CyberKnife registration from the State of Texas, and even Baylor's own policies regarding physician supervision. Baylor ignored Dr. Berger's and Delp's objections to the failure to provide proper supervision of Gamma Knife and CyberKnife procedures. In fact, Baylor management outright rejected Dr. Berger's and Delp's attempts to change this dangerous practice. In addition to Baylor's blatant refusal to comply with regulations intended to ensure the safety of patients undergoing highly dangerous radiation treatments, Dr. Berger and Delp also observed illegal kickbacks and a pattern of fraudulent billing practices committed by the medical staff at Baylor as well as the TOPA physicians that leased space from Baylor in Sammons Cancer Center and treated patients at Baylor Radiosurgery Center.

(1) Gamma Knife

(a) Defendants Failed to Ensure Compliance with NRC and CMS Supervision Requirements During Gamma Knife Procedures.

117. Dr. Berger and Delp repeatedly observed Baylor's failure to comply with the NRC's and CMS's supervision requirements as well as its own written policies regarding the supervision of Gamma Knife procedures. As discussed in more detail below, Dr. Berger and Delp brought the lack of proper supervision during Gamma Knife procedures to the attention of Baylor and HealthTexas management numerous times, including to Joel Allison (President and Chief Executive Officer of Baylor Health Care System), John McWhorter (President of Baylor University Medical Center and Senior Vice President of Baylor Health Care System), Dr. Irving Prengler (Vice President of Medical Staff Affairs of Baylor University Medical Center), Gary Brock (Chief Operating Officer of Baylor Health Care System), Bill Roberts (President of HealthTexas), and Sarah Gahm (Chief Administrative Officer of HealthTexas). Baylor, however, refused to enforce the supervision requirements and instead permitted the procedures to occur without the proper staff supervision.

118. Concerns regarding Baylor's compliance with the direct supervision requirement (and the NRC's physician presence requirement) came to a head when Baylor decided to move the radiation oncologist and neurosurgeon offices out of Baylor Radiosurgery Center. When Baylor Radiosurgery Center was founded, the radiation oncologist and neurosurgeon offices were located in the radiosurgery center so that the doctors could treat radiosurgery patients and consult with additional patients in the center's clinic. In 2007, however, Baylor mandated that the radiation oncologists and neurosurgeons move their offices and patient exams/consults to a completely different part of Baylor University Medical Center's campus. As a result of the move, the physician offices were relocated from the first floor of Hoblitzelle Hospital (where Baylor Radiosurgery Center is located) to the Wadley and Barnett Towers, with many of the radiation oncologists being relocated to the sixth floor of Barnett Tower. *See* Exhibit 1.

119. Dr. Berger strenuously objected to the move because, in order to comply with the supervision requirements during Gamma Knife procedures, doctors would no longer be able to conveniently consult with patients because they would not be physically present throughout the course of the procedure if they were consulting with patients in a completely different part of the campus. Dr. Berger was also concerned that the move would only serve to encourage the continued disregard of the supervision requirements. As noted above, Dr. Berger discussed his objections with Baylor and HealthTexas management, including Joel Allison, John McWhorter, Dr. Irving Prengler, Gary Brock, Bill Roberts, and Sarah Gahm.

120. In an e-mail dated November 12, 2007 to Gail Maxwell, Vice President of Administration at Baylor University Medical Center, Dr. Berger explained his frustration regarding the issues at Baylor Radiosurgery Center:

> I know we are currently at odds with each other over the recent BRC issues. Specifically, I'm referring to issues that directly affect patient care quality such as

> the [NRC] requirement of a radiation oncologist to be present during treatment, [and] the probable dislocation of my office and patient exams/consults out of the BRC . . . I want you to know that the reason I am passionate about these issues is out [of] undivided concern for patient quality of care . . . **It only takes one mishap on a patient before everyone realizes this importance. We have an extremely dangerous tool that, if misused, can kill people**.

See November 12, 2007 E-mail from Dr. Berg to Gail Maxwell, attached as Exhibit 9 (emphasis added).

121. Throughout November and December, Dr. Berger met with John McWhorter and Dr. Prengler to discuss the supervision issue; his concerns fell on deaf ears. *See* December 20, 2007 Letter from Joel Allison to Dr. Berger, attached as Exhibit 10. On December 10, 2007, Dr. Berger met with Joel Allison, Gary Brock, and John McWhorter to voice his objection to the proposed move and his concerns regarding the supervision requirements. Instead of addressing Dr. Berger's concerns, Joel Allison referred Dr. Berger to Bill Roberts, the head of HealthTexas. In order to emphasize his concerns regarding the supervision requirements, Dr. Berger suggested to Bill Roberts that other doctors be brought in to explain to Baylor the importance of the supervision requirements during Gamma Knife procedures. At this meeting, Bill Roberts told Dr. Berger that if he brought in other doctors for that reason, he would be fired. Dr. Berger then reported Bill Roberts' comment back to Joel Allison. Within one week of the meeting between Dr. Berger and Mr. Roberts, Mr. Roberts informed Dr. Berger that his contract would not be renewed.[53]

122. Despite the great reluctance on the part of Baylor and TOPA to follow the supervision requirements—as urged by Dr. Berger and Delp—there is no question that they knew the rules. With respect to the NRC physician presence requirement, the minutes from the Radiosurgery Operation Council Meeting on October 17, 2006 reflect that Gail Maxwell

[53] Interestingly, just a few weeks before, John McWhorter told Dr. Berger that he wanted to promote him because he was doing such a great job.

"explained that there had been a request from two of the physicians to change the practice of the physician being required to be present during the entire Gamma Knife treatment. . . Information regarding license, other facility practices, IRSA position statements, NRC Regulatory Clarification, and Federal Register regulations were included." *See* October 17, 2006 Meeting Minutes, attached as Exhibit 11. The physician presence requirement was again discussed during a Radiosurgery Operation Council Meeting on January 8, 2008, which was facilitated by Gail Maxwell. *See* January 8, 2008 Meeting Minutes, attaches as Exhibit 12.

123. In an e-mail dated July 23, 2007, Gail Maxwell asked Dr. Berger and Dr. Giller (the medical director of Baylor Radiosurgery Center) whether they had any contacts with University of Pittsburgh Medical Center ("UPMC") so that they could "get more information related to why [UPMC] got [c]ited [by the NRC] for not meeting 'physical presence requirements.'"[54] *See* July 23, 2007 Maxwell E-mail, attached as Exhibit 13. Dr. Berger then contacted Dr. John Flickenger, a radiation oncologist at UPMC, who was intimately involved in the Gamma Knife procedures. Dr. Flickenger explained to Dr. Berger that the NRC had cited UPMC because he not within a certain number of feet from the Gamma Knife treatment area. As UPMC had two or three machines, Dr. Flickenger would have to be within certain number of feet of each if more than one treatment was being provided at the same time. After speaking with Dr. Flickenger, Dr. Berger reported this information back to Gail Maxwell, either verbally or via an e-mail.

124. In her capacity as a radiation therapist, Delp often witnessed and continues to witness Gamma Knife procedures performed without the required supervision. A text message exchange between Delp and one of the radiation oncologists, Dr. O'Connor, on October 9, 2009

[54] *See UPMC Cited for Safety Violations in Gamma Knife Surgery Procedures*, PITTS. POST-GAZETTE, July 14, 2007, *available at* http://www.post-gazette.com/pg/07195/801675-114.stm.

illustrates the utter disregard for the Gamma Knife supervision requirements and patient safety. At 7:32 a.m., Delp sent a message to Dr. O'Connor stating: "I tried to page you a couple times. Did you forget we were supposed to start at 6:00? Are you almost here?" Dr. O'Connor responded, "I'm around." At 7:52 a.m., Delp sent another text message to Dr. O'Connor stating that the nurse was "having problems" with the Gamma Knife patient because her "blood pressure is really high and I think she is calling the rapid response team." *See* October 9, 2009 Text Messages, attached as Exhibit 14.

125. The rapid response team responded immediately to the nurse's call, and took the Gamma Knife patient to the emergency room. Dr. O'Connor, however, did not arrive at the treatment room until almost thirty minutes after Delp's last text message. Notably, Baylor Radiosurgery Center's schedule reveals that Dr. O'Connor was supposed to be performing this Gamma Knife procedure as well as two CyberKnife procedures while these text messages were exchanged.

126. In fact, Baylor Radiosurgery Center's schedule amply illustrates Baylor's failure to comply with Gamma Knife supervision requirements. *See* Schedule Excerpts, attached as Exhibit 15.[55] For example, on May 22, 2009, Dr. O'Connor was scheduled to supervise a Gamma Knife procedure on a Medicare patient on the first floor of Hoblitzelle Hospital beginning at 11:00 a.m. Dr. O'Connor, however, went to a meeting at 12:00 p.m., and then to the clinic, which is located near his office on the sixth floor of Barnett Tower, at 2:00 p.m.[56] Because Dr. O'Connor was not even in the radiosurgery department throughout the Gamma

[55] Baylor Radiosurgery Center's is color-coded. For a detailed explanation of the color-coding system, see Exhibit 16 attached hereto.

[56] Generally, it takes approximately ten to fifteen minutes to walk from the clinics located on the sixth floor of Barnett Tower to Baylor Radiosurgery Center located on the first floor of Hoblitzelle Hospital.

Knife procedure, he failed to provide direct supervision throughout the procedure as required by CMS, and also violated the NRC's physical presence requirement.

127. On March 10, 2009, Dr. O'Connor was scheduled to perform a Gamma Knife procedure on a Medicare patient from 6:00 a.m. to 6:00 p.m. From 8:00 a.m. to 9:00 a.m., Dr. O'Connor attended a meeting outside of the radiosurgery department. From 11:00 to 11:30, he went to the clinic located on the sixth floor of Barnett Tower. Again, because Dr. O'Connor was not present in the department nor immediately available during the procedure, he failed to provide direct supervision throughout the Gamma Knife procedure, in violation of CMS regulations and the NRC's physical presence requirement.

128. Similarly, on June 9, 2009, Dr. O'Connor was scheduled to perform a Gamma Knife procedure on a Medicare patient from 6:00 a.m. to 4:00 p.m., but attended a meeting from 8:00 a.m. to 9:00 a.m. outside of the radiosurgery department and then went to the clinic from 1:30 p.m. to 3:30 p.m.—the same time he was also supposed to be supervising a CyberKnife treatment.

129. Another blatant violation of both CMS and NRC supervision requirements occurred on October 24, 2008. Dr. O'Connor was scheduled to perform a Gamma Knife procedure on a Medicare patient from 6:00 a.m. to 3:00 p.m. The radiosurgery center's schedule, however, clearly reflects that Dr. O'Connor was "out of the office" from 7:00 a.m. to 10:00 a.m. Similarly, on June 19, 2009 Dr. O'Connor was scheduled to perform two Gamma Knife procedures (both Medicare patients) from 6:00 a.m. to 6:00 p.m., but left for the day at 12:00 p.m. Also, on October 14, 2009, Dr. O'Connor was scheduled to perform a Gamma Knife procedure on a Medicare patient from 6:00 a.m. to 6:00 p.m., but left the department at 10:00

a.m., 11:00 a.m., and 12:30 p.m. for patient consults and clinic appointments, and was then "out of the office" from 1:00 p.m. to 5:00 p.m.

130. On March 17, 2010, Delp witnessed both the neurosurgeon and the radiation oncologist leave the radiosurgery department during a Gamma Knife procedure that they were supposed to be performing. This left only Delp (a radiation therapist), Otto Zeck (a physicist), Rebecca Tesfaye (a nurse), and Donald Stout (a nurse) in the treatment area while the patient was being radiated with highly dangerous cobalt-60 gamma rays. Similarly, on April 22, 2010, Delp witnessed both the neurosurgeon and the radiation oncologist leave the radiosurgery department during a Gamma Knife procedure on a Medicare patient.

131. On April 8, 2010, Delp received a complaint from a nurse that both the radiation oncologist and neurosurgeon left the treatment area during a Gamma Knife treatment. Furthermore, on April 15, 2010, the radiation oncologist left for several hours during a Gamma Knife procedure, leaving only Delp, a nurse, and a medical physicist in the treatment room.

132. Because the radiation oncologist is not actually present during stereotactic radiosurgery procedures, they are often paged by other members of the treatment team whenever questions arise during a procedure. Generally, Dr. O'Connor takes twenty minutes or more to answer a page. On May 25, 2010, Dr. O'Connor took over an hour to respond to a page that was sent after questions arose concerning the treatment of a Medicare CyberKnife patient.

133. On May 27, 2010, Dr. O'Connor was scheduled to perform a CyberKnife simulation on a Medicare patient. Because there were concerns regarding the patient's kidney function, the treatment team needed to discuss these concerns with Dr. O'Connor before they could administer the contrast that is required for planning scans. Dr. O'Connor (who was treating a patient in the clinic on the sixth floor of Barnett Tower) was paged, but, after he failed

to respond for over twenty minutes, the radiologist made the decision regarding the use of the contrast. The team continued to try and reach Dr. O'Connor at the clinic, but their attempts were unsuccessful.

(b) Baylor Fraudulently Used Unqualified Neurosurgeons to Satisfy the NRC's "Authorized User" Requirement.

134. As previously discussed, in order to qualify as an authorized user, a physician must either (1) be listed as an authorized user on a license or permit, or (2) comply with the stringent training and education requirements imposed by the State. In order to be listed as an authorized user on a license or permit, the physician must be qualified to perform Gamma Knife procedures as a result of the necessary training and education.

135. Several Baylor physicians, including Dr. Giller—the medical director of Baylor Radiosurgery Center—repeatedly pushed for neurosurgeons to act as authorized users during Gamma Knife procedures despite the fact that their training and education clearly fell short of the requirements of the NRC and State of Texas. Dr. Giller's motivation for pushing to allow unqualified neurosurgeons to serve as authorized users for Gamma Knife treatments—and for pushing to relax the supervision requirements for stereotactic radiosurgery procedures in general—was purely financial. Because Dr. Giller's compensation was directly tied to the number of patients he treated at Baylor Radiosurgery Center,[57] Dr. Giller was especially concerned with the number of patients TOPA referred to the center. As will be discussed in greater detail below, Baylor relied heavily on TOPA physicians—who repeatedly complained about the stringent supervision requirements for stereotactic radiosurgery procedures—to refer stereotactic radiosurgery patients to Baylor Radiosurgery Center as well as chemotherapy patients to Baylor University Medical Center for inpatient hospital services. In order to induce

[57] Dr. Giller's compensation contract provided for bonuses based on the number of patients Dr. Giller treated.

TOPA to refer these patients (thereby increasing the number of patients Dr. Giller could treat), Dr. Giller routinely pushed to relax the supervision requirements.

136. Dr. Berger brought the neurosurgeons' lack of qualifications to the attention of Joel Allison, John McWhorter, Bill Roberts, Dr. Irving Prengler, and Gail Maxwell (Vice President of Administration at Baylor University Medical Center); Dr. Berger's concerns, however, were once again ignored.

137. In fact, Baylor misrepresented the training and education of the neurosurgeons on their State license application so that the neurosurgeons would be listed on Baylor's license. The Texas Department of State Health Services Application for Radioactive Material License for Medical Uses requires the applicant to certify compliance with the requirements of the application. *See* Application for Radioactive Material License, attached as Exhibit 17. Referencing Regulatory Guide 3.1, Item 10 of the application requires a description of the minimum training requirements of authorized users. Regulatory Guide 3.1 provides that "[a]ll personnel who will be authorized to handle radioactive material must be qualified through training and experience to use the material in question for the purpose requested . . . ." *See* Regulatory Guide 3.1, attached as Exhibit 18.

138. Although it knew that its neurosurgeons did not have the proper training and education to performed Gamma Knife procedures, Baylor nonetheless had at least three unqualified neurosurgeons included on its license: Dr. Giller, Dr. Bidiwala, and Dr. Michael. Baylor continues to add unqualified physicians. For example, Baylor recently added Dr. Kyle Doughty, a neurosurgeon, and Dr. Ricardo Cristobal, an ear, nose and throat doctor, to its CyberKnife license. These neurosurgeons had not completed the necessary training and education in order to qualify as authorized users for Gamma Knife procedures and therefore

should not have been listed on Baylor's license. In fact, Dr. Bidiwala was not even board certified in Neurosurgery at the time he was listed on Baylor's license. Regardless, Baylor encouraged these neurosurgeons—as opposed to qualified radiation oncologists—to act as authorized users during Gamma Knife procedures. The use of these unqualified neurosurgeons, however, did not satisfy the NRC's physician presence requirement or CMS's direct supervision requirement.

139. Furthermore, while Baylor neurosurgeons were fraudulently serving as the authorized users during Gamma Knife procedures, TOPA radiation oncologists routinely treated their own patients in their offices in Sammons Cancer Center while their radiosurgery patients were being radiated by unqualified physicians at Baylor Radiosurgery Center. As will be discussed in more detail *infra*, Baylor was fully aware of this practice and actually approved of it in order to induce TOPA to refer patients to Baylor University Medical Center.

(2) Defendants Failed to Ensure that CyberKnife Procedures were Properly Supervised.

140. In addition to the CMS regulations requiring direct supervision of CyberKnife procedures as a Medicare condition of payment, Baylor's registration with the State of Texas requires a radiation oncologist and a medical physicist to be immediately available during CyberKnife procedures. Several Baylor and TOPA physicians, however, repeatedly challenged these requirements. On April 25, 2007, Dr. Giller suggested changing the policies so that the radiation oncologist would only have to available on campus by phone during CyberKnife procedures. *See* April 25, 2007 Giller E-mail, attached as Exhibit 19. In the e-mail, Dr. Giller acknowledged that such a change in policy would require a change to Baylor's CyberKnife license. *See id.* Similarly, in an e-mail to Gail Maxwell and others dated June 11, 2007, Dr. Giller pushed to relax the required level of supervision with respect to the medical physicist:

> The physical presence of a physicist does not seem to be required to start our early morning CyberKnife cases – if this is a problem, the therapist will simply stop and ask for physics help. What do you think about changing the rules so that – just at the start – the physicist need only be reachable by phone (or perhaps reached by phone that AM, or perhaps on his way in . . .)? This would require a change of our license, but that seems possible and would help our scheduling.

See June 11, 2007 Giller E-mail, attached as Exhibit 20.

141. Because of the ongoing debates over the required level of supervision, on May 14, 2007, Delp sent an e-mail to Dr. Giller, Dr. Berger, and others requesting clarification of the supervision requirements:

> Our license requires that the radiation oncologist be immediately available . . . If these policies have been changed or clarified, we need to know ASAP . . . We are more than willing to follow the policy decided upon (as long as it doesn't violate the state license) but we have been [] told conflicting things in the last week and we were not made aware of an official changes to the current policy.

See May 14, 2007 E-mail from Janice Delp, attached as Exhibit 21.

142. The minutes from a Radiosurgery Operation Council meeting held on June 7, 2007 illustrate Baylor's disregard for CMS's requirement that the radiation oncologist be present in the department and immediately available throughout the course of the procedure. After much discussion, "the decision was made the radiation oncologist must be on campus during the treatment and provide information to the staff prior to the treatment as to the most efficient/timely way to be reached if needed. The surgeon must be on campus for the first treatment but can be available by phone for additional treatments." *See* June 7, 2007 Meeting Minutes, attached as Exhibit 22.

143. This decision, which clearly violated the CMS regulations in effect in 2007, resulted in staff members voicing major concerns regarding Baylor's compliance with the supervision requirements. In a December 10, 2007 e-mail from Gail Maxwell to the radiation oncologists and neurosurgeons at Baylor Radiosurgery Center, Gail Maxwell requested that the

center "revert back to having a radiation oncologist present until we can have further discussion at our [January 8, 2008 Radiosurgery Center Operations] meeting. I have had staff voicing major concerns related to not having a physician present." *See* December 10, 2007 Maxwell E-mail, attached as Exhibit 23. The prevailing official policy, however, permitted CyberKnife procedures to be performed without the direct supervision of a radiation oncologist; instead, Baylor permitted the procedures to be performed as long as the radiation oncologist was present somewhere on Baylor's campus and available by telephone—a clear violation of Medicare's direct supervision requirement.

144. As with Gamma Knife procedures, Baylor Radiosurgery Center's schedule profoundly illustrates Baylor's failure to comply with the direct supervision requirement for CyberKnife procedures. For example, on November 11, 2009, Dr. O'Connor was scheduled to supervise a CyberKnife treatment beginning at 8:00 a.m. At 8:24 a.m., Delp sent a text message to Dr. O'Connor asking whether he was around so that the treatment could begin. Dr. O'Connor replied that he was attending a Tumor Board meeting in Truett Hospital, which is clearly outside of the radiosurgery department. Baylor Radiosurgery Center's time log confirms that the CyberKnife treatment began at 8:30 a.m., without Dr. O'Connor being present in the department to directly supervise the treatment. *See* CyberKnife Time Log Excerpts, attached as Exhibit 24.

145. That same day, Dr. O'Connor was scheduled to attend an off-campus conference starting at 9:00 a.m., and was also scheduled to be in the clinic on the sixth floor of Barnett Tower at 11:00 a.m. and 2:30 p.m. Despite being out of the radiosurgery department during these times, Dr. O'Connor was scheduled to supervise CyberKnife treatments beginning at 9:30 a.m. and 1:00 p.m. *See* Exhibit 15. Because Dr. O'Connor was not present in the department or immediately available throughout the course of these procedures, these CyberKnife treatments

were performed without the direct supervision of a radiation oncologist, in violation of Baylor's license with the State and CMS regulations.

146. The center's time log confirms Baylor's failure to comply with the direct supervision requirement on other occasions as well. For example, on November 30, 2009, the log illustrates that a CyberKnife treatment began at 8:16 a.m., but notes that the radiation oncologist did not arrive in the department until 8:25 a.m. Also, on December 1, 2009, the log indicates that a CyberKnife treatment began at 8:12 a.m., but that the radiation oncologist did not arrive in the department until 8:42 a.m. Baylor Radiosurgery Center's schedule indicates that the radiation oncologist was at a meeting outside of the radiosurgery department that began at 8:00 a.m.

147. On October 13, 2009, Dr. O'Connor attended a meeting outside of the radiosurgery department at 8:00 a.m., but was also scheduled to perform a CyberKnife treatment beginning at 8:00 a.m. Later that afternoon, Dr. O'Connor was scheduled to perform a CyberKnife treatment on a Medicare patient at 1:00 p.m., but at the same time was at the clinic on the sixth floor of Barnett Tower. On October 19, 2009, Dr. O'Connor was "out of the office" from 8:00 a.m. to 5:00 p.m.; yet, he allegedly supervised one CyberKnife simulation and two CyberKnife treatments while he was out.

148. On March 13, 2009, Dr. O'Connor was scheduled to perform a CyberKnife treatment on a Medicare patient from 8:30 a.m. to 10:00 a.m., but attending a meeting outside of the radiosurgery department from 9:00 a.m. to 9:30 a.m. Similarly, on May 12, 2009, Dr. O'Connor was scheduled to perform a CyberKnife treatment on a Medicare patient from 7:30 a.m. to 9:30 a.m., but attended a meeting from 8:00 a.m. to 9:00 a.m. outside of the radiosurgery department, and then went to the clinic on the sixth floor of Barnett Tower after the meeting.

149. On July 14, 2009, Dr. O'Connor was scheduled to perform a CyberKnife treatment on a TRICARE patient from 8:00 a.m. to 10:30 a.m., but attended a meeting outside of the radiosurgery department from 8:00 a.m. to 9:00 a.m., and then went to the clinic in Barnett Tower at 10:00 a.m. Again, because Dr. O'Connor was not present in the radiosurgery department throughout the performance of the CyberKnife treatment, the procedure was not directly supervised in accordance with CMS regulations.

150. In addition to not ensuring the proper supervision of CyberKnife procedures, Baylor also fails to properly perform the required quality assurance testing on the CyberKnife machine. As previously discussed, Baylor's CyberKnife registration provides that, if a medical physicist does not personally perform the daily radiation output testing, he or she must verify the results of the output testing within five days. Delp performs the daily radiation output testing; the medical physicist, however, does not verify the results of the testing within the required time period, but instead back-dates the verifications so that it appears as though the results were verified within five days. Out of concern for patient safety, Delp brought this to the attention of Dr. Giller as well as two of Baylor Radiosurgery Center's managers, Benny Bolin and Karen Zwerneman; nothing was done about this practice.

C. Defendants Fraudulently Billed Medicare, Texas Medicaid, and CHAMPUS/TRICARE for Stereotactic Radiosurgery Procedures.

(1) Defendants Fraudulently Billed Medicare, Texas Medicaid, and CHAMPUS/TRICARE for Gamma Knife and CyberKnife Procedures that Were Not Properly Supervised.

151. Defendants clearly violated CMS and NRC rules by allowing Gamma Knife and CyberKnife procedures to be performed without the required supervision by radiation oncologists. Despite their failure to observe the safety regulations enacted to ensure the safety of patients undergoing hazardous radiation therapy, Defendants billed and were reimbursed by

Medicare, Texas Medicaid, and CHAMPUS/TRICARE for Gamma Knife and CyberKnife procedures that were not properly supervised by the required qualified physicians and were performed in violation of the Defendants' licenses from the State of Texas.

152. For example, for Fiscal Year 2006, Baylor's radiosurgery department received the following payments for outpatient radiosurgery procedures, including Gamma Knife: $1,278,312 from Medicare, $3,916 from Texas Medicaid, and $188,848 from CHAMPUS/TRICARE and CyberKnife: $1,278,312 from Medicare, $3,916 from Texas Medicaid, and $188,848 from CHAMPUS/TRICARE.

153. In November 2009, Baylor University Medical Center received $25,170.50 from Medicare Part A for Patient 9560,[58] who received five fractions of CyberKnife treatment from October 19, 2009 through October 23, 2009. *See* Patient 9560 Billing and Reimbursement Information, attached as Exhibit 25. Dr. O'Connor was the assigned radiation oncologist. Baylor Radiosurgery Center's schedule amply illustrates Dr. O'Connor's failure to provide direct supervision during at least four of the five CyberKnife treatments:

- On October 19, 2009, Patient 9560 was scheduled for his/her first CyberKnife treatment beginning at 8:00 a.m. Dr. O'Connor, however, was out of the office from 8:00 a.m. to 5:00 p.m.
- On October 20, 2009, Dr. O'Connor attended a meeting outside of the radiosurgery department during Patient 9560's second CyberKnife treatment.
- On October 21, 2009, Dr. O'Connor was in the clinic on the sixth floor of Barnett Tower throughout Patient 9560's third CyberKnife Treatment.
- On October 22, 2009, Patient 9560 was scheduled for a CyberKnife treatment from 10:00 a.m. to 12:00 p.m. Dr. O'Connor, however, went to the clinic on the sixth floor of Barnett Tower from 10:00 a.m. to 10:30 a.m., and then again from 11:00 a.m. to 11:45 a.m.

[58] In order to protect this patient's identity, this patient is referred to by the last 4 digits of the patient's medical record number.

(2) TOPA Physicians Engaged in Fraudulent Double-Billing.

154. Because Baylor neurosurgeons were fraudulently serving as authorized users during Gamma Knife procedures, TOPA radiation oncologists were often across the street from Baylor Radiosurgery Center at their own offices in Sammons Cancer Center treating other patients while their radiosurgery patients were being radiated by unqualified physicians. As with Gamma Knife procedures, TOPA radiation oncologists were often across the street from Baylor Radiosurgery Center treating other patients at Sammons Cancer Center while their radiosurgery patients were being undergoing CyberKnife treatments. Despite TOPA radiation oncologists' failure to provide the proper supervision, TOPA fraudulently billed federal and state programs for Gamma Knife procedures that were not directly supervised by qualified physicians. Upon information and belief, TOPA also billed federal and state programs for the other treatments they provided while they were supposed to be directly supervising the Gamma Knife and CyberKnife procedures, thus double-billing these federal and state programs.

(3) Baylor Overbilled Medicare, Texas Medicaid, and CHAMPUS/TRICARE for CyberKnife Procedures.

155. In her capacity as Clinical Coordinator, Delp learned that Baylor was not billing correctly for CyberKnife procedures. Specifically, Delp learned that Baylor was fraudulently unbundling certain CyberKnife CPT codes and was also overbilling for CyberKnife calculations.

(a) Baylor Fraudulently Unbundled CyberKnife Treatment Codes.

156. From January 1, 2007 to April 1, 2008, providers were prohibited from billing CPT codes 77300 and 77334 in conjunction with 77371 because the codes were bundled. Despite this prohibition, Baylor Radiosurgery Center routinely billed CPT Codes 77300 and 77334 in conjunction with 77371 during the period in which the codes were bundled. In fact,

Baylor Radiosurgery Center's management instructed the billing department to unbundle the codes in order to maximize billing.

(b) Baylor Fraudulently Overbilled CyberKnife Calculation Units.

157. According to Trailblazer's[59] Local Coverage Determination ("LCD"), providers may appropriately report 77300 (Basic Radiation Dosimetry Calculation) up to one unit for each arc in a linear accelerator system or up to one unit for each shot in a cobalt-60 system. However, if the total units of this code exceed six, there must be a detailed explanation of medical necessity in the medical record, which may be subject to retrospective review. The medical record must include detailed documentation explaining the factors such as multiple isocenters, irregularity of target volume(s), proximity of critical structures, or other reasons which justify the units of service for dosimetry or treatment devices.

158. In order to maximize billing, Baylor Radiosurgery Center's physicist changed the manner in which CyberKnife dosimetry calculations were performed by performing the calculation on a maximum dose point instead of the prescribed dose point. This change in dosimetry calculations resulted in Baylor billing well over six units (and up to approximately sixty units) of 77300. *See* E-mails Regarding CyberKnife Calculations, attached as Exhibit 26. Despite this requirement, Baylor, upon information and belief, did not include detailed explanations of medical necessity in their patients' medical records.

(c) Baylor Billed Medicare, Medicaid, and CHAMPUS/TRICARE for Fake CyberKnife Treatment Plans

159. Another scheme Baylor used to defraud Medicare, Medicaid, and TRICARE involved billing for fake CyberKnife treatment plans. Because CyberKnife patients may be treated over the course of several days, the stereotactic radiosurgery team may decide to conduct

[59] Trailblazer administers the Medicare program under contracting arrangements with CMS.

the simulation and planning phases on the first day and start the treatment the next day. In these instances, the physicians would sometimes delay in approving the treatment plans. Unfortunately for Baylor, from July 1, 2004 until January 1, 2006, planning codes could not generally be billed on the same day as G codes, also referred to as the global codes, that encompass the simulation, planning, and treatment delivery codes for a procedure that was performed on the same day. In other words, if the simulation, planning, and treatment occurred on the same day, Baylor was required to bundle the codes for each phase and bill a global code rather than bill each component separately. Because the physicians were late in approving the treatment plans, Baylor would not be able to bill for the plan separately, but would instead have to bundle the planning code with the global code and lose the reimbursement for the planning code.

160. In order to overcome Baylor's problem of not being able to bill for plans that were approved late, Dr. Giller suggested that the physicians create "fake" plans by printing out preliminary 3-D simulation plan, doing preliminary calculations, and conducting a preliminary special physics consult. The physicians placed stickers reading "For Review Only" on these fake plans to avoid confusion with the actual plan that was later approved. *See* Fake CyberKnife Treatment Plans, attached as Exhibit 27. Baylor then billed Medicare, Medicaid, and TRICARE for the planning code as if the plans were actually created and approved the day before treatment rather than the day of treatment.

161. Beginning in January 2006, CMS lifted the ban on billing planning codes separately from the global code on the treatment date. Baylor nevertheless continued to create and bill for "fake" treatment plans and still does so.

D. Baylor Paid Illegal Kickbacks to TOPA in Exchange for Patient Referrals.

(1) Baylor Allowed TOPA Physicians to Violate Supervision Requirements in Order to Induce Patient Referrals.

162. As noted above, TOPA radiation oncologists routinely failed to supervise their Gamma Knife and CyberKnife procedures, and instead treated their own patients at Sammons Cancer Center while their radiosurgery patients were undergoing radiation treatments at Baylor Radiosurgery Center. The motivation for this was financial: because Baylor owned the equipment at Baylor Radiosurgery Center, Baylor received the reimbursement for the technical component of each service performed at the radiosurgery center, while TOPA only received the reimbursement for the professional component of each service.

163. Because TOPA physicians wanted to maximize their billing, they routinely scheduled appointments with TOPA patients at Sammons Cancer Center during the time in which they were supposed to be supervising Gamma Knife and CyberKnife treatments at Baylor Radiosurgery Center. Because Baylor wanted these TOPA physicians to refer stereotactic radiosurgery patients to Baylor Radiosurgery Center as well as chemotherapy patients to Baylor University Medical Center for inpatient hospital services, Baylor approved of this practice. In other words, Baylor permitted TOPA radiation oncologists to violate Gamma Knife and CyberKnife supervision requirements in order to induce TOPA to refer patients to Baylor University Medical Center. This inducement constituted an illegal kickback under the Medicare and Medicaid Protection Act of 1987 (the "Anti-Kickback Statute")[60] and violated the Stark Act.[61]

[60] 42 U.S.C. § 1320a-7b.
[61] 42 U.S.C. § 1395.

(2) Baylor Set Up a Medical Directorship for a TOPA Physician in Order to Induce Patient Referrals.

164. Baylor set up a medical directorship for Dr. Scott Cheek, A TOPA physician, in order to induce TOPA to refer patients to the hospital. This inducement also constituted an illegal kickback under the Anti-Kickback Statute.

165. When Baylor Radiosurgery Center was founded, Baylor University Medical Center created Dr. Cheek's directorship. Dr. Berger objected to Dr. Cheek being the "Associate Director" as he was not going to be involved in supervising employees or manage day-to-day affairs. Dr. Berger thought that Dr. Cheek's directorship was created solely as a way to appease TOPA and to induce referrals to the Baylor Radiosurgery Center. In response to his objections, Baylor executives, including John McWhorter and Gail Maxwell, made it clear to Dr. Berger that TOPA was very important to Baylor University Medical Center in terms of referrals.

IX. Defendants' Actionable Conduct Under the False Claims Act

166. This is an action to recover damages and civil penalties on behalf of the United States and Relators Dr. Berger and Delp arising from the false or fraudulent statements, claims, and acts by the Defendants made in violation of the False Claims Act ("FCA").[62]

A. False Claims Act

167. The False Claims Act ("FCA") provides for the award of treble damages and civil penalties for knowingly causing the submission of false or fraudulent claims for payment to the United States Government. For conduct occurring before May 20, 2009, the FCA provides in pertinent part that:

> (a) Any person who
>
> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member

[62] 31 U.S.C. §§ 3729–3732.

> of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;
>
> (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; [or]
>
> ****
>
> (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government

is liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each such claim, plus three times the amount of damages sustained by the Government because of the false or fraudulent claim.[63]

168. For conduct occurring on or after May 20, 2009, the FCA provides that any person who:

> (a) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim (except that this language applies to all claims pending on or after June 7, 2008);
>
> (c) conspires to defraud the Government by committing a violation of the FCA; or
>
> (d) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal material to an obligation to pay or transmit money or property to the Government

[63] 31 U.S.C. § 3729(a).

is liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each such claim, plus three times the amount of damages sustained by the Government because of the false or fraudulent claim.[64]

169. The FCA allows any persons having knowledge of a false or fraudulent claim to bring in action in federal district court for themselves and for the United States Government and to share in any recover as authorized by 31 U.S.C. § 3730.

170. Based on these provisions, Dr. Berger and Delp, on behalf of the United States Government, seek through this action to recover damages and civil penalties arising from the submission of false claims as described herein. Dr. Berger and Delp believe that the United States has suffered significant damages as a result of these false claims.

171. There are no bars to recovery under 31 U.S.C. § 3730(e), and, or in the alternative, Dr. Berger and Delp are original sources as defined therein. Relators have direct and independent knowledge of the information on which the allegations are based. As required pursuant to 31 U.S.C. §§ 3730(b) and (e), Relators have voluntarily provided information, oral and/or written, and has sent disclosure statement(s) of all material evidence, information, and/or documents related to this complaint, both before and contemporaneously with filing, to the Attorney General of the United States, the United States Attorney for the Northern District of Texas, and the Attorney General of Texas.

B. Federal Anti-Kickback Statute and Stark Act

172. The Medicare-Medicaid Anti-Fraud and Abuse Amendments, known as the Medicare Anti-Kickback Statute[65] (the "Anti-Kickback Statute"), make it illegal for an individual knowingly and willfully to offer or pay remuneration in cash or in kind to induce a

[64] 31 U.S.C. § 3729(a)(1).
[65] 42 U.S.C. § 1320a-7b(b).

physician to provide a good or service that is reimbursed by a federal healthcare program.[66] "Remuneration" is broadly defined to include anything of value offered or paid in return for purchasing, ordering, or recommending the purchase or order of any item reimbursable by a federal healthcare program. The Stark Act prohibits any physician from making a referral to a provider of designated health care services if the physician has a financial relationship with the provider.

173. The purpose of both the Anti-Kickback Statute and the Stark Act is to prohibit improper remuneration, in order to secure proper medical treatment and referrals and to limit unnecessary treatment, services, or goods that are based not on the needs of the patient but on improper incentives given to others, thereby limiting the patient's right to choose proper medical care and services.

174. Paying kickbacks taints an entire medical service, regardless of its medical propriety. The kickback inherently interferes with the doctor-patient relationship and creates a conflict of interest, potentially putting the patient's health at risk.

175. Furthermore, under the Patient Protection and Affordable Care Act ("Affordable Care Act"), any claim submitted for a service, the provision of which resulted from a violation of the Anti-Kickback Statute, is "false" for purposes of the FCA.[67] Therefore, the payment of illegal kickbacks constitutes a violation of the FCA in addition to the Anti-Kickback Statute.

C. Baylor, HealthTexas, and TOPA Submitted False Claims for Stereotactic Radiosurgery Procedures that were Not Performed Under the Required Level of Physician Supervision.

176. Since 2005, Baylor, HealthTexas, and TOPA have failed to ensure that stereotactic radiosurgery procedures performed on Medicare, Texas Medicaid, and

[66] *See* 42 U.S.C. § 1320a-7b(b)(2).

[67] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6402, 124 Stat. 119 (2010).

CHAMPUS/TRICARE patients were performed under the required level of physician supervision.

177. In their Medicare and Texas Medicaid provider applications, Baylor, HealthTexas, and TOPA expressly certified that they would comply with all laws, regulations, and rules governing Medicare and Texas Medicaid. By submitting claims for Gamma Knife and CyberKnife procedures that were not properly supervised, Baylor, HealthTexas, and TOPA falsely certified compliance with the Medicare and Texas Medicaid rules governing these procedures.

178. Furthermore, by signing the HCFA 1500 forms submitted to Medicare, Texas Medicaid, and CHAMPUS/TRICARE by HealthTexas and TOPA, the radiation oncologists expressly certified that they had personally rendered the services provided to the patients.

179. Moreover, by submitting claims for stereotactic radiosurgery procedures, Baylor, HealthTexas, and TOPA impliedly certified that they followed all laws, regulations, and rules applicable to Medicare, Texas Medicaid, and CHAMPUS/TRICARE with respect to the procedures listed on the claims.

180. Baylor, HealthTexas, and TOPA failed, however, to ensure the proper supervision of these procedures as required by Medicare, Texas Medicaid, and CHAMPUS/TRICARE. Additionally, Baylor, HealthTexas, and TOPA failed to comply with laws, rules, and regulations necessary to maintain their licenses to provide health care services. Thus, the claims submitted to Medicare, Texas Medicaid, and CHAMPUS/TRICARE for reimbursement for these procedures were false and/or fraudulent.

181. Baylor Radiosurgery Center's schedule reinforces what Dr. Berger and Delp repeatedly observed: HealthTexas and TOPA radiation oncologists and Baylor routinely failed to comply with supervision requirements during Gamma Knife and CyberKnife procedures.

182. Knowing that the required levels of supervision had not been met, Baylor, HealthTexas, and TOPA continued to submit claims for reimbursement for these procedures. The ultimate submission by Baylor, HealthTexas, and TOPA of false and/or fraudulent claims to Medicare, Texas Medicaid, TRICARE, and other federal and state healthcare programs was a foreseeable factor in the Government's loss, and a consequence of the scheme. Given the structure of the healthcare systems, Defendants' false statements, representations, and records had the potential to influence the Government's payment decision. Consequently, Medicare, Texas Medicaid, CHAMPUS/TRICARE, and other federal and state healthcare programs have sustained damages.

D. Baylor Paid Illegal Kickbacks In Exchange for Patient Referrals from TOPA

183. TOPA submitted Medicare, Texas Medicaid, and upon information and belief TRICARE, provider applications and/or signed provider agreements requiring it to comply with applicable Medicare, Texas Medicaid and TRICARE laws, regulations, and program instructions including, but not limited to, the Anti-Kickback Statute and the Stark Act. By participating in the Medicare, Texas Medicaid, and TRICARE programs, and in submitting applications, and/or entering agreements with Medicare, TOPA certified compliance with applicable Medicare laws, regulations, and program instructions including, but not limited to, the Anti-Kickback Statute and the Stark Act.

184. The Anti-Kickback Statute prohibits the offer or acceptance of remuneration to induce the purchase of a good or service reimbursed by a federal healthcare program.

Additionally, under the Affordable Care Act, a violation of the Anti-Kickback Statute constitutes a false claim for purposes of the FCA. The Stark Act prohibits any physician from making a referral to a provider of designated health care services if the physician has a financial relationship with the provider.

185. Baylor and TOPA violated the Anti-Kickback Statute and the Stark Act by engaging in a scheme in which TOPA would refer patients to Baylor Radiosurgery Center for stereotactic radiosurgery and would refer its chemotherapy patients to Baylor University Medical Center if Baylor would lower the physician supervision requirements for these procedures so that TOPA and its radiation oncologists could continue to bill for procedures performed at the same time that the radiation oncologists should have been supervising their patients' stereotactic radiosurgery procedures. Furthermore, in the hopes of garnering business from TOPA, Baylor set up a medical directorship for Dr. Cheek. This medical directorship was nothing more than a sham to funnel money directly to Dr. Cheek in exchange for patient referrals.

186. Baylor and TOPA knew that their schemes would result in the submission of false and/or fraudulent claims to Medicare, Texas Medicaid, TRICARE, and other federal or state healthcare programs. Baylor and TOPA also knew that their scheme would lead to patient referrals to Baylor for stereotactic radiosurgery that were tainted by the kickbacks.

187. The ultimate submission by Baylor, HealthTexas, and TOPA of false and/or fraudulent claims to Medicare, Texas Medicaid, TRICARE, and other federal and state healthcare programs was a foreseeable factor in the Government's loss, and a consequence of the scheme. Given the structure of the healthcare systems, Defendants' false statements, representations, and records had the potential to influence the Government's payment decision.

Consequently, Medicare, Texas Medicaid, CHAMPUS/TRICARE, and other federal and state healthcare programs have sustained damages.

E. TOPA Engaged in Fraudulent Double-Billing.

188. Instead of directly supervising Gamma Knife and CyberKnife procedures, TOPA radiation oncologists were often across the street from Baylor Radiosurgery Center at their own offices in Sammons Cancer Center treating other patients while allowing their stereotactic radiosurgery patients to be radiated by unqualified physicians. Upon information and belief, in addition to billing for the unsupervised stereotactic procedures, TOPA radiation oncologists knowingly billed federal and state programs for the other treatments they provided while they were supposed to be directly supervising the Gamma Knife procedures, thus double-billing these federal and state programs.

189. The ultimate submission by TOPA of false and/or fraudulent claims to Medicare, Texas Medicaid, TRICARE, and other federal and state healthcare programs was a foreseeable factor in the Government's loss, and a consequence of the scheme. Given the structure of the healthcare systems, TOPA's false statements, representations, and records had the potential to influence the Government's payment decision. Consequently, Medicare, Texas Medicaid, CHAMPUS/TRICARE, and other federal and state healthcare programs have sustained damages.

F. Defendants Conspired to Defraud Medicare, Texas Medicaid, and CHAMPUS/TRICARE.

190. Upon information and belief, Baylor, HealthTexas, and TOPA entered into agreements and conspired with one another to submit false claims for reimbursement for stereotactic radiosurgery procedures to Medicare, Texas Medicaid, TRICARE, and other federal and state healthcare programs.

191. As a part of the scheme and agreement to obtain reimbursement for stereotactic radiosurgery procedures in violation of the reimbursement policies of Medicare, Texas Medicaid, TRICARE, and other federal and state healthcare programs, the Defendants conspired and agreed to perform acts to effectuate the conspiracy.

192. The Defendants knew that their actions would result in the submission to Medicare, Texas Medicaid, TRICARE, and other federal and state healthcare programs of false and/or fraudulent claims for reimbursement for stereotactic radiosurgery procedures. The ultimate submission by Baylor, HealthTexas, and TOPA of false and/or fraudulent claims to Medicare, Texas Medicaid, TRICARE, and other federal and state healthcare programs was a foreseeable factor in the Government's loss, and a consequence of the scheme. Given the structure of the healthcare systems, Defendants' false statements, representations, and records had the potential to influence the Government's payment decision. Consequently, Medicare, Texas Medicaid, CHAMPUS/TRICARE, and other federal and state healthcare programs have sustained damages.

X. Damages

193. Under the FCA and applicable law, Defendants should not have been reimbursed by Medicare, Texas Medicaid, CHAMPUS/TRICARE, and other federal healthcare programs, given the circumstances discussed herein. Consequently, the United States Government and the State of Texas have suffered substantial damages.

XI. Causes of Action

A. First Cause of Action—False Claims (31 U.S.C. § 3729(a))

194. Relators reallege and hereby incorporate by reference each and every allegation contained in paragraphs 1 through 193 of this Complaint.

195. Defendants submitted or caused to be submitted claims to federal and state healthcare programs for stereotactic radiosurgery procedures that were not performed under the required physician supervision. Defendants also submitted or caused to be submitted claims for stereotactic radiosurgery procedures that were not properly billed. Accordingly, Defendants knowingly presented or caused to be presented false or fraudulent claims for payment or approval, in violation of 31 U.S.C. § 3729(a)(1).

196. The United States Government paid the false and/or fraudulent claims.

197. By virtue of the false or fraudulent claims Defendants knowingly caused to be presented, the United States Government has suffered substantial monetary damages.

B. Second Cause of Action—False Records or Statements (31 U.S.C. § 3729(a))

198. Relators reallege and hereby incorporate by reference each and every allegation contained in paragraphs 1 through 197 of this Complaint.

199. Defendants knowingly made or used false records or statements (a) to get false or fraudulent claims paid or approved by the Government, or (b) material to false or fraudulent claims, in violation of 31 U.S.C. § 3729(a). The false records or statements included, but were not limited to, the Defendants' false certifications and representations of full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the supervision requirements imposed by the NRC, CMS, and the State of Texas, the Anti-Kickback Statute, the Stark Act, and requirements to maintain their licenses to provide healthcare services to patients..

200. By virtue of the false records or statements Defendants made or used, the United States Government has suffered substantial monetary damages.

C. Third Cause of Action—Conspiracy (31 U.S.C. § 3729(a))

201. Relators reallege and hereby incorporate by reference each and every allegation contained in paragraphs 1 through 200 of this Complaint.

202. Defendants conspired with one another to violate the supervision requirements applicable to stereotactic radiosurgery procedures, thereby submitted or causing to be submitted false or fraudulent claims to federal and state healthcare programs for payment. Accordingly, Defendants conspired to defraud the Government by (a) getting false or fraudulent claims allowed or paid, or (b) committing a violation of the FCA, in violation of 31 U.S.C. § 3729(a).

203. By virtue of the false or fraudulent claims submitted, paid, or approved as a result of Solvay's conspiracy to defraud the Government, the United States has suffered substantial monetary damages.

204. Furthermore, Baylor permitted TOPA physicians to violate the supervision requirements in order to induce patient referrals, in violation of the Anti-Kickback Statute, the Stark Act, and the FCA.

RELIEF

205. On behalf of the United States Government, Relators Dr. Berger and Delp seek to recover monetary damages equal to three times that suffered by the United States Government. In addition, Relators Dr. Berger and Delp seek to receive all civil penalties on behalf of the Unites States Government in accordance with the False Claims Act.

206. Relators Dr. Berger and Delp seek to be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(b) of the False Claims Act.

207. Relators Dr. Berger and Delp seek to be awarded all costs and expenses for this action, including attorneys' fees and court costs.

208. Relators Dr. Berger and Delp seek to be awarded all other relief on behalf of the United States Government to which it may be entitled and that the Court deems just and proper.

PRAYER

WHEREFORE, Relators Dr. Berger and Delp pray that this Court enter judgment on behalf of the United States and against Defendants for the following:

a. Damages in the amount of three (3) times the actual damages suffered by the United States as a result of Defendants' conduct;

b. Civil penalties against Defendants up to $11,000 for each violation of 31 U.S.C. § 3729;

c. Relators be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d);

d. Relators be awarded all costs and expenses of this litigation, including attorneys' fees and costs of court; and

e. All other relief on behalf of the United States Government to which it may be entitled and that the Court deems just and proper.

D. Fourth Cause of Action—Texas False Claims Act

209. Relators Dr. Berger and Delp reallege and hereby incorporate by reference each and every allegation contained in paragraphs 1 through 208 of this Complaint.

210. This is a *qui tam* action brought by Relators Dr. Berger and Delp and the State of Texas to recover double damages and civil penalties under V.T.C.A. Hum. Res. Code §36.001 *et seq.*

211. V.T.C.A. Hum. Res. Code § 36.002 provides liability for any person who

(1) knowingly or intentionally makes or cases to be made a false statement or misrepresentation of a material fact:

(a) on an application for a contract, benefit, or payment under the Medicaid programs; or

(b) that is intended to be sued to determine its eligibility for a benefit or payment under the Medicaid program.

(2) knowingly or intentionally concealing or failing to disclose an event:

(a) that the person knows affects the initial or continued right to a benefit or payment under the Medicaid program of:

(i) the person; or

(ii) another person on whose behalf the person has applied for a benefit or payment or is receiving a benefit or payment; and

(b) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized;

(3) knowingly or intentionally makes, causes to be made, induces, or seek to induce the making a false statement or misrepresentation of material fact concerning information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program.

212. Defendants knowingly violated V.T.C.A. Hum. Res. Code § 36.002 and knowingly caused hundreds of false claims to be made, used, and presented to the State of Texas from at least 2005 to the present by their violations of federal and state laws.

213. The State of Texas, by and through the Texas Medicaid program and other state health care programs, and unaware of the fraudulent and illegal practices of Defendants, paid the false and/or fraudulent claims.

214. Compliance with applicable Medicare, Medicaid, and the other various other federal and state laws cited herein was an implied and also an express condition of payment of claims submitted to the State of Texas in connection with the fraudulent and illegal practices of Defendants.

215. Given the structure of the health care systems, the false statements, representations, and records made by the Defendants had the potential to influence the State of Texas's payment decision.

216. The ultimate submission by the Defendants of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of Texas's loss, and a consequence of the scheme.

217. As a result of Defendants' violations of V.T.CA. Hum. Res. Code § 36.002, the State of Texas has been damaged.

218. There are no bars to recovery under V.T.C.A. Hum. Res. Code § 36.113(b), and, or in the alternative, Relators Dr. Berger and Delp are original sources as defined therein. Relators Dr. Berger and Delp are private persons with direct and independent knowledge of the allegations of the Complaint and have brought this action pursuant to V.T.C.A. Hum. Res. Code § 36.101 on behalf of the State of Texas. As required, Relators Dr. Berger and Delp have served the Attorney General of the State of Texas with a statement of material evidence and information related to this Complaint. These disclosure statements were supported by documentary evidence.

219. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

PRAYER

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF TEXAS:

- The amount of actual damages that the State of Texas has sustained as a result of Solvay's fraudulent and illegal practices;
- Three times the amount of actual damages that the State of Texas has sustained as a result of Solvay's fraudulent and illegal practices;

- A civil penalty of not less than $5,000 as described in V.T.C.A. Hum. Res. Code Section 36.052(a)(3) for each false claim that Solvay caused to be presented to the state of Texas;

- Prejudgment interest; and

- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to V.T.C.A. Hum. Res. Code Section 36.110, and/or any other applicable provision of law;

- Reimbursement for reasonable expenses that Relators incurred in connection with this action; and

- An award of reasonable attorneys' fees and costs.

XII. Demand for Jury Trial

220. Pursuant to Federal Rule of Civil Procedure 38, Relators demand a trial by jury.

WHEREFORE, Relators Dr. Berger and Delp respectfully request all relief described herein.

Dated: June 3, 2010

Respectfully submitted,

Joel M. Androphy /RLG

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ATTORNEYS FOR RELATORS
BRIAN BERGER AND JANICE DELP

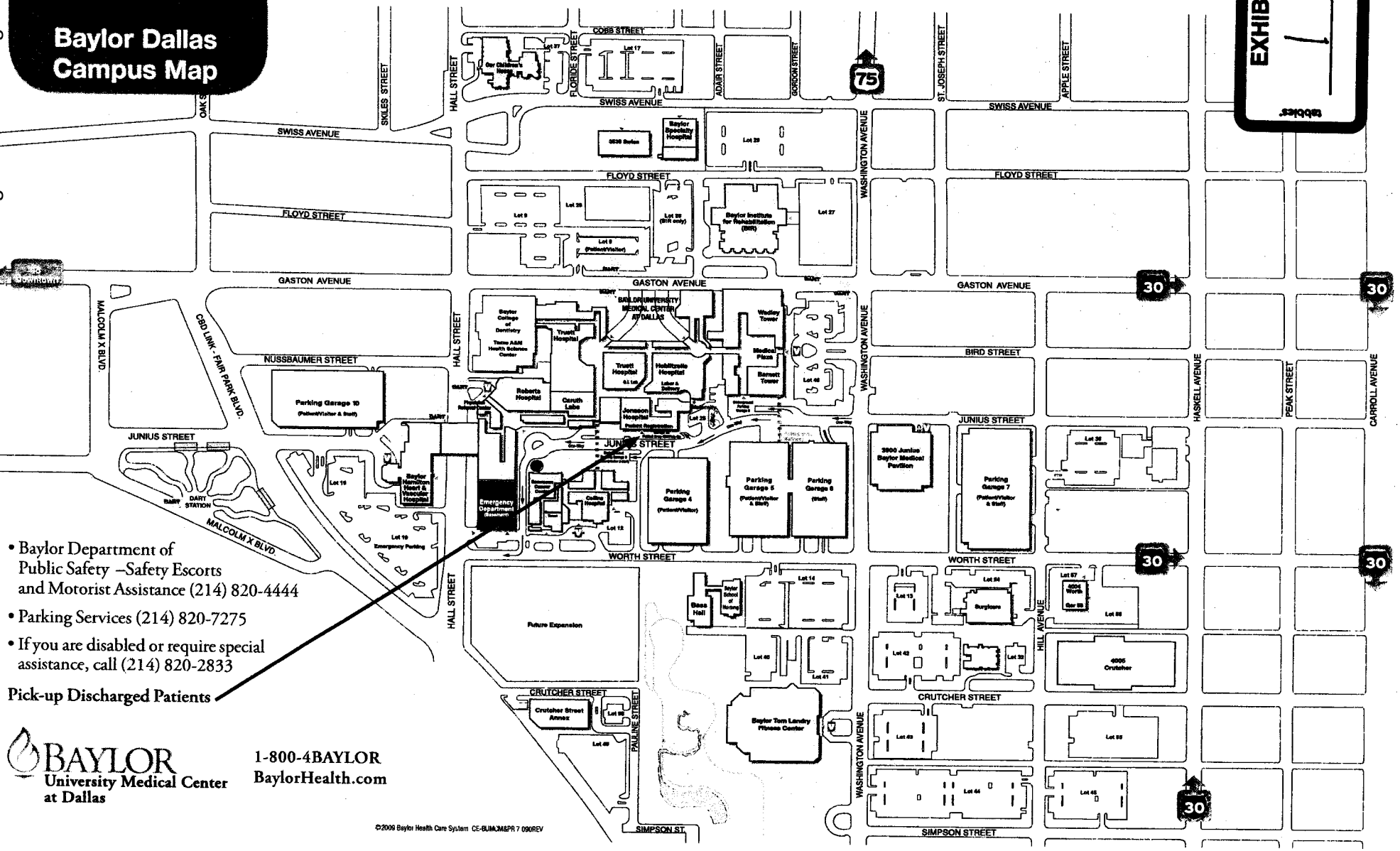
CERTIFICATE OF SERVICE

I hereby certify that on June 3, 2010, a true and correct copy of the above and foregoing complaint was forwarded via the United States Mail, certified, return receipt requested, by facsimile, by electronic mail, or by messenger to the United States Attorney's Office in Dallas, Texas, United States, the Department of Justice in Washington, D.C., and the Attorney General of the State of Texas.

Joel M. Androphy

EXHIBIT 1

Baylor Dallas Campus Map



- Baylor Department of Public Safety –Safety Escorts and Motorist Assistance (214) 820-4444
- Parking Services (214) 820-7275
- If you are disabled or require special assistance, call (214) 820-2833

Pick-up Discharged Patients

BAYLOR University Medical Center at Dallas

1-800-4BAYLOR
BaylorHealth.com

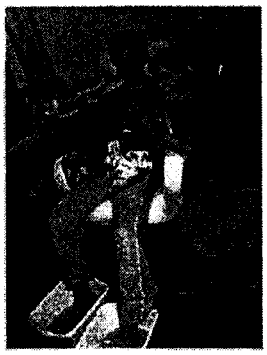
THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

by WALT BOGDANICH
Published: January 23, 2010

As Scott Jerome-Parks lay dying, he clung to this wish: that his fatal radiation overdose — which left him deaf, struggling to see, unable to swallow, burned, with his teeth falling out, with ulcers in his mouth and throat, nauseated, in severe pain and finally unable to breathe — be studied and talked about publicly so that others might not have to live his nightmare.

Enlarge This Image



For his last Christmas, Scott Jerome-Parks rested his feet in buckets of sand his friends had sent from a childhood beach. More Photos »

The Radiation Boom
When Treatment Goes Awry
This is the first in a series of articles that will examine issues arising from the increasing use of medical radiation and the new technologies that deliver it.

Multimedia

Sensing death was near, Mr. Jerome-Parks summoned his family for a final Christmas. His friends sent two buckets of sand from the beach where they had played as children so he could touch it, feel it and remember better days.

Mr. Jerome-Parks died several weeks later in 2007. He was 43.

A New York City hospital treating him for tongue cancer had failed to detect a computer error that directed a linear accelerator to blast his brain stem and neck with errant beams of radiation. Not once, but on three consecutive days.

Soon after the accident, at St. Vincent's Hospital in Manhattan, state health officials cautioned hospitals to be extra careful with linear accelerators, machines that generate beams of high-energy radiation.

But on the day of the warning, at the State University of New York Downstate Medical Center in Brooklyn, a 32-year-old breast cancer patient named Alexandra Jn-Charles absorbed the first of 27 days of radiation overdoses, each three times the prescribed amount. A linear accelerator with a missing filter would burn a hole in her chest, leaving a gaping wound so painful that this mother of two young children considered suicide.

Ms. Jn-Charles and Mr. Jerome-Parks died a month apart. Both experienced the wonders and the brutality of

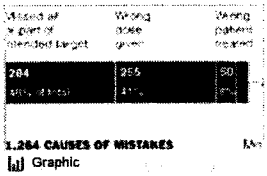
EXHIBIT 2

Interactive Graphic

Fatal Radiation

Photographs

Medical Radiation: A Plan Goes Wrong



Radiation Mistakes: One State's Tally

Related

Well: When Radiation Treatment Turns Deadly

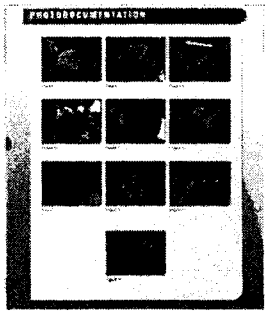
Enlarge This Image

Alexandra Jn-Charles, center, with her husband, Rene, and their children, died in 2007. More Photos >

Enlarge This Image

Scott Jerome-Parks, with his wife, Carmen, was 43 when he died in 2007 from a radiation overdose. More Photos >

Enlarge This Image



While being treated for breast cancer, Ms. Jn-Charles was overradiated for

radiation. It helped diagnose and treat their disease. It also inflicted unspeakable pain.

Yet while Mr. Jerome-Parks had hoped that others might learn from his misfortune, the details of his case — and Ms. Jn-Charles's — have until now been shielded from public view by the government, doctors and the hospital.

Americans today receive far more medical radiation than ever before. The average lifetime dose of diagnostic radiation has increased sevenfold since 1980, and more than half of all cancer patients receive radiation therapy. Without a doubt, radiation saves countless lives, and serious accidents are rare.

But patients often know little about the harm that can result when safety rules are violated and ever more powerful and technologically complex machines go awry. To better understand those risks, The New York Times examined thousands of pages of public and private records and interviewed physicians, medical physicists, researchers and government regulators.

The Times found that while this new technology allows doctors to more accurately attack tumors and reduce certain mistakes, its complexity has created new avenues for error — through software flaws, faulty programming, poor safety procedures or inadequate staffing and training. When those errors occur, they can be crippling.

"Linear accelerators and treatment planning are enormously more complex than 20 years ago," said Dr. Howard I. Amols, chief of clinical physics at Memorial Sloan-Kettering Cancer Center in New York. But hospitals, he said, are often too trusting of the new computer systems and software, relying on them as if they had been tested over time, when in fact they have not.

Regulators and researchers can only guess how often radiotherapy accidents occur. With no single agency overseeing medical radiation, there is no central clearinghouse of cases. Accidents are chronically underreported, records show, and some states do not require that they be reported at all.

In June, The Times reported that a Philadelphia hospital gave the wrong radiation dose to more than 90 patients with prostate cancer — and then kept quiet about it. In 2005, a Florida hospital disclosed that 77 brain cancer patients had received 50 percent more radiation than prescribed because one of the most powerful — and supposedly precise — linear accelerators had been programmed incorrectly for nearly a year.

Dr. John J. Feldmeier, a radiation oncologist at the University of Toledo and a leading authority on the treatment of radiation injuries, estimates that 1 in 20 patients will suffer injuries.

Most are normal complications from radiation, not

BA-SRS000003

27 days, burning a gaping hole in her chest. The photos of the wound's progression were used on a poster presented at a medical convention. More Photos >

mistakes, Dr. Feldmeier said. But in some cases the line between the two is uncertain and a source of continuing debate.

"My suspicion is that maybe half of the accidents we don't know about," said Dr. Fred A. Mettler Jr., who has investigated radiation accidents around the world and has written books on medical radiation.

Identifying radiation injuries can be difficult. Organ damage and radiation-induced cancer might not surface for years or decades, while underdosing is difficult to detect because there is no injury. For these reasons, radiation mishaps seldom result in lawsuits, a barometer of potential problems within an industry.

In 2009, the nation's largest wound care company treated 3,000 radiation injuries, most of them serious enough to require treatment in hyperbaric oxygen chambers, which use pure, pressurized oxygen to promote healing, said Jeff Nelson, president and chief executive of the company, Diversified Clinical Services.

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HEALTH
Hidden Danger
Radiation accidents like those that injured Scott Jerome-Parks and Alexandra Jn-Charles don't have to be made public under New York state law, leaving many unaware of treatment risks.

While the worst accidents can be devastating, most radiation therapy "is very good," Dr. Mettler said. "And while there are accidents, you wouldn't want to scare people to death where they don't get needed radiation therapy."

Because New York State is a leader in monitoring radiotherapy and collecting data about errors, The Times decided to examine patterns of accidents there and spent months obtaining and analyzing records. Even though many accident details are confidential under state law, the records described 621 mistakes from 2001 to 2008. While most were minor, causing no immediate injury, they nonetheless illuminate underlying problems.

The Times found that on 133 occasions, devices used to shape or modulate radiation beams — contributing factors in the injuries to Mr. Jerome-Parks and Ms. Jn-Charles — were left out, wrongly positioned or otherwise misused.

On 284 occasions, radiation missed all or part of its intended target or treated the wrong body part entirely. In one case, radioactive seeds intended for a man's cancerous prostate were instead implanted in the base of his penis. Another patient with stomach cancer was treated for prostate cancer. Fifty patients received radiation intended for someone else, including one brain cancer patient who received radiation intended for breast cancer.

New York health officials became so alarmed about mistakes and the underreporting of accidents that they issued a special alert in December 2004, asking hospitals to be more vigilant.

As this warning circulated, Mr. Jerome-Parks was dealing with what he thought was a nagging sinus infection. He would not know until two months later that cancer had been growing at the base of his tongue. It was a surprising diagnosis for a relatively young man who rarely drank and did not smoke.

In time, his doctors and family came to suspect that his cancer was linked to the neighborhood where he had once worked, on the southern tip of Manhattan, in the shadow of the World Trade Center.

Several years before, he had taken a job there as a computer and systems analyst at CIBC World Markets. His starting date: September 2001.

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