't need it." Committee Meeting Transcript at page 204.

    iv. "-- yes, 2002, and -- but from the time the physician had received training to the time they started the implant program, there was some delay. And there was no -- there was no effort on the part of the physician to maybe proctor or observe or be involved with some implants before they decided to go and proceed and treat their first patient.... that was a decision that was made by the Authorized User". Committee Meeting Transcript at page 221.

    v. "No. According to him, it was clinically acceptable. As a matter of fact,

his exact words are, "43 Gray is better than zero Gray."" Committee Meeting Transcript at page 241.

vi. "But it is mindboggling to me that a physician could say that a dose of 40 Gray, 24 Gray, is acceptable, and then look at these implants and not realize that this is gross incompetence." Committee Meeting Transcript at page 243.

a. These inflammatory actions and statements that are being attributed to a key physician are being attributed to me, but are **not** accurate. I neither said these statements nor took the actions described.

b. These false attributions are appropriately alarming and inflamed the subsequent discussions of the Committee.

Conclusion

I have come to the hearing today to answer questions and to submit this written statement in order to correct the record and salvage my reputation. I hope that, through the hearing process, the investigations and through media reports, the truth will emerge. I am not the physician who has been portrayed in the media. I am not willing to be the scapegoat for the complex, systematic problems that affected the Brachytherapy Program at the PVAMC. I hope that the information I have provided today will help the Committee understand my role and responsibilities in developing and directing the Brachytherapy Program. More importantly, it is also my hope that this information will help improve future medical care for veterans.