

Gunapathy Muniandy v James Khoo and Others  
[2001] SGHC 165

**Case Number** : Suit 1768/1999  
**Decision Date** : 04 July 2001  
**Tribunal/Court** : High Court  
**Coram** : G P Selvam J  
**Counsel Name(s)** : Michael Khoo SC with Andy Chiok Beng Piow (Michael Khoo & Partners) for the plaintiff; Michael Hwang SC (Counsel) with Christopher Daniels and Renuka Chettiar (Karuppan Chettiar & Partners) for the 1st and 3rd defendants; Tan Beng Swee (Netto Tan & S Margin) for the 2nd defendants  
**Parties** : Gunapathy Muniandy — James Khoo; Neurological Surgery Pte Ltd; Khor Tong Hong

**JUDGMENT:**

**Chapter 1 : An Overview**

1.1. This is a medical negligence case of some importance. It is a case with a difference. It concerned the use of a relatively new medical procedure involving the delivery of single-high-dose irradiation, by X-ray photons, to the dominant hemisphere of the brain of the plaintiff, a lady by the name of Gunapathy Muniandy ("Gunapathy"). The procedure is called radiosurgery. It was planned and performed by using a computer and a high-tech physics-based machine known by its proprietary trade-name "XKnife". One year before the radiosurgery, the plaintiff had undergone another procedure called "radiotherapy". The plaintiff contended that in consequence of the two treatment procedures, she suffered a constellation of neurological complications and symptoms. They were, she alleged, as follows :

headaches, numbness, weakness, hemiparesis, ataxia, radionecrosis, cranial nerve damage, Parinaud's syndrome, hemianopia, apraxia, obtundation, dyesthesia, aphasia, tremor and decreased gait.

Hence this suit. The events that brought the defendants to the Court occurred at Mount Elizabeth Hospital ("Mt E Hospital").

1.2. There were three significant events involving three different treatments over a period of 15 months. The first event was a trans-callosal tumourectomy, by which a tumour in Gunapathy's brain was removed. It was done on 15 November 1995 by Dr James Khoo (the first defendant), a neurosurgeon. The second event was irradiation of the brain substance surrounding the bed of the tumour (conventional radiotherapy). This was done from 6 December 1995 to 13 January 1996 by Dr Khor Tong Hong (the third defendant) on Dr James Khoo's advice and suggestion. Dr Khor is a radiation oncologist. The final event was radiosurgery of a small nodule in the roof of Gunapathy's left brain ventricle. This was performed by Dr James Khoo, Dr Khor and Mr Toh Hang Jin, a radiation physicist, on 31 January 1997. As a result of those three major events, and by the end of 1997, the plaintiff developed severe disorders and disabilities.

The pathology

1.3. A broad outline of the first two significant events is as follows. Gunapathy married a little late in life, in March 1995, when she was 36 years old. In October that year she showed symptoms of an illness. She experienced headaches and weakness in her right arm. These related to a complication in

her brain. Her pathological problems led her to the doors of a neurologist, Dr Devathasan. A magnetic resonance image (MRI) of her head was done on 7 November 1995. The MRI confirmed that her complaints were due to obstructive hydrocephalus (accumulation of water in her head), which was, in turn, caused by a tumour in her left lateral ventricle. It measured 24 x 19 x 16mm. The mass was later characterized and categorized as a "neurocytoma" (a tumour of nerve cells).

#### The first surgery

1.4. Dr Devathasan referred the plaintiff to Dr James Khoo, a well-experienced neurosurgeon. On 15 November 1995, Dr James Khoo surgically resected and removed the tumour. He wrote in his records that he had performed : "Anterior transcallosal craniotomy and total excision of tumour". After the tumour's removal, Dr Carol Kwan, attached to Mt E Hospital described the tumour as a neurocytoma. Dr Carol Kwan is a histopathologist, that is, a doctor specialising in the diagnosis of diseases relating to cells and tissues of the human body.

#### The radiotherapy

1.5. Shortly after that, Gunapathy underwent conventional radiotherapy in December 1995 and January 1996. The purpose of the radiotherapy was, in the words of Dr James Khoo, "to prevent a relapse". The radiotherapy was performed by Dr Khor, an employee of Mt E Hospital. The high-tech equipment which was used to administer radiotherapy to Gunapathy was owned by Mt E Hospital. After this, she resumed her normal self, although Dr James Khoo and Dr Khor continued to monitor her condition.

#### The radiosurgery

1.6. Now the third event. On 26 February 1996, an MRI was done. It was done by Dr Esther Tan, a diagnostic radiologist attached to one of the Mt E Hospital stable of companies. It showed a lesion. It was a small nodule, hanging from the roof of the left ventricle of Gunapathy's brain in the region where Dr James Khoo had surgically removed the neurocytoma. It did not cause much concern but a follow-up was advised to determine whether the nodule was a residual tumour. On 27 December 1996, another MRI was done. After this the doctors decided to do something to the nodule. Dr James Khoo, Dr Khor and Dr Toh Hang Jin performed stereotactic radiosurgery (or "XKnife procedure"), a form of high-tech medicine, on the lesion. The term "Knife" in the label "XKnife procedure" is an inappropriate and misleading description of what the procedure involves, for the instrument is not a metal scalpel but comprises of invisible high-energy photon beams artificially generated and directed to penetrate the brain of the patient through a collimator. The collimator collimates. It concentrates and guides the x-ray beams into parallel lines.

#### The side effects

1.7. Not long after undergoing the stereotactic radiosurgery, Gunapathy developed a collection of adverse symptoms which proved to be the serious side-effects of the radiosurgery. Her brain began to balloon because of the radiation effect. At the same time, millions of brain cells began to die. Doctors call this radionecrosis (death by radiation). The reactions in her brain can be likened to an explosion of a minute invisible atom bomb in the dominant (left) hemisphere. Functionally, she became disabled disastrously. This drove her to the doors of the clinic of Dr Prem Pillay, a neurosurgeon who knew a good deal about stereotactic radiosurgery, for he had established the Gamma Knife Centre at the Singapore General Hospital. The Gamma Knife Centre provides another form of radiosurgery called "Gamma Knife" procedure, which is broadly similar to the *XKnife* procedure. In the result, she brought this medical negligence suit against Dr James Khoo and Dr Khor (together "the doctor defendants")

and Dr James Khoo's company, Neurological Surgery Pte Ltd (the second defendant).

(See The Chronology – Appendix I)

### The plaintiff's allegations

1.8. The basic allegations Gunapathy made in the pleadings were as follows :

- (i) The doctors failed to give competent advice or conduct the diagnostic procedures available to determine the nature of the nodule in her left ventricle.
- (ii) They incompetently and wrongly advised and performed radiosurgery on her when there was no reason for it.
- (iii) They failed to warn her of the serious side-effects of radiosurgery, particularly when it overlapped the previously irradiated volume of brain tissue.
- (iv) They were incompetent in the execution of the radiosurgery and in not using Gamma Knife radiosurgery, another form of radiosurgery available at the Gamma Knife Centre.
- (v) They used too large a collimator and used too large a dosage of irradiation in a single fraction.

1.9. The sole legal basis of her claim against the doctors was in the tort of negligence. She could have brought an action against Dr James Khoo on the basis of contract but she did not do that. However, that does not make any difference because a contractual claim would not have given her any legal or procedural advantage over the claim based on tort. She could also have added Mt E Hospital as a defendant because Dr Khor was in its employment, and the *XKnife* equipment was owned by the hospital. If she had done that she would have been in a more advantageous position with regard to discovery of documents. Also, she did not found her claim on the tort of trespass to person or battery on the basis that she did not give consent to radiosurgery. Even on the point of inadequate and inappropriate information, she confined her claim to the tort of negligence.

1.10. In terms of damages, she asked for general damages for pain and suffering. Additionally she asked for special damages in the region of \$2.5 million. The claim was based on the allegations that she has lost her earning capacity totally and that she has to pay for supervised care for the rest of her life.

1.11. In her pleadings she relied on the legal doctrine of *res ipsa loquitur*. I will comment on this in Chapter 9.

### Judicial attitude and latitude

1.12. It would be appropriate now to say something about the judicial attitude and latitude towards cases of this kind. In ***Hatcher v Black and Others*** (1954 - unreported) Denning LJ sat as a Judge of first instance. It was a medical negligence case. He tried the case with a jury. The plaintiff, Mrs Hatcher, was a lady who occasionally broadcast for the BBC. She went into St Bartholomew's Hospital suffering from a toxic thyroid gland. An operation was advised. She asked if there was any risk to her voice. She was reassured by her doctors that there was no cause for worry. The operation was

performed. In the course of it, the nerve was so badly damaged that she could not speak properly. She could not broadcast again. So she brought an action asking for damages. The jury found in favour of the doctors. In his summing-up to the jury, Denning LJ said :

Mr Marven Everett sought to liken the case against a hospital to a motor-car accident or to an accident in a factory. That is the wrong approach. In the case of an accident on the road, there ought not to be any accident if everyone used proper care; and the same applies in a factory; but in a hospital, when a person who is ill goes in for treatment, there is always some risk, no matter which care is used. Every surgical operation involves risks. It would be wrong, and, indeed, bad law, to say that simply because a misadventure or mishap occurred, the hospital and the doctors are thereby liable. It would be disastrous to the community if it were so. It would mean that a doctor examining a patient, or a surgeon operating at a table, instead of getting on with his work, would be for ever looking over his shoulder to see if someone was coming up with a dagger – for an action for negligence against a doctor is for him like unto a dagger. His professional reputation is as dear to him as his body, perhaps more so, and an action for negligence can wound his reputation as severely as a dagger can his body. You must not, therefore, find him negligent simply because something happens to go wrong; if, for instance, one of the risks inherent in an operation actually takes place or some complication ensues which lessens or takes away the benefits that were hoped for, or if in a matter of opinion he makes an error of judgment. You should only find him guilty of negligence when he falls short of the standard of a reasonably skilful medical man, in short, when he is deserving of censure – for negligence in a medical man is deserving of censure.

See ***The Discipline of Law***, by Lord Denning (1979) at p 242-243.

1.13. Counsel for the doctors in this case brought the summing-up to my attention. It was a bright and brilliant summing-up. I am not, however, trying this case with a jury. I am mindful of the fact that a Court of Law must not be swayed by any sympathy for the dismal condition of the plaintiff. No professional must be condemned for negligence lightly. Human nature, being what it is, has a proclivity to blame the doctor when he cannot realize the expectations of the patient. Having said that I must also remember that "sauce for the goose is sauce for the gander". The Court of Law must not be too ready to find for the doctors merely because their professional reputation is likely to be damaged and their insurance premium may escalate. If the doctor is at fault, it is the responsibility of this Court to give a remedy to the plaintiff. In cases of this kind, the quest of the plaintiff often is for something in addition to damages – namely, catharsis. This quest should not be rejected lightly either.

1.14. The ultimate basis of liability is breach of the law. The Court can give damages only if the defendants have been proved "to be guilty of negligence": See ***Bolam v Friern Hospital Management Committee*** [1957] 1 WLR 582. In other words, the sole concern of the Court is to find liability only when there is fault. There is no room for no-fault liability in the Court of Law. Fault is the foundation of negligence. My responsibility in this case is therefore to decide whether the defendants have been proved to be guilty of negligence in the manner asserted by the plaintiff.

1.15. The right attitude the Court should adopt was stated by Denning LJ in ***Roe v Minister of Health*** [1954] 2 QB 66 at 87 :

We must insist on due care for the patient at every point, but we must not condemn as negligence that which is only a misadventure.

1.16. In Appendix I, I set out as an aide-memoir a chronology of the important events leading to the issue of the Writ. Additionally I have reproduced text book pictures of the brain ventricles and the adjacent organs of the brain. See Pictures 1,2and 3. Italics throughout, unless otherwise indicated, are mine.

## **Chapter 2 : The Medical Documents**

### November 1995 MRI

2.1. It would be appropriate now to describe the three events in some detail with reference to the notes, letters and records made by the doctors. In late 1995 Dr Devathasan commissioned an examination of Gunapathy's head by MRI. The MRI report, dated 9 November 1995, showed a mass measuring 24 by 19 by 16 mm in the left lateral ventricle of her brain. The mass, (later characterised as a tumour), was causing dilation of the left lateral ventricle. In fact, it had pushed itself against the intraventricular septum pellucidum (transparent wall) which separated the lateral ventricles. About one-third of the tumour trespassed into the right lateral ventricle. The brain has four ventricles. The first two are called right and left lateral ventricles. No number is assigned to them. The other two are called the third and fourth ventricles. The tumour was also obstructing the interventricular foramen (of Monroe) through which cerebro-spinal fluid (CFS) from the left ventricle flowed into the third ventricle. There was dilation of the left ventricle which was exerting pressure on the brain, causing much pain to Gunapathy. This was noted as causing severe headaches and weakness of her right arm.

### The operation note

2.2. Dr Devathasan referred her to Dr James Khoo. She was operated upon on 15 November 1995 by Dr James Khoo. The operation particulars recorded by Dr James Khoo on 15 November 1995 contained the following notes :

**Transcollosal craniotomy and total excision of tumour.**

**Tumour resected totally macroscopically.**

**Diagnosis : Glioma (Neurocytoma).**

### Preliminary diagnosis of tumour

2.3. On the same day, 15 November 1995, a frozen section report was done by Dr Anjula Thomas of Mount Elizabeth Laboratories. Dr Thomas was unsure as to a definitive diagnosis. She reported the following diagnosis :

Primary glial tumour, low grade.

Moderate cellularity, mild pleomorphism. Mitosis are hard to find.

? low grade glioma

?? neurocytoma

### Final diagnosis

2.4. Dr Carol Kwan of Mount Elizabeth Laboratories did a histopathology report on sample tumour tissue that Dr James Khoo had submitted. Histopathology was the best available method for a definitive diagnosis of the exact nature of the mass. The histopathology report gave a microscopy of

the tissues as follows :

The moderately cellular tumour is composed of evenly spaced, uniform looking cells which display round, finely vascular nuclei with inconspicuous nucleoli. The background shows a fine neurofibrillary stroma and delicate, thin walled vessels divide the tumour into vague "packets". Pleomorphism is minimal and *mitosis could not be found*. In many areas, the nuclei are surrounded by a clear rim and a polygonal cell border is evident. Focally some siderophages are seen. No calcifications, necrosis or endocapillary proliferation seen.

Immunoperoxidase studies : The tumour is strongly positive for NSE and synaptophysin. Chromogranin was faint and equivocal. GFAP showed entrapped glial fibres.

The histopathology report gave this definitive diagnosis :

Intraventricular Tumour  
Neurocytoma

Dr Carol Kwan's report abandoned the earlier possibility of the tumour being a low grade glioma as earlier postulated by Dr Anjula Thomas.

2.5. In December 2000, Dr Jennifer Teo, Neuropathologist of the National Neuroscience Institute, did a microscopic examination of the 1995 slides. Her examination concluded that : "No mitoses, necrosis or microvascular proliferation are seen." Dr Jennifer Teo further concluded that the proliferation index "was less than 1% in keeping with the low grade nature of this tumour."

2.6. The class of "low grade" was a histological classification. The World Health Organisation (WHO) has classified brain tumours according to this histological nature. The common understanding of the phrase "low grade" means nearer the lower end and not the higher end. Dr Jennifer Teo explained that the terms "benign" and "malignant" are not widely used in the context of brain tumours. I asked her whether for my purpose it was not malignant. She answered : "Yes, that is basically what I'm trying to say." Dr Jennifer Teo explained why they do not use the words "benign" and "malignant". She said :

It's because in brain tumours, the outcome of the tumour is not strictly dependent solely upon the histology of the tumour.

The outcome, the behaviour of the tumour is not dependent solely upon the histology features of the features of the tumour under the light microscope. It also depends upon other factors like the age of the patient and the location of the tumour so that you might have a very low--a low grade tumour if it is situated in a very crucial part of the brain, the patient might also not have a good prognosis because the tumour is located in a crucial part of the brain.

Like the brain stem.

So, that is why we do not use the terms "benign" and "malignant".

From a layman's of view, this tumour has a low grade appearance and it's expected to behave in an indolent benign fashion. [NE 306-307]

2.7. It is to be noted that the neurocytoma in the plaintiff's brain was not a central neurocytoma in the true sense of the expression. It was not in her brain parenchyma. It was an intraventricular neurocytoma that is in the ventricle and only in the ventricle.

2.8. It is important to note that the histopathology report of Dr Carol Kwan did not describe this neurocytoma as cancerous, malignant or semi-malignant or of low-grade malignancy.

#### Neurocytoma

2.9. A leading medical textbook, **Neurosurgery** by Dr Robert H Wilkins and Setti S Rengachary, 2<sup>nd</sup> Edition 1996, (Wilkins and Rengachary) says as follows on neurocytoma at p 1462 :

These tumors are uncommon and have become well documented and understood only in the last few years. *They are benign* and occur in young adults in the second, third, and fourth decades of life. The site of origin is usually at or near the midline at the base of the septum pellucidum and usually in close proximity to the foramen of Monroe. These tumors are often quite large before they cause symptoms and the usual presentation is with hydrocephalus causing headache and other symptoms and signs of increased intracranial pressure. The presence of focal neurological deficits or the appearance of seizures has been reported but is uncommon.

These tumors can be solid or have cystic areas within them and there are often small areas of calcification. If the tumor extends into or through one foramen of Monro, asymmetrical hydrocephalus can be produced.

On MRI the tumor is isointense or slightly hyperintense relative to the brain. The septum pellucidum is seen to be bowed away from the tumor although it may be hard to separate the septum pellucidum from the medial aspect of the tumor. The neurocytoma is usually well demarcated from surrounding brain. On CT as well as MRI, the tumor appears to be totally within the ventricle. *These tumors are best treated with surgical removal and careful postoperative observation. At times, even when a small amount of tumor has been left, there may be no growth for quite some time. Radiation therapy at present does not seem to have a role in treatment.*

2.10. An article entitled "Central Neurocytoma" by nine authors led by Figarelle-Branger was published in **The American Journal of Surgical Pathology** (1992) Vol. 16(2), pp 97-109. The highlights of the article are as follows :

Central neurocytomas are clinically characterised by their intraventricular localization, occurrence in young adults, and good prognosis. It rarely occurs in patients over 50, but such cases have a poor prognosis. *Total surgical excision is the best treatment. Radiotherapy is appropriate if surgery is incomplete or contraindicated.* [p 97 – summary]

Intracerebral neurocytomas have histological features in keeping with oligodendrogliomas: small regular and clear cells, a rich capillary network, and calcifications. Large fibrillary areas, sometimes including a vessel, were also found in almost all cases. Both features – an oligo-like pattern and fibrillary areas – are highly suggestive of central neurocytomas. However, the differential

diagnosis should include oligodendroglioma, ependymoma, and pineocytoma. Additional pathological features usually observed in neuroblastomas have rarely been reported in intracerebral neurocytomas. [pp 102-104]

Central neurocytomas are formed by cells committed to a neuronal phenotype and not by multipotent cells. These tumours probably arise from the granular neurons of the small gray nuclei of the septum pellucidum or the fornix. [p 108]

2.11. A recently published work, **Neuro-Oncology** edited by Mark Bernstein and Mitchel S Berger, 2000, includes a section on neurocytoma. The following are extractions from it :

Neurocytoma is characteristically found in the ventricles of young adults. Commonly found in the lateral ventricle, these lesions can also be found in the pons, cerebellum, and spinal cord and are thought to compose less than 1% of CNS tumours, but the diagnosis has been under-represented in the past. The lesions may be cystic and have calcification. On MRI, signal intensity is heterogeneous with variable enhancement. These lesions have been frequently misdiagnosed as oligodendroglioma, but although similar in histological appearance these lesions are composed of synaptophysin-staining mature neurons. Electron microscopy has demonstrated neuritic processes with microtubular cytoskeletons and terminal boutons with clear synaptic vesicles. *Lesions located entirely within the parenchyma of the cerebrum have been described and are called central neurocytoma to distinguish them from those with intraventricular extension* . Miller proposed that, based on the similarities noted among central neurocytoma, intraventricular neurocytoma, cerebral neurocytoma, and dysembryoplastic neuroepithelial tumours, these lesions be considered together and called ganglioneurocytoma. *Although the typical course is indolent, malignant cases have been reported* . *Complete surgical resection is the recommended therapy, but even after subtotal resection, radiation therapy has not been strongly recommended*.

These authors suggested that, on the basis of their clinical follow-up, these lesions should be considered as low-grade malignant tumours and that the terminology "benign" be eliminated.

2.12. The following points should be noted :

Firstly: *The typical neurocytoma is indolent. Its growth is slow*

Secondly: There are several sub-categories of neurocytoma. So much so that the new main category should be called "ganglioneurocytoma". *Central neurocytoma* is one of them and this is entirely within the parenchyma of the cerebrum which forms the functional, especially the intellectual, part of the brain. It does not show up in the lateral ventricle. A neurocytoma in the ventricle should properly be termed *"intraventricular neurocytoma"* and not "central neurocytoma" which is found in the parenchyma of the cerebrum. Each neurocytoma must be studied histologically to determine its true pathology and prognosis. Gunapathy's neurocytoma belonged to this sub-category of intraventricular neurocytoma and not "central neurocytoma". The plaintiff's neurocytoma when sighted in November 1995, was not attached to or embedded in a crucial part of the brain namely the eloquent brain



- Thirdly: The recommendation that the terminology "benign" be eliminated does not apply to all the neurocytomas. It is a good recommendation. In particular it would be unwise to append the term "benign" to cerebral parenchymal neurocytomas and other neurocytomas whose proliferation index exceeds two
- Fourthly: It is important to note that "radiation therapy" has not been recommended by the authors. The reason is obvious – the side-effects of radionecrosis. This applies especially if a diagnosis proves a low mitosis signifying slow growth or negligible growth and the bulk has been resected. An intraventricular neurocytoma, unless it magnifies itself to an unacceptable size, remains truly benign, especially if it has been totally or almost totally resected.
- Fifthly: The comment in the textbook debunks the doctrines advanced by the doctor defendants about intraventricular neurocytoma being a cancer justifying radiation therapy and it being an excellent option for radiosurgery. They seem to have fallen into the category error of confusing an intraventricular neurocytoma with a malignant glioma

#### November 1995 CT scan

2.13. On 20 November 1995, five days after Dr James Khoo performed surgical removal of Gunapathy's neurocytoma, the Department of Diagnostic Radiology of Mt E Hospital, at the behest of Dr James Khoo, did a CT Scan of Gunapathy's head. The report on the CT Scan noted that the ventricles did not appear to be dilated. There was no evidence of intracranial haemorrhage. The report recorded the following impressions :

There is a well defined left paramedian hypodensity of CSF attenuation deforming the left lateral ventricular contour. The lateral aspect of this lesion shows slightly increased attenuation bulging into the left ventricular contour but there is no abnormal enhancement associated with this lesion.

A few small air pockets are seen in the frontal subarachnoid spaces anteriorly. The brain shows no other abnormal density change. The ventricles do not appear to be dilated. There is no evidence of intracranial haemorrhage.

#### Impression

There is a left paramedian hypodensity deforming the left lateral ventricle. There is slightly bowing of the midline to the right. *There is no enhancing nodule to suggest residual tumour.* This hypodensity is probably post-surgical change.

2.14. Later evidence established that CT scan was not sensitive enough to detect a lesion or nodule in the circumstances of the present case. An MRI would have been the appropriate procedure.

#### Radiation (radio) therapy

2.15. The first documentary evidence relating to radiation therapy was a letter from Dr Devathanan to "Dr Khor, Radiotherapist Mt E". The letter, dated 25 November 1995, read as follows :

REF: Gunapathy K F/36

History: Patient was operated on the 15 November 1995 for an intraventricular tumour by Dr James Khoo. She presented with one month of headaches and mild

weakness of the right arm. The tumour was more left sided and blocked the foramen of Monroe. It was completely (macroscopically) excised as seen on the check CT scan and she has no deficits post op. The histology is a definite Neurocytoma which is a recently recognised subset of primary brain tumours and has been distinguished from the oligodendrogliomas recently in 1992 by some Japanese researchers. James Khoo felt that, although completely excised, it would be safer to subject her to chemo or radiation and left it to me to work out the best treatment options.

I discussed it with the oncologist and apparently *chemo is not of much use and Dr Tan Yew Oo feels that if she is planning a family (Pt was just married) chemo is best avoided due to the effects on the ovaries*. A literature search for the last five years also supports this view.

I am therefore referring her to you for localised radiotherapy. The films are with her. Due to size of field involved I understand from you that Linac therapy is not applicable here.

2.16. There was no letter or notes by Dr James Khoo recommending radiotherapy or chemotherapy.

2.17. By a letter dated 1 December 1995 Dr Khor agreed to give radiotherapy :

Thank you for so kindly referring Mdm Gunapathy for radiotherapy to her left ventricular region, following gross total resection of a neurocytoma by Dr James Khoo.

I agree she would benefit from post-operative radiotherapy and arrangements have been made for this to be given.

2.18. Dr Khor later confirmed that he had a corridor conversation with Dr Devathanan who asked for radiotherapy for Gunapathy.

#### Dr Khor's notes

2.19. Clinical Notes (Patient's Progress/Treatment) made by Dr Khor on 30 November 1995 and 31 January 1996 read as follows :

Date

Progress Notes

- 30.11.95                      Headaches for a week and she consulted Dr Devathasan.  
                                     Given Tanakan and reassured – headache cleared and  
                                     recurred only a month ago. She again saw Dr Deva and  
                                     examined clinically – nad Again given Tanakan but  
                                     severe headache recurred and she requested for head  
                                     scan. MRI done 7.11.95 which showed intra-cranial  
                                     pathology. Surgery by Dr James Khoo – resection of 3<sup>rd</sup>  
                                     ventricle tumour blocking (L) foramen of Munroe.  
                                     Histology – neurocytoma (previously grouped with  
                                     oligodendroglioma).  
                                     O/E : GS satis. Healed scar (R) lower neck (node  
                                     excised 1991 – no tumour).  
                                     Slightly enlarged thyroid  
                                     Minimal weakness (R) arm.  
                                     Healed vertex (head) scar.  
                                     P.H. PTB, asthma, diabetes, hypertension, IHD. Allergic  
                                     to Erythromycin-oral medication rashes.
- 31.1.96                        Completed RT.  
                                     No change in menses.  
                                     GC satis. No cranial nerve palsies.

#### Advent of XKnife at Mt E Hospital

2.20. There are two important events that need to be noted at this juncture. First, around the end of September 1996, Mt E Hospital acquired a new piece of high-tech equipment to perform radiosurgery. That was the *X-Knife* stereotactic radiosurgery equipment. *XKnife* is a trademark of the American Corporation Radionics Inc ("Radionics"). It was called *XKnife* because it uses X-rays. Radiosurgery was a Swedish invention. It was made and marketed under the trademark *Gamma-Knife* and it uses gamma rays unlike the *XKnife* which uses X-rays. At that time, there was no one in Mt E Hospital who understood *XKnife* or who was trained to use it.

2.21. A monograph published by Radionics said this about *XKnife* radiosurgery :

Stereotatic radiosurgery is a very critical procedure, by its very nature. Close attention to the accepted clinical methods and *years of experience of clinical radiosurgery* are essential for proper use of this technique.

2.22. The monograph manual published by **Radionics** contained this "General Warnings and Precautions".

As described in this monograph, stereotactic radiosurgery is indicated, clinically effective, and cost-effective for certain brain metastases and other indications. However, it is a very critical procedure, by its nature. Close attention to the accepted clinical methods and experience of years of clinical radiosurgery are essential for proper use of this technique. In every case, good clinical judgment for the particular patient being treated is paramount.

This monograph represents the method used by the authors at the time of writing and should not be interpreted as the only way to deliver radiosurgery for brain metastases. The monograph provides general guidelines for the use of *XKnife* radiosurgery, but since no two patients are identical; specific care and judgment for each patient is essential. It is the responsibility of the individual clinicians treating the patient to decide on the appropriateness of any aspect of

the technique described in this monograph, or indeed radiosurgery in general. This monograph should in no way substitute for the use of such proper clinical judgment by the caring physician for the patient's specific needs.

It is the basic philosophy of the monograph authors and Radionics that the team approach is essential for good stereotactic radiosurgery. A competent and well trained neurosurgeon, radiation oncologist, radiation physicist, and support staff must work together in order to develop and maintain a high quality program in radiosurgery.

The XKnife System represents careful design of stereotactic instrumentation, software, and quality assurance processes that have evolved over many years of work in collaboration with practicing clinicians. These procedures have been designed for the purpose of avoiding the possibility of errors and providing the maximum information and security for this technique. The user should follow, at all times, the Radionics' recommendations for use of this equipment and the protocols for use of the quality assurance methods associated with it.

Radionics has established a procedure for installation of its XKnife instrumentation and software at the user site and extensive training of the users themselves at Radionics, at clinical sites, and at their own site, so that they can use the equipment confidently. The key members of the XKnife clinical team should be fully trained in this manner, and that training subsequently propagated among their colleagues who may use the system. Competent and trained physics/engineering support should be associated with each XKnife site so that proper use and maintenance of the XKnife equipment will be carried out.

As part of the training and support material, Radionics has prepared an extensive user's manual for the XKnife System. This manual should be read and understood by all of its users and followed carefully for proper use of the XKnife System for radiosurgery.

In general, awareness of proximity of radiation to critical structures is mandatory. Every effort should be made in treatment planning to minimize the dose to cranial nerves, the optical system, the brain stem, and other such vital and critical structures. Cranial neuropathies may be transient or permanent. The variables of dose and volume are responsible, but the exact relationship remains incompletely understood.

2.23. In September 1996, there was no one in Mt E Hospital trained in the use of the *XKnife* at Mt E Hospital. So a four-day week-end course was organized by its manufacturers at Prince of Wales Hospital in Sydney. This was in October 1996. Dr Khor was the only employee of Mt E Hospital who attended the course at Sydney. He took notes of the lectures. Dr Khor also obtained and kept a manual on the use of the *XKnife*. The lecture notes and the *XKnife* manual will play a crucial role in the case.

2.24. After his return, Dr Khor and the *XKnife* were ready to receive patients and doctors who might wish to be the users of this high-tech treatment of stereotactic radiosurgery. Dr James Khoo offered it to Gunapathy and referred her to Dr Khor. I shall relate how this happened.

February 1996 MRI

2.25. After Gunapathy completed her course of conventional radiotherapy, in February 1996, Dr James Khoo asked for an MRI of her brain. Radiologic Clinic, which was within the Mt E Hospital Group, did the MRI. Dr Esther Tan did an interpretive report on the MRI. It read as follows :

#### MRI scans of the brain

Scans were performed in the sagittal, axial and coronal planes before and after administration of intravenous Gadolinium DTPA.

The lobulated enhancing mass lesion noted within the left lateral ventricle in the previous MR examination of November 1995 has been removed. There is a defect noted in the body of the corpus callosum and skull vault, with areas of abnormal signal in the left fronto-parietal region, adjacent to the interhemispheric fissure, compatible with previous surgery.

The left lateral ventricle remains asymmetrically more prominent than the right. The degree of dilation however, is not as pronounced as before. There is a small nodular density protruding from the roof of the body of the left lateral ventricle, which appears to enhance slightly following administration of contrast. This may represent scar tissue related to the previous surgery than the residual tumour, but should be followed-up.

The midline structures are not shifted. No other areas of abnormal signal are seen in the cerebral hemispheres. There are no areas of abnormality demonstrated in the brain stem or cerebellum either.

#### Comments

There is evidence of previous surgery anteriorly with defect in the skull vault and the corpus callosum with some abnormal signal in the left cerebral hemisphere adjacent to the interhemispheric fissure. The lobulated mass demonstrated in the left lateral ventricle in the previous MRI study of November 1995 has been removed. There is some residual dilatation of the left lateral ventricle but no midline shift is seen.

Note the small nodular lesion at the roof of the left lateral ventricle which appears to enhance slightly. This should be followed-up.

2.26. After completion of the radiotherapy on 31 January 1996, Dr Khor monitored the plaintiff's condition on three occasions. His notes on those three occasions were as follows :

<u>Date</u>	<u>Progress Notes</u>	<u>Weight</u>
4.3.96	C/o memory loss. GC satis. No Neurological deficit. MRI - ? scar at roof of (L) lateral ventricle	Wt 60.7kg
30.3.96	Experiences "heatiness" on and off. Menses normal GC satis. Alopecic patches over RT areas.	Wt 60.6kg

28.9.96

Wt 61.2kg

Quite stable.  
GC satis.  
No neurological Deficits.  
Regular menses.

2.27. Dr Khor who had sight of the MRI of 26 February 1996 on 4 March 1996 recorded this remark in relation to this MRI :

MRI - ? Scar at roof of (L)lateral ventricle.

2.28. After the 26 February 1996 MRI, according to Dr James Khoo's notes, Gunapathy visited his clinic on eight occasions in 1996. The last of them was made on 25 October 1996. He did not record anything about the MRI of 26 February 1996 in his clinical notes on any of these visits. On 29 February 1996, however, Dr James Khoo wrote to Dr Devathanan as follows :

Mdm Gunapathy is well.

The check MRI shows a small nodule that enhances only slightly on the roof of the ventricle. *I am not sure if this residual tumour or some granulation tissue have advised check MRI again in 4/12's time.*

2.29. However, no check MRI was done in four month's time, even though Gunapathy visited Dr James Khoo on 3 occasions in June, once in July 1996, once in September 1996 and twice in October 1996. Obviously he was not concerned.

#### December 1996 MRI

2.30. In December 1996, when the *XKnife* was ready to receive patients, Dr James Khoo used it on other patients on four occasions. In December 1996, he also asked for an MRI on Gunapathy. This was done just after Christmas. Dr James Khoo's clinic sent a request form for the MRI. It described the resected tumour as "glioma" and not "neurocytoma". This was a serious category mistake, for gliomas are very different from neurocytomas. They present radically different problems and prognosis. I shall say more about this later. As requested by Dr James Khoo, an MRI was carried out on Gunapathy, and Dr Esther Tan did an interpretive report on the MRI on 27 December 1996. It read as follows :

#### MRI Scans of the Brain

Scans were performed in the sagittal, axial and coronal planes, before and after administration of intravenous Gadolinium.

Evidence of previous surgery is noted. There are defects observed in the skull vault anteriorly. There is also a defect in the body of corpus callosum. Abnormal signal is observed in the left parietal lobe. The left lateral ventricle is asymmetrically slightly larger than the right. There is still an enhancing nodular opacity protruding from the roof of the left lateral ventricle. This measures approximately 11 x 12 x 6mm in size. *It does not appear to have enlarged significantly when compared with the previous study of February 1996.* There is also some patchy enhancement in the brain parenchyma along the margin of the left lateral ventricle, adjacent to this lesion. *These abnormalities are probably*

*due to scarring from previous surgery.*

Normal separation of the grey and white matter is observed. No focal lesions are seen in the right cerebral hemisphere. There are no brain stem or cerebellar abnormality observed. No hydrocephalus is seen. The midline structures are not shifted.

#### Comments

Evidence of previous surgery is noted on the left. There is abnormal signal observed in the left parietal lobe with deformity and asymmetric enlargement of the left lateral ventricle. *There is still an enhancing nodular opacity protruding from the roof of the lateral ventricle with some abnormal enhancement along the margins of the left lateral ventricle.*

*Comparison with the previous examination of February 1996 suggests no significant change in appearances*

.

2.31. Dr James Khoo on 14 January 1997 made the following note on the December 1996 MRI :

Still has small nodule – roof of ventricle.

#### The plaintiff visits Dr Ho

2.32. On 21 January 1997, Gunapathy was referred by Dr Devathasan to another neurosurgeon, Dr Ho Kee Hang, whose clinic was at Mt Elizabeth Medical Centre. In October 1996, he had attended the same course in Sydney as Dr Khor. He saw Gunapathy for about 10 minutes. His clinical record noted the diagnosis as "(L) lat. ventricle neurocytoma". These were his other notes :

Problem :

*Small residual neurocytoma hanging from roof of (L) lat. ventricle.*

Hed RT.

?? for stereotatic radiosurgery.

Option discussed advised to go back to J Khoo.

If she wishes for linac radiosurgery by Dr Khor

Verbal reply to Dr Deva..

#### The plaintiff consults Dr Khor

2.33. Dr Khor made these short notes on 23 January 1997 :

Still anxious re pregnancy risks etc. Discussed implications and assured no medical contra-indication to conceiving – social aspects to be considered.

General condition satisfactory. No neurological deficits.

#### Dr Devathasan writes to Dr James Khoo

2.34. Then there was a one-sentence letter from Dr Devathasan to Dr James Khoo on 27 January 1997. It read as follows :

Pt. After careful deliberation & discussion prefers to have Radio Surgery to the residual lesion.

The plaintiff visits Dr James Khoo

2.35. Gunapathy visited Dr James Khoo on 27 January 1997, probably delivering Dr Devathan's note. Dr James Khoo made this note :

Wants RS / small residual nodule.  
Discussed Pro/Cons.

It is to be noted that neither Dr Devathan nor Dr James Khoo described the nature of the residual nodule in their notes.

The radiosurgery

2.36. On 31 January 1997, Dr Khor performed radiosurgery on the plaintiff. He recorded these notes :

Had seen Dr J Khoo – finally requested R/S to increase probability of tumour control before proceeding to conception.  
R/S given – single isocentre, 4+1 arcs used. 2000cGy at 85% isodose, single fraction.

2.37. Three days later, on 3 February 1997, Dr Khor wrote to Dr James Khoo's clinic (the second defendant) as follows :

This is to provide you with details of the radiosurgery which was performed for Mdm Gunapathy on 31.1.97.

Following attachment of the frame by yourself, treatment was given to the mass lesion at the left lateral ventricle, using a single isocentre. The collimator size was 2.25cm in diameter and 5 arcs were used as shown in the accompanying worksheet. A single fraction of 2000cGy was delivered to the 85% isodose. Treatment was well tolerated and on removal of the frame later that day, there were no signs of bleeding from the skull pin wounds.

2.38. There was an admission and a discharge note of Mt E Hospital which recorded, among other things, this :

Final Diagnosis : Residual Neurocytoma Intraventricular  
Operation performed: Stereotactic radiosurgery.

2.39 Clinical notes of Mt E Hospital made on 31 January 1997 read as follows :

Admitted for RS  
*Neuro-Astrocytoma removed*  
Subtotally in 1995 end.  
(Undecipherable)  
Now wants residual nodule removed.  
Pregnancy motive.



2.40. There was no satisfactory explanation as to how the term "neuro-astrocytoma" came about when the histological characterisation of the tumour was "neurocytoma". This was a category error. Furthermore, the non-specific description "residual nodule" was again repeated. It was not described as a tumour, a glioma or a neurocytoma on the day the radiosurgery was done.

### Chapter 3 : Dr Baratham States the Plaintiff's Case

3.1. Gunapathy called Dr Gopal Baratham as her medical expert witness. Dr Baratham, a neurosurgeon, is in semi-retirement. He does not perform surgery any more. He produced a report on Gunapathy and for Gunapathy. The report, in some ways, traversed territory which was outside his experience and expertise. On some areas, he relied on the opinion of others and references, not within his own knowledge and experience.

3.2. The report, however, has this merit : Dr Baratham, has an attractive writing style. He has the art of translating complicated medical concepts into popular parlance. He has used his facility of expression to construct an intelligible account of the medical aspects of the plaintiff's case. I shall now set out the report in full, but with the caveat that it is nothing more than a statement of the plaintiff's case by someone who was on her side. It is not proof of her case and I did not treat it as such. A judicial decision must be founded on the totality of evidence after consideration of all the witnesses and not just one witness.

#### DR BARATHAM'S REPORT

(1) This report is based on the various doctors' reports presented to me, study of the hospital records, an examination of the histological (microscopic study of the tumour) material, discussion with the various colleagues and references to the literature on the subject.

#### Case History

(2) In September 1995, Madam Gunapathy Muniandy, just turned 36 years old and recently married began to suffer headaches of progressive severity. These were not associated with vomiting or any mental or physical disability. She consulted a neurologist, Dr G Devathasan in October 1995 for these headaches which according to his note was associated with numbness of the right arm. On 9 November an MRI scan was performed. This showed a tumour in the left lateral ventricle.

(3) The lateral ventricles are two cavities which lie deep in the brain, one on the left and one on the right side. They contain a fluid CSF (cerebro-spinal fluid) which after being formed here passes through channels in the centre of the brain and on to its surface, providing, among other things, a shock absorbing system for the brain. Blockage of these CSF pathways lead to dilation of the ventricles and an increase in pressure within the brain which causes headaches. This was the case with Gunapathy.

(4) Dr Devathasan referred Gunapathy to a neurosurgeon, Dr James Khoo. On 15 November 1995, Dr Khoo removed this tumour. According to his operation note the tumour was totally removed.

(5) Microscopic examination of the tumour showed it to be a neurocytoma. This is a rare tumour first described in 1982. Dr Carol Kwan, a pathologist at Mount Elizabeth Hospital reports as follows : "Pleomorphism is minimal and mitosis could not be found. ... No ... necrosis or endocapillary proliferation

seen." (Dr Baratham's Italics).

(6) One of the critical features which distinguish a malignant (high grade) from a benign (low grade) brain tumour is the rate at which the tumour grows. The following are histological (what can be seen under the microscope) evidence of rapid tumour growth :

1. Mitosis : this is the presence of cells in the process of active division. The more such divisions are seen the more malignant is the tumour.
2. Pleomorphism : Literally in many shapes or forms. As the speed of cell division in a tumour increases the shape and staining properties of the cells comprising it vary. (In a manner of speaking, quality control has been sacrificed to the speed of cell division so products of differing types occur.) The degree of different types of cells seen in a tumour is, therefore, an indication of its malignancy (grade).
3. Necrosis : is the death of clumps of tumour cells. Paradoxically this indicates a fast growing tumour. The cells multiply so rapidly that they outrun their blood (nutrition) supply and die.
4. Endocapillary proliferation : is the growth of new small blood vessels. Malignant tumours stimulate the growth of new blood vessels to maintain their abnormal growth rate. The absence of these new blood vessels indicates that the tumour was benign (low grade).
5. A special staining technique using a cell proliferation marker Ki-67 (MIB-1) was performed at my request by Dr Jennifer Teo, Neuropathologist at the National Neuroscience Institute. This special study, which indicates the degree of cell multiplication, showed the proliferation index "... was less than 1% in keeping with the low grade of this tumour."

(7) Radiotherapy is usually reserved for malignant tumours and generally the more malignant the tumour the better its response to radiotherapy. Radiation works by causing blood vessels to close down thereby depriving tumour cells of their nutrition which leads to their death. It produces the same effect in normal brain but to a lesser degree. Radionecrosis is the death of tissue due to irradiation.

(8) Gunapathy recovered well from the surgery and a CT scan with contrast showed that there was no tumour remaining. The difference between the CT scan and the MRI is that the CT scan works by X-rays, the MRI by powerful magnets. While the CT can only really produce images of slice of the brain in the axial plane (cuts along the axis of the body) the MRI can provide pictures of the brain in the sagittal (profile), coronal (full face) and axial cuts ie in three dimensions. Though the films cannot be viewed in the way that 3D pictures can, they, nevertheless, give more information about brain tumours than do CT's.

(9) Despite this negative finding, Madam Muniandy was, between the 6 December 1995 and 13 January 1996, given radiotherapy, total dose of 5400cGy over 39 days. She remained well after this and returned to work. I have, however, no doubt that that it contributed to the disaster that ensued after radiosurgery.

(10) An MRI done on the 26 of February 1996 showed a nodule in the roof of the lateral ventricle,

measuring 11mm x 12mm x 6mm. It was impossible to say, with any degree of certainty, if this was scar or tumour. She was advised to have a follow-up MRI to see if there was any change in the nodule. Repeat MRI was performed on the 27 December 1996. It showed that the nodule seen in the MRI of 26 February had not increased in size. She was offered the option of either watching the nodule with further MRI's or radiosurgery. As far as I can ascertain from the records and questioning the patient, the possibility of doing a stereotactic biopsy and obtaining a sample of the nodule to determine whether it was tumour or scar was not broached. Nor was MR spectroscopy as a diagnostic aid mentioned.

(11) On the 31 January 1997, the radiosurgery was performed by Dr Khor Tong Hong, a radio-oncologist working at Mount Elizabeth Hospital. The responsibility for undertaking radiosurgery is that of both the surgeon and the radio-oncologist, in this case Dr James Khoo and Dr Khor Tong Hong. A single dose of 2000cGy was administered through a collimator diameter 2.25 cm.

(12) In May 1997 she developed tingling and numbness of the right arm. This progressed to weakness of both arm and leg.

(13) An MRI done on the 17 June showed marked swelling of the left side of the brain associated with areas of irregular enhancement. Enhancement means that there is an area of brain damage (a breakdown of the barrier between blood and brain). The damage can be from tumour, surgery or radiation. In view of its general distribution it was most likely due to radiation necrosis.

(14) She was treated by Dr Devathasan with steroids, physiotherapy and anticoagulants, substances which prevent blood clots forming in the vessels of the brain. Her condition varied.

(15) In December 1997 she sought advice of Dr Prem Pillay, a neurosurgeon, working at Mount Elizabeth and Gleneagles Hospitals. Dr Pillay attempted to control the swelling but due to worsening of her symptoms, operated to remove tissue damaged by radiation which was causing the swelling of the brain. Radionecrotic (brain killed) brain causes normal adjacent brain to swell. The normal, after a period, itself dies and a vicious circle is established. Dr Pillay removed only dead brain (performed an internal decompression) breaking the circle. Dead tissue is easily recognised and removed without damaging living brain. The fact that the patient's symptoms relating to raised pressure inside the head viz headache and loss of alertness, improved after surgery and that all the tissue removed by Dr Pillay showed evidence of radionecrosis indicates quite clearly that the operation was competently performed.

(16) The tissue removed was examined under the microscope by a consultant pathologist, Dr Fong Chee Meng. It was found to contain no tumour but to be brain which had undergone radionecrosis.

### Examination

(17) I examined Gunapathy on the 28 November 2000 for the purpose of this report. She was fully conscious and attentive of her surroundings. According to her husband her headaches had been cured by the operation performed by Dr Prem Pillay and her level of alertness greatly improved. The paralysis and speech disability remained.

(18) Her speech was difficult to understand partly because of a problem in articulation and partly because she had difficulty in finding appropriate words. She was, however, able to understand English and Tamil. However, she could not state the names of things or people even those dear to her.

(19) Her memory was unreliable and she was given to outbursts of weeping. These were sometimes triggered by the frustration of not finding the words she wanted but often occurred for no reason.

(20) She had a severe, spastic (stiff) right sided weakness. Her right hand was completely useless and walking without support was very difficult. This affected the right side of her face but was not the cause of her incoherence.

(21) She is not in a position to socialise and spends her day at home. She is able to read, watch television though it is difficult to establish how much she comprehends. She is able to look after her toilet needs but cannot answer the phone. Her husband and she continue to have sexual relations and the marriage, at this point in time, does not appear to be threatened by her disability.

#### Opinion

(22) Madam Muniandy's disability is certainly the result of radionecrosis and is permanent. She will never be able to live an independent existence and will always need care at home. The initial diagnosis and surgery of the tumour are without fault.

(23) However, subsequent management can be faulted in the following areas :

1. Post operative radiotherapy was given to a large field despite the fact that the tumour was benign, was totally excised as is the recognised treatment for tumours of this nature and a post-operative CT scan with contrast did not reveal any remnants of tumour. Adjuvant radiotherapy in fractionated doses to a total of 5400cGy by itself did not harm. There was, however, no indication for it and it unquestionably sensitised the brain and was responsible for the disabilities that occurred after radiosurgery.

2. An MRI done some five weeks after the course of radiotherapy showed a nodule in the left lateral ventricle. There was some doubt as to whether this was tumour or scar. There were three options at the time .

- (a) To observe its behaviour with serial MRI's.

- (b) To perform MR spectroscopy (a non-invasive procedure, which as far as the patient is concerned is identical to an MRI). This could, by identifying some of the chemical contents of the tumour, help towards the decision as to whether it was tumour or some other process like scarring. This is by no means a perfect method of diagnosis but taken with contrast

enhanced MRI can certainly assist towards diagnosis.

(c) Stereotactic biopsy which in expert hands is accurate to 1-2mm and there would have been no danger in structures 22mm (1 inch) away. It has in the best circumstances an accuracy of 90%. The procedure requires putting a frame on the head, making a tiny hole in the skull and assisted by CT or MRI guiding a needle into the tumour and removing a small piece of it for diagnostic, microscopic examination. It is done under local anaesthesia and, at most requires a day's admission to hospital. It is, in competent hands, a low risk procedure.

It was decided to observe the nodule rather than adopt alternatives (b) or (c).

3. Ten months later the MRI was repeated. This showed the nodule had not increased or decreased in size. Without discussing the diagnostic possibilities of MR spectroscopy or stereoscopic biopsy, radiosurgery was offered although just a year had passed since she had been subject to conventional radiotherapy. It is generally accepted that second doses of irradiation are especially prone to produce radionecrosis in normal surrounding tissue. This is especially so if the single dose technique is used rather than if the dose were split up (fractionated) and given over several weeks. This is because 90% of normal brain recovers from the injury done by radiation in 24 hours. The article cited in defence of using a single dose of such magnitude had patients followed up three months only and my impression is that the dosages recommended were used in patients with a very poor prognosis unlike Madam Muniandy who had a low grade tumour which was said to have been complete removed. Moreover, Madam Muniandy's symptoms came on more than three months after radiosurgery. What is more, no cases of neurocytoma are included in the series.

4. The radionecrosis here involved the left hemisphere of the brain. This is called the dominant hemisphere in right handed persons like Madam Muniandy. It is thus called because it controls movements of the right side of the body, speech and logical thought processes. Damage to this side of the brain could lead to severe disturbance or loss of all these functions. A 4% chance of this occurring is a big

chance (Consider that coronary bypass surgery has a mortality of under 1%). Such being the case, the horrific results of radionecrosis of the dominant hemisphere should have been spelled out to Madam Muniandy by both surgeon and radiooncologist and that this should have been documented in the notes. I can find no evidence of such having been done in the records.

5. Apart from tumours of the pituitary gland which regulates the endocrine system and meningiomas (a benign tumour) with female hormone receptors, the claim that pregnancy increases the growth rate of tumours is apocryphal. It has no scientific basis. The relevance of this to Madam Muniandy circumstances are obvious.

3.3. Dr Baratham gave evidence at the trial as the plaintiff's medical expert and he was cross-examined. I shall consider his evidence at a later stage when it becomes relevant to the issue under consideration.

#### **Chapter 4 : The Doctors' Letters**

##### *Dr James Khoo's letter (August 1997)*

4.1. It is important now to refer to certain letters by the defendant doctors after the *XKnife* radiosurgery. On 19 August 1997, Dr James Khoo wrote a letter addressed to "The Physician Concerned". This letter was written because the plaintiff desired to consult another neurosurgeon. In this case it was Dr Prem Pillay. Set out below is the entire text of the letter (certain obvious errors have been corrected. The paragraphs have been numbered by me).

(1) This right handed Indian lady executive was referred by Dr G Devathason with headaches associated with papilledema in November, 1995.

(2) A large intraventricular neurocytoma was found and resected totally on 15.11.95 she recovered well and subsequently had a course of radiotherapy.

(3) A post operative scan was entirely clear. Over the next 12 months she had occasional tension headaches and no neurological deficit.

(4) A check MRI scan in January, 1997 showed a small nodule about 12mm diameter in the roof of the left lateral ventricle in the parietal lobe. It was not clear if this could be *a small recurrence or a granuloma*.

(5) 2 approaches were advised, an expectant and conservative line or radiosurgery. *Mdm Gunapathy was keen on the latter as she was hoping to become pregnant soon, an event that could aggravate a malignant neoplasm.*

(6) On 31.1.1997, this was done with 2000cGy given to a single isocentre by Dr Khor Tong Hong, consultant radiation Oncologist. She took the procedure well.

(7) However by 25.3.1997, she developed numbness of the right side of the body, and by 12.6.1997, she developed a right sided hemiparesis with the leg

suffering significant weakness. Scan showed cerebral edema due to radionecrosis.

(8) She was treated with steroids and anticonvulsants and physiotherapy. Mdm Gunapathy is now improving gradually with these treatments and it is expected that she will improve much more once the edema is controlled.

It is to be noted that Dr James Khoo did not allege in this letter that the nodule was a residual or a recurrent neurocytoma. Dr James Khoo reaffirmed his inability to categorise it.

Dr James Khoo's letter (November 1997)

4.2. On 29 November 1997 Dr James Khoo wrote another letter also addressed to "The Physician Concerned". The following is the full text of the letter :

- (1) Madam Gunapathy was seen again on 20.11.1997.
- (2) She complained of having some slurring of speech and also some memory problems.
- (3) On examination, she was alert and rational and had no papilledema but was in distress as her speech was slightly hesitant due to mild dysphasia.
- (4) Her hemiparesis has remained stable and her gait had, I felt, improved slightly.
- (5) I feel Mdm Gunapathy's post radiation cerebral edema has remained a difficult problem and she will need to be treated rigorously with steroids and physiotherapy for a prolonged period.

Dr James Khoo's letter to plaintiff's lawyers

4.3. Two years later on 1 November 1999 Gunapathy consulted the legal firm of Michael Khoo & Partners. They wrote to Dr James Khoo and Neurological Surgery Pte Ltd (the second defendants). It was a short letter. It stated that they had been instructed to "seek an expert opinion to see whether or not you were negligent in treating her". They asked for "all the case notes and our client's medical records in respect of our client within the next 14 days from the date hereof".

4.4. Dr James Khoo and his company decided not to discover the notes and records. During the trial it was asserted that it was their right not to reveal the notes. Instead Dr James Khoo responded with a letter on 10 November 1999. He gave his version of the events. It read as follows :

- (1) Thank you for your letter dated 1.11.1999.
- (2) I am enclosing a previous medical report (dated 19.8.1997) which summarises the history of this lady's intraventricular *neurocytoma (a malignant primary tumour of the brain)* since 1995.
- (3) I have no objection to your obtaining the hospital's record on her treatment.
- (4) I agreed to do the radiosurgery for her as there was a new nodule seen in a check MRI Scans on February 1996 and December 1996 and this was suspected to be a recurrent tumour. Mdm Gunapathy was keen to have a baby and not in

favour of an expectant line of treatment nor any form of open surgery again.

(5) Radiosurgery is always done by a Neurosurgeon, Radiotherapist and Radiation Physicist.

(6) The role of Neurosurgen is to apply the stereotactic frame by skull fixations check a brain scan with this installed and subsequently mark out the target lesion (tumour) on the computer, as well as to mark out the optic chiasm, the brain stem structures, for the planning of the trajectories of the high energy photon beams, so that these vital structures are avoided.

(7) The role of the Radiotherapist and Physicist is to plan and calculate the dose of radiation to the target and also to oversee the arcs and trajectories of the rays so as to avoid the above vital structures.

(8) I have informed Mdm Gunapathy that radiosurgery with the X-knife or Gamma is less invasive than open surgery but still carried a risk of complications of about 5% which included significant brain swelling. I understand that Dr Khor Tong Hong, the consultant radiotherapist who had seen and consulted with her before the treatment, also warned her of the risks involved.

(9) I am sorry that she developed such a complication, especially as she had done so well after the initial major operation.

The point to note is that this was the first time that Dr James Khoo categorised Gunapathy's neurocytoma as a malignant primary tumour. It was utterly unwarranted because the histopathological report did not support such a characterisation. In fact, the contents of the histopathological report established the tumour as benign. This was also the first time he stated that the nodule could be a recurrent neurocytoma.

#### Dr Khor's letter to the plaintiff's lawyers

4.5. Also on 1 November 1999 Michael Khoo & Partners wrote a similar letter to Dr Khor. He too decided not to reveal any of the notes and records available to him. Instead he, like Dr James Khoo, wrote a letter to Gunapathy's lawyers on 8 December 1999. It would be salutary to set out the full text of the letter. It read as follows :

(1) Madam Gunapathy Muniandy was referred to me on 30.11.95 by Dr G Devathanan for adjuvant radiotherapy. She had presented with headaches for a duration of a month and had mild weakness of her right arm. MRI head scan on 9.11.95 reported a lobulated mass at the frontal horn and body of the left lateral ventricle, measuring 24 x 19 x 16 mm. Surgery was performed by Dr James Khoo on 15.11.95, during which he found the tumour obstructing the left foramen of Monroe. He had biopsied the tumour, which was reported on frozen section to be a low grade glioma, ? neurocytoma. The tumour mass was completely resected macroscopically, and the patient made an uneventful recovery. The paraffin sections subsequently confirmed a neurocytoma. *Post-operative CT head scan showed no evidence of residual tumour.*

(2) On examination, there was a healed scar over the vertex of her head with another over her right lower neck. The thyroid was slightly enlarged, but there



were no other significant findings in the neck. Minimal weakness in the right arm was the only neurological deficit that was noted. On direct questioning, she gave a history of having a lymph node excised from her right lower neck in 1991. She was told there was no tumour present in this node.

(3) Adjuvant radiotherapy was given with 6MVP photons, treating a volume of 4.5cm x 5.5cm x 4cm to 5,400cGy in 27 treatments over 39 days, from 6.12.95 to 13.1.96. A three port plan was used, with a pair of lateral wedged (30 wedges) ports measuring 4.5cm x 5.5 cm each, and a third, anterior port, 4.5cm x 4cm in size.

(4) She was subsequently followed up and remained well on clinical examination. A progress MRI of the head was done on 26.2.96 and this reported abnormal signal at the left cerebral hemisphere, with a small nodular lesion at the roof of the left lateral ventricle. A follow-up examination was suggested, as *the reporting radiologist was not able to tell whether the lesion was just scar tissue or residual tumour.*

(5) When she was seen on 23.1.97, there was a long discussion regarding the implications of a pregnancy should she conceive. The patient had been married for over a year and was anxious to have a child. She was assured that there were no medical contra-indications to pregnancy, but that the social aspects should be considered, as she could not be regarded at that time to be cured of her brain tumour. *A progress MRI on 27.12.96 had again shown the enhancing nodular opacity protruding from the roof of the left lateral ventricle – this had not changed significantly from the findings of February 1996.*

(6) She saw Dr James Khoo soon after and requested further treatment to ensure that there was complete tumour control before proceeding to conception, perhaps with assisted reproduction. The role of radiosurgery was discussed and it was decided to proceed with this treatment, which was performed on 31.1.97. "X-knife" radiosurgery was given with 6MVP photons from a Clinac 600C. A collimator diameter of 2.25cm was employed, treating with a single isocentre and 4+1 arcs. A single dose of 2,000cGy was delivered to the 85% isodose surface.

(7) On 2.6.97, she complained of numbness of her right leg and pain over her right chest. She had also consulted Dr Devathasan, who had started her on steroid therapy. At that time, there were no cranial nerve palsies and no motor weakness. However, she developed weakness of her right limbs subsequently and MRI head scan on 17.6.97 showed considerable oedema in the left posterior parietal region, with contrast enhancement in the subependymal region of the left ventricle and left posterior parietal region. Another area of enhancement was noted in the right frontal lobe. The changes in the left posterior parietal area were attributed to the previous radiation, but the changes in the right frontal lobe and the subependymal region could not be explained by the previous treatments and further follow-up examination was recommended. This was performed on 28.8.97, and showed similar findings in the left brain to the June 97 examination; however, the enhancement at the right frontal region was no longer visualised.

(8) On comparison of the June 1997 and August 1997 MRI examinations, when

she was reviewed on 15.9.97, it was noted that the ring enhancing lesion at the left parietal region had become smaller. There was weakness of her right upper and lower limbs, both with Grade 4 power. Dr Devathasan had started anti-coagulant treatment on the clinical diagnosis of radiation induced brain necrosis. In November 1997, she developed slurring of her speech and there was weakness of her right facial nerve. The power in the right arm had decreased to Grade 2+ and that in her right leg to Grade 3+. She also complained of difficulty in micturition and defaecation.

(9) She next attended for review on 22.1.98 when her neurological status remained unchanged from November 1997. She had by then seen Dr Prem Pillay, who had resumed steroid therapy. The patient had also been to Paris for a medical consultation there.

(10) She was again seen at this Centre on 17.3.99, and was then able to walk with the help of a crutch. The power for her right arm was Grade 1, and Grade 3 for her right leg. The left arm had normal power, whilst the left leg was assessed at Grade 4 motor power. There was still slurring of speech, but with no additional cranial nerve involvement. Dr Prem Pillay had performed a biopsy on 17.3.98 of the left frontal lobe, which reported radionecrosis with no evidence of tumour.

(11) The patient had not been seen at this Centre since.

#### Some salient points

4.6. The salient points in the letters are admissions by the doctors that in the three months after radiosurgery, Gunapathy had developed numbness of the right side. They also admitted that by the end of 1997 she was afflicted with and affected by right sided hemiparesis, cerebral edema due to radionecrosis, aphasia and amnesia, weakness of right facial nerve, difficulty in micturition and defaecation, and overall debility. Neither doctor, and in particular Dr Khor, said in his letter that she was warned of these or any such very adverse side-effects. Dr James Khoo confirmed that as late as January 1997 (the month of the radiosurgery itself) it was not clear if this could be "a recurrence or a granuloma". He introduced the word "recurrence" and abandoned the phrase "residual nodule". Dr Khor did not assign any specific pathology to justify radiosurgery. It was also admitted in Dr Khor's letter that there had been no significant change to the nodule between the MRI scan of 26 February 1996 and 27 December 1996.

### **Chapter 5 : The Defendants' Pleadings**

5.1. I now turn to the salient points in the defence of the defendants. Each defendant filed an individual defence. The defences of the doctor defendants shall be studied first. It should be noted that the doctor defendants were represented by the same lawyers.

#### Dr James Khoo's defence

5.2. Dr James Khoo filed his defence on 28 August 2000, 24 days after the first amended statement of claim was filed. He made the following admissions or assertions :

(a) There was a deep-seated intraventricular neurocytoma in Gunapathy's left lateral ventricle.

(b) He had removed the neurocytoma on 15 November 1995 by an anterior transcollosal microsurgical operation.

(c) Post-operative scans showed no obvious lesion remaining.

(This was the CT scan report dated 20 November 1995).

(d) Gunapathy then received fractionated radiotherapy from Dr Khor Tong Hong to prevent any relapse, as advised by Dr James Khoo because neurocytoma is a semi-malignant tumour that has a tendency to relapse.

(The radiotherapy was administered from 6 December 1995 to 13 January 1996).

(e) In February 1996, Dr James Khoo "conducted a routine check scan on Gunapathy and detected a small nodular lesion of about 1.1 cm diameter in the lateral ventricle wall, posteriorly." It was not possible to determine the nature or the cause of the lesion. So he advised her to be conservative and adopt an expectant approach.

(f) In December 1996, he conducted another MRI Scan on her. The nodule showed an enhancement. He advised her "to have a conservative expectant approach". However, she wanted to have fertility treatment with hormones. This would cause a flare-up of the tumour remnant, if any. So she "was anxious to have any suspected tumour remnant cleared up as quickly as possible". (At first blush the words "remnant tumour" objectively meant that he had not totally removed the neurocytoma. He, of course, was not entirely certain about the nature of the lesion because the crucial words were "any suspected tumour").

(g) The plaintiff did not want a further operation. So he suggested treatment by radiosurgery with Linac as the best option. Then there were these four assertions :

(i) The dorsal, lateral aspect of the nodule in the ventricular wall site was not the site of the previous surgical dissection, which was anterior (in front) and attached to the floor of the ventricle. Hence, the nodule was less likely to be a scar.

(The thrust of what was stated in (g) (i) was that the sites of the original tumour and lesion had been removed. There was no overlap. This assertion, if true, had ominous implications. It meant that Gunapathy had a metastatic malignant neoplasm. In popular parlance, she had an aggressive cancer that had travelled from one place to another. In other words it was a secondary tumour – an extreme malady requiring extreme remedy. This was the first time this allegation had raised its ugly head. But he contradicted that possibility in the next paragraph of his defence by describing the nodule as a "primary" tumour).

(ii) A repeat craniotomy or repeat fractionated radiotherapy were ruled out due to the high risk as compared to radiosurgery.

(iii) There was no significant difference in the use of Gamma Knife as opposed to Linac-based radiosurgery, as the lesion detected was small and rounded.

(iv) The tumour, although a primary, semi-malignant brain tumour, is often slow growing or quiescent until triggered by other factors, such as pregnancy or stress.

(h) He advised the plaintiff as to the possible risks of radiosurgery – usually cerebral edema and/or radionecrosis with morbidity in about 3% to 4% of the cases.

(i) Then, the plaintiff agreed to the treatment and gave informed consent to undergo radiosurgery.

(j) On 31 January 1997 he, Dr Khor and a physicist (Toh Hang Jin) performed radiosurgery on the plaintiff.

(Most of the assertions were raised for the first time in the defence and after the lapse of more than three years after the radiosurgery).

5.3. Dr James Khoo's defence then denied any negligence on his part. He gave the following four reasons for denying any negligence on his part :

(1) There was no simple and totally safe way to verify whether the nodule was a granuloma or a recurrent neurorcytoma.

(2) A stereotactic biopsy was ruled out for the following reasons :

(a) the procedure was invasive and as the nodule detected was small and situated on the lateral wall of the left ventricle about an inch away from the internal capsule containing motor fibres, there was a significant risk that biopsy might cause paralysis;

(b) the yield in getting an accurate biopsy was less than approximately 65-70%, as the target was only approximately 1 cm in diameter, and because the nodule was densely surrounded by glial or scar tissue which would be difficult to aspirate.

(c) Gunapathy did not want a further craniotomy. Also a craniotomy was entirely unsuitable with all the attending risks of a craniotomy. Recent studies showed that radiosurgery was an excellent option for residual central neurocytoma.

(3) MR Spectroscopy was not an established method for histological diagnosis and was still considered a technique in developmental stages in the diagnosis of brain tumours.

(4) Position Emission Tomography (PET) Scanning had only recently been used in differentiating cancer recurrence and scar formations and was still not available in Singapore and South East Asia. In 1997, tumour experts did not consider PET to be of significant reliability.

5.4. Two further points were pleaded by Dr James Khoo. First, Gunapathy was deemed to have consented to the injuries, if caused by the radiosurgery; this is the appropriate defence to an allegation of trespass to person. No such allegation was made by Gunapathy. Secondly, her injuries were aggravated by the plaintiff receiving treatment from others. The "others" here meant Dr Prem Pillay.

#### Dr Khor's defence

5.5. Dr Khor in his defence made the following admissions and assertions :

(a) He is a radiation oncologist.

(b) Gunapathy consulted him on 27 occasions for her post operative radiotherapy which was given from 6 December 1995 to 13 January 1996.

(c) After the radiotherapy and before the radiosurgery she consulted him on the following dates :

31 January 1996

4 and 30 March 1996

28 September 1996

23 January 1997

On those occasions, he had advised her "to observe the lesion shown on the MRI scan".

(d) He had advised her of the risks of radiosurgery – namely cerebral edema and/or radionecrosis.

(e) He had also advised her of "the option of continuing monitoring the lesion shown on the MRI scan with no definitive treatment". However, because the plaintiff was anxious to have children and wished to embark on a program of assisted reproduction she insisted that all possible tumour remnant in the brain be controlled. Dr James Khoo suggested radiosurgery for this purpose.

(f) She then consulted Dr Devathan, and obtained his advice on the procedure. After having considered all available options, she agreed to undergo the procedure of radiosurgery.

5.6. Dr Khor, like Dr James Khoo, denied any negligence on his part. He pleaded these grounds :

(a) Using Gamma Knife instead of Linac-based radiosurgery system would not have reduced the risk or radiation complications as both were only variants of single fraction, high-dose radiotherapy.

(b) The radiosurgery procedure was competently carried out according to accepted international guidelines.

(c) The tumour as reported on the December 1996 MRI scan was approximately 11 mm x 12 mm x 6 mm in size. At treatment planning, the maximum diameter of the tumour was 19 mm. This required a collimator size of 22.5 mm for adequate coverage. The usage of a smaller collimator was totally inappropriate as it would have resulted in the use of a very low isodose surface prescription, with a very high dose at the isocentre leading to an unacceptably high risk of subsequent radionecrosis.

(d) The dosage of 2000 cGy at the 85% isodose was not excessive as it was well within the dosage guidelines from the RTOG 90-05 study in the United States and quoted in the *X-Knife* radiosurgery monograph of 1996 (Sperduto et al). The RTOG 90-05 study gave the maximal tolerated dose at 2400 cGy for a tumour up to 20 mm in diameter, even if the patient had received previous conventional radiotherapy of doses of 6000 cGy, which was higher than the dosage (5400 cGy) received by Gunapathy before the radiosurgery.

5.7. Dr Khor's defence said that he would refer to the full guidelines from the RTOG 90-05 study in the United States and quoted in the *X-Knife* radiosurgery monograph of 1996 (Sperduto et al) as well as the final report on that study published in 1 May 2000 issue of the ***International Journal of Radiation Oncology, Biology and Physics*** by Edward Shaw et al at the trial.

5.8. Dr Khor repeated Dr James Khoo's claim that Gunapathy had consented to the radiosurgery with full knowledge of its risks and complications. Accordingly she was deemed to have consented to the injuries, if any, caused by the radiosurgery. Finally Dr Khor, like Dr James Khoo, asserted that Gunapathy's injuries were caused and/or aggravated by the treatment she received subsequently (the subsequent treatment was given by Dr Prem Pillay. It did not involve any radiation).

#### The defence of the company defendant

5.9. The second defendant, Neurological Surgery Pte Ltd, a company owned by Dr James Khoo and his wife, filed the longest defence to the common amended statement of claim. Like the defences of the doctors the company defendant filed a defence to the First amended statement of claim.

5.10. The company's defence, in general, followed the trail of the doctor defendants. There were, however, several additional points. I shall set out the important points.

(a) After the resection of the neurocytoma, Dr James Khoo suggested to Dr Devathasan that Gunapathy be given either chemotherapy or radiotherapy because, according to him, neurocytoma was a semi-malignant brain tumour that had a tendency to relapse. He left it to Dr Devathasan to make the choice. Dr Devathasan ruled out chemotherapy because Gunapathy was planning a family and chemotherapy was best avoided due to the effects on the ovaries. It was Dr

Devathasan who referred the plaintiff to Dr Khor for radiotherapy. Neither Dr James Khoo nor his company was involved in the radiotherapy treatment.

(b) Sometime at the end of 1996 or early 1997, Gunapathy told Dr James Khoo that before she could embark on the fertility program, her gynaecologist had advised her to have the small nodule completely treated. Otherwise the fertility treatment might aggravate a malignant growth of the small nodule. But (and this is important) Dr James Khoo's view was that the December 1996 MRI showed no significant change in the appearance of the small nodule from the February 1996 MRI. He advised her to "undergo the conservative or expectant line of treatment for another 6 months before considering other forms of treatment". She refused to wait for another six months and insisted on another form of immediate and complete treatment of the small nodule. He agreed, but only after he warned her of the inherent risk of complications of radiosurgery, namely, significant brain swelling, radionecrosis and possibly hemiparesis and neurological deficits.

(c) Dr James Khoo never told Gunapathy that radiosurgery involved the use of laser.

(d) Dr James Khoo had received a letter from Dr Devathasan which stated :

Patient after careful deliberation and discussion prefers to have radiosurgery to the residual lesion.

(e) The exact nature and dose of radiation was solely determined by Dr Khor, and Dr James Khoo owed no duty of care to the plaintiff in its determination. The company defendant knew of the nature and dosage of radiation only on or about 3 February 1997 when Dr James Khoo received reports on it.

(f) Dr James Khoo was fully aware of the fact that there had been no significant change in the small nodule from February 1996 to December 1996. It was at the specific request and insistence of Gunapathy herself for an alternative and immediate form of treatment that Dr James Khoo recommended radiosurgery. She decided on radiosurgery after consultation with Dr Devathasan.

(g) The small nodule was less likely to be a scar because its location was not the same as the site of the previous surgical dissection. The location of the small nodule was in the posterior ventricular wall. The surgical dissection was anterior (in front) and attached to the floor of the ventricle.

(h) There was insistence and clear instructions from Gunapathy herself to have complete clearance of all gliomas/tumours that could be aggravated by powerful fertility hormonal therapy as soon as possible.

(i) A repeat craniotomy on her for the small nodule of approximately 11 mm in diameter was out of question and was definitely not the standard of care in the circumstances. Any risk of complications from re-operation would far outweighed the risks of complications from radiosurgery. She clearly instructed Dr James Khoo that she did not want to undergo a second craniotomy.

### The highlights of the defences

5.11 As an overview of the three defences of the three defendants, the high-point of the doctors pleaded defences was that as they could not positively assign any pathological categorization to the nodule which was hanging from the roof of the left ventricle, they were unable to determine whether it was scar or tumour. On that basis, Gunapathy was not in any need of a therapy or prophylactic. However, they agreed to perform radiosurgery because she herself insisted on radiosurgery, against Dr James Khoo's advice and warnings. Gunapathy insisted on radiosurgery because she wanted to conceive without the probably harmless nodule in her brain. This was despite knowing that she might be afflicted with cerebral edema, radionecrosis and possibly hemiparesis and neurological deficits. Indeed, in their defences that was their only point which had the semblance of a positive answer to the plaintiff's case.

5.12. The defences did not reveal what skill, knowledge, training, experience and competence Dr James Khoo and Dr Khor had in diagnostic histopathology and diagnostic radiology. On the pleaded case, they relied on Dr Carol Kwan for histopathology and Dr Esther Tan for diagnostic radiology. Neither did the defences reveal what skill, knowledge, training or professional touch Dr James Khoo or Dr Khor had, to advise on, prescribe or administer radiosurgery.

5.13. Many of the matters raised in the defences were not part of the clinical notes and records kept by Dr James Khoo and Dr Khor or the letters they wrote before the action. I should also note here that for the record that after the commencement of the trial there were radical changes in the colour and character of the defences.

## Chapter 6 : A Journey to the Bottom of the Brain

### One for all and all for one

6.1. Some basic knowledge of brain and cell biology is essential to understand the medical issues in this case.

6.2. Bioscience informs us that the adult human body is made up of 10,000,000,000,000 (10 trillion) cells. Cells are the smallest units of living organism that can live independently. Cells are organised to form organs and ultimately the body. For that astronomical a number of cells to function as an organic whole, there must be an underlying law. The law which the 10 trillion cells obey is at once simple and profound : "One for all, and all for one". Each cell of the organism has a specially allocated task for the survival of the whole. That is the first law of life. This law transcends race and religion. It applies to prince and pauper alike.

### Limitations as to space and time

6.3. The remarkable feature of cell biology is that, in general, cells have the capacity to reproduce by a process called replication or mitosis (cell division) whereby the DNA (deoxyribonucleic acid) makes copies of itself. The capacity for multiplication by replication operates all the time in the normal body. Cells always multiply in a carefully controlled manner in that the maximum limit of 10 trillion cells is maintained. The body is thus governed by the law of limitation. First, there is limitation in relation to the number of cells and the space they take up. When any tissue is damaged, there is a celerity of cell action and replication to repair the damaged tissue. Cells in the body, because of action and inaction and deprivation, are always dying. Replication produces new cells to replace the lost dead cells and maintains the body as an organic whole. But there is another law of limitation which controls the capacity of cells to replicate. The number of divisions permitted by nature during a human life-



span of say 80 years is about 50 times at birth. This falls to 20 to 40 by middle age. In old people it is 10 to 20. When the replication process comes to an end the human body dies unless forces like disease, damage, accidents and deprivation intervene and bring about an earlier end to life. Thus, the second limitation relates to time.

#### Exception to the two laws

6.4. There are two exceptions to what has been stated :

##### First exception :

Certain cells in the human body do not have the capacity to replicate themselves. Neurons in the brain (to be explained next) and heart muscle cells come within this exception.

##### Second exception:

Rogue cells which emanate within the human body are not controlled by the two laws of limitations stated above. Cell division in them is unchecked. The only cells that come within this second exception are cancer cells, that is malignant and malevolent tumour cells.

#### Neurons

6.5. The human brain has been described as the "three-pound universe" – "three-pound" because that represents the weight of the brain. The brain is at its largest in early adulthood. At that stage it has some 100 billion (100,000,000,000) brain cells, in medical parlance, "neurons". Another word for a neuron is a "neurocyte". "Neuro" means nerve and "cyte" denotes cell. There are about 50 billion neurons in the cerebrum, about 40 billion in the cerebellum and about 10 billion in the spinal cord. The neurons in the three components constitute nerves making up the central nervous system (CNS). Other nerves form the peripheral nervous system (PNS).

6.6. To repeat what has been stated above, unlike practically all the other types of cells in the body, neurons do not have the capacity to regenerate. This means that the human body lives its entire life span with the neurons that it was born with, without creating new neurons. The inability of neurons to divide and replicate is by design. If too many neurons die there would be no long-term memory and previous learning and recognition would be lost. Even then, each day the brain loses a great number of neurons. The number is anything between 10,000 to 100,000. The loss need not be a cause for alarm because the brain has many times more neurons than it needs to get on healthily and happily. Furthermore, when neurons die, other viable neurons take over and retain the memory of the dead neurons by a phenomenon called redundant circuitry. Excess neurons are eliminated by self-destruction. At the same time, memory is transferred to the viable neurons.

#### The neuro-glia (glial cells)

6.7. The brain is not made of neurons only. For each neuron in the brain, there are 10 cells which protect, support and feed the neuron. There are some one trillion (1,000,000,000,000) such supporting cells. These supporting cells make up a substance called glia. "Glia" is a Greek word meaning glue. It was called glia because the brain substance, also called neuroglia, was considered to resemble glue. The brain is a very soft organ. It is like oats porridge. Again the softness is intentional. If the brain were made of some hard matter like dry wood there would be very little activity within it and learning, intelligence and sagacity would be very limited.

6.8. The neuroglia is the connective tissue of the nervous system, consisting of more than one type of glial cells. These several types of glial cells perform different functions and present different features. For example, there are glial cells called astrocytes because they are star-shaped. There are glial cells called oligodendrocytes because it was considered that there were not very many of them. The Greek word "oligos" means few or little. Oligodendrocytes resemble astrocytes but with fewer protuberances. They are concerned with the production of myelin, the white substance which forms a sheath around certain nerve fibres called axons in the central nervous system. There are glial cells called ependymocytes because they make up the ependyma of the ventricles of the brain. The Greek word "ependyma" means upper covering and therefore the membrane of an organ. There are glial cells known as phagocytes which devour dead cells and alien microorganisms in the brain. "Phago" derives from a Greek word for "swallow" or "eat".

6.9. The glial cells, like most other cells of the body, have the capacity to repair and regenerate. The capacity of the glial cells to replicate, regenerate and repair, and the incapacity of the neurons or neurocytes to divide and multiply, bear a great relevance to the medical issues in this case. The relevance relates to the disease called malignant neoplasm or cancer. The next paragraphs will elaborate on this.

### Tumour

6.10. It is appropriate now to introduce the Greek suffix "oma" and the Latin word "tumour". "Oma" is a noun-forming suffix. The noun with the suffix "oma" signifies a growth of the part indicated by the stem or tissue to which it is attached. For example, Pic's neuroma is a tumour on a nerve in a nerve tissue. Glioma is a tumour of glial cells. Astrocytoma is tumour of astrocytes. The Latin word "tumour" also signifies growth or swelling. It almost always comes as the last word of a phrase in which the part of the body from which a new and abnormal growth is seen – for example brain tumour. In medical parlance, a tumour is called a neoplasm. The formation of a neoplasm (i.e. a tumour) is called neoplasia.

### Neoplasia

6.11. "Neoplasia" is defined in ***Dorland's Medical Dictionary***, 29<sup>th</sup> Edition, (2000) as follows :

The formation of neoplasm, ie, the progressive multiplication of cells under conditions that would not elicit, or would cause cessation of, multiplication of normal cells.

6.12. Every tissue in the body has a specific name and unique characteristics. Cytology (the science of cells, their origin, structure, function and pathology) can distinguish a normal cell from an abnormal or tumour cell. In other words a cytologist can detect the presence of a tumour and categorise it if a sample of the tissue is presented for his study. More importantly, an oncologist, (one who studies tumours or neoplasms), can tell whether a growth is a neoplasm of a given tissue. Further, oncology divides tumours (or neoplasms) into two categories : benign neoplasms and malignant neoplasms. The popular name for a malignant neoplasm is the detested word "cancer".

6.13. The principal feature of a cancer or malignant neoplasm is this : what began as an innocent extension or lesion, magnifies itself into a most malevolent malady within a relatively short period. The principal property of a malignant neoplasm is that the growth is fast, purposeless, parasitic and pernicious to the human host. It causes local destruction, invades and consumes the adjacent area tissues and spreads to other organs or parts by metastasis. "Metastasis" means the travel or transference from one organ to another.

Difference between benign and malignant tumours

6.14. **Professional Guide to Diseases**, Sixth Edition, (1998), gives the essential differences between benign and malignant tumours as follows :

<u>Factor</u>	<u>Benign</u>	<u>Malignant</u>
Growth	Slow expansion push aside surrounding tissue but do not infiltrate	Usually infiltrate surrounding tissues rapidly, expanding in all directions
Limitation	Commonly encapsulated	Seldom encapsulated; in many cases poorly delineated
Recurrence	Rare after surgical removal	When removed surgically, commonly recur due to infiltration into surrounding tissues
Morphology	Cells closely resemble cells of tissue of origin	Cells may differ from considerably those of tissue of origin
Differentiation	Well differentiated Variable	Variable Extensive
Mitotic Activity		
Tissue destruction	Usually slight	Extensive due to infiltration and metastatic lesion
Spread	No metastasis	Spread via blood and/or lymph systems; establish secondary tumours
Effect on body	Cachexia rare; usually not fatal but may obstruct vital organs, exert pressure, produce excess hormones; can become malignant	Cachexia typical, with such symptoms as anemia, loss of weight, and weakness; fatal if untreated

6.15. It is to be noted from the above that a benign tumour will not recur or spread to other parts of the body and will not cause much damage after it is surgically resected. In other words, exceptions excepted, the usual treatment for benign tumour, if and when it becomes morbid, is surgical resection.

#### Diagnostic methods

6.16. On diagnostic methods, **Professional Guide to Diseases** at p 47 lists the various sophisticated diagnostic procedures including CT scan and MRI scan and adds :

The single most important diagnostic tool is a biopsy for direct histologic study of tumour tissue.

6.17. Referring to "grading" the book says at p 47 :

Grading, another way to define a tumour, classifies the lesion according to corresponding normal cells, such as lymphoid or mucinous lesions; it compares tumour tissue to normal cells (differentiation); and it estimates the tumour's growth rate. For example, a low-grade tumour typically has cells more closely resembling normal cells, whereas a high-grade tumour has poorly differentiated cells.

#### Metastasis

6.18. Dr Baratham's report contains an unchallenged explanation of benign and malignant tumours. It is therefore unnecessary to multiply the explanations of these expressions. However, it is necessary to state the meaning of the word "metastasis". A metastasis is a secondary tumour. It appears in a spot removed from the original spot. An explanation of the word "metastasis" is given in **Robbins Pathologic Basis of Disease**, 6<sup>th</sup> Edition, (1999) at p 268 :

##### **Metastasis**

Metastases are tumour implants discontinuous with the primary tumour. *Metastasis unequivocally marks a tumour as malignant because benign neoplasms do not metastasize.* The invasiveness of cancers permits them to penetrate into blood vessels, lymphatics, and body cavities, providing the opportunity for spread. *With few exceptions, all cancers can metastasize.* The major exceptions are most malignant neoplasms of the glial cells in the central nervous system, called gliomas, and basal cell carcinomas of the skin. Both are highly invasive forms of neoplasia (the latter being known in the older literature as rodent ulcers because of their invasive destructiveness), but they rarely metastasize. It is evident then that the properties of invasion and metastasis are separable.

In general, the more aggressive, the more rapidly growing, and the larger the primary neoplasm, the greater the likelihood that it will metastasize or already has metastasized. There are innumerable exceptions, however. Small, well-differentiated, slowly growing lesions sometimes metastasize widely, and, conversely, some rapidly growing lesions remain localized for years. No judgment can be made about the probability of metastasis from pathologic examination of the primary tumour. Many factors relating to both invader and host are involved, as is pointed out later.

Approximately 30% of newly diagnosed patients with solid tumours (excluding skin cancers other than melanomas) present with metastases. Metastatic spread strongly reduces the possibility of cure; hence short of prevention of cancer, no achievement would confer greater benefit on patients than methods to prevent distant spread.

### High and Low Grade Tumours

6.19 **Cancer Therapy** by Malin Dollinger MD, Ernest H Rosenbaum MD and Greg Cable, Third Edition, 1997, at p 10 comments on another classification of tumours :

#### **High Grade and Low Grade Tumours**

There is another classification system that sometimes overlaps with the system based on differentiation. This system refers to tumours as "high grade" or "low grade". A high grade tumour is immature, poorly differentiated, fast growing and aggressive. A low grade tumour is usually mature, well differentiated, slow growing and less aggressive. The grading of tumours is used to help determine cancer prognosis.

### ***Dorland's Medical Dictionary***

defines "high grade" as "occurring near the high end of the range". "Low grade" is defined as "occurring near the low end of a range". Other dictionaries assign the same meaning to those two expressions.

### Brain tumours

6.20. The neurons and in particular the neurofibres (axons) make up the toughest tissues in the human body. The cells which make up these tissues do not regenerate. Over and above that, the neurons are well protected by the glial cells. Any damage to the glia generally is repaired very fast. Damage in the glia dissolves very fast and does not leave a scar. There is another remarkable thing about the brain : it is the cleanest organ in the human body. The glial cells feed and wash the neurons and keep them clean, trim, strong and fit. It is brainwashing within the brain. These facts render the brain the least prone to produce tumour cells. Statistics prove that to be so. Tumours in the brain are few when compared with other organs. Most of the brain tumours are gliomas and relate to the neuroglia.

6.21. Even though non-brain tumours outnumber brain tumours, the latter fall into a category of their own. **Robbins Pathologic Basis of Disease**, 6<sup>th</sup> Ed, explains at page 1343 :

Tumors of the nervous system have unique characteristics that set them apart from neoplastic processes elsewhere in the body. First, the distinction between benign and malignant lesions is less evident in the CNS than in other organs. Some glial tumors with histologic features of a benign neoplasm, including low mitotic rates, cellular uniformity, and slow growth, may infiltrate large regions of the brain thereby leading to serious clinical deficits and poor prognosis. Second, the ability to surgically resect infiltrating glial neoplasms without compromising neurologic function is limited. Third, the anatomic site of the neoplasm can have lethal consequences irrespective of histologic classification; for example, a benign meningioma, by compressing the medulla, can cause cardiorespiratory arrest. Finally, the pattern of spread of primary CNS neoplasms differs from that of other tumors: even the most highly malignant gliomas rarely metastasize

outside the CNS. The subarachnoid space provides a pathway for spread, so that seeding along the brain and spinal cord can occur in highly anaplastic as well as in well-differentiated neoplasms that extend into the CSF pathways.

6.22. The fact that neurons do not divide and multiply must mean that they would be the last to produce tumour cells. Indeed it is so. Tumours of the neurons are very rare. Neuroblastoma, a neuron tumour, is often a malignant tumour. Although it is a tumour of the neuron, it seldom originates in the brain. It usually develops in the adrenal glands. Furthermore, when it develops in the brain the host cell is not a fully developed neuron. It is not a fully differentiated neuron. The word "blast" means bud – "an immature stage in cellular development before appearance of the definitive characteristics of the cell". See **Dorland's Medical Dictionary**.

6.23. The term "neurocytoma" (rightly) suggests that it is a tumour of neurons. It means – nerve cell tumour. Again the theory is that neurocytoma emanates from immature cells which, unlike fully differentiated cells, have not lost the capacity to replicate. The article on **Central Neurocytoma** by Figurella Branger and eight others says so. Dr Ho Kee Hang who gave evidence for the defendants subscribed to this theory.

6.24. The majority of brain tumours stem from the glial cells which have the capacity to divide and multiply. Glial tumours are known by the generic term "glioma". Within the general genre of "glioma", there are several types. The most common type of glioma is the astrocytoma. An astrocytoma can be benign or malignant. Oligodendroglioma, ependymoma and glioblastoma (also known as spongioblastoma) are all gliomas which grow within the brain. These gliomas can be benign or malignant.

6.25. The following passage from **Cancer and Vitamin C** (1993) by Ewan Cameron M.B., Ch.B. F.R.C.S. (Edinburgh and Glasgow) and Linus Pauling at p 42 provides a succinct explanation of tumours of the brain :

Tumors of the brain may be benign or malignant, and because of the rigid containment of the skull they cause equal havoc by brain compression. There are two main tumor types, *meningiomas* (arising from the membranes covering the brain) and *gliomas* (arising from the brain cells). There are many varieties of the latter, such as *astrocytomas*, *oligodendrocytomas*, and *medulloblastomas*, classified according to primary cell type. For our purposes it is sufficient to note that all these varieties of intracranial tumors may be relatively benign, slow-growing, and well-encapsulated and, therefore, if other anatomical considerations permit, suitable for clean surgical removal with minimal damage to brain structure, or highly malignant and diffusely infiltrative with little prospect of any neurosurgical success. However, like every other form of cancer, these highly malignant tumors respond well to radiotherapy, which can offer considerable palliation and even the occasional cure. Brain tumors can occur at any age, but have a peak incidence in children up to the age of 10 and again in the fifth decade of life. Their causation has often been related to previous head injury but the evidence for this is extremely tenuous. The symptoms are increasing headache and interference with some specific brain function, depending upon the anatomical site.

### Brain Metastasis

6.26. Then there are the brain tumours which occur by metastasis, which in most cases are not true

brain tumours. They are very virulent. These tumours almost always originate in other organs and then travel to and invade the brain. Most commonly they emigrate from the lung, liver or breast. By definition they are all malignant tumours with extremely poor prognosis. In such cases, what oncologists often do is to prolong the life of the patient a little and palliate pain and suffering. In practical terms there is no total cure for brain metastases. In general, a metastasis within the brain does not occur – that is to say a tumour emanating within the brain does not travel to another part of the brain. It could spread within the brain but not metastasize.

### Primary and secondary tumours

6.27. There are two more terms that need to be further explained, namely "primary tumour" and "secondary tumour".

6.28 Primary here means first in time. "Secondary" means next in time. The first leads to the secondary. "Primary tumour" says the **Dictionary of Medicine** by P H Collin is the "site of original malignant growth from which the cancer spreads". In other words it is the site where the tumour appears the first time. The same dictionary defines "secondary growth" as "metastasis, the spreading of a malignant disease from one part of the body to another through the blood stream or the lymph system". "Secondary tumour" therefore means the site or sites where the tumour, having travelled from the primary site, reappears at a later time.

6.29. The term "secondary tumour" is by medical convention reserved for those malignant growths that have travelled from one site in the body to another by metastasis. "Secondary tumour" should not be confused with "recurrent tumour". If a primary brain tumour is apparently totally excised, but later reappears in the same location as in the brain, it is called a "recurrent tumour". Although the reappearance or recurrence is second in time, and therefore "secondary" in English language, it is not called a "secondary tumour" in strict medical parlance, but a "recurrent tumour". Thus, "brain metastasis" means the reappearance of a malignant tumour in the brain, when the tumour actually first sprung up in a lower organ (often the liver or lungs). However, if a brain tumour is totally excised and then reappears in a different location in the brain, that is also metastasis, a secondary tumour. This is rare in the extreme.

6.30. The important point about a brain tumour recurrence is that there must be a total microscopic excision resulting in apparent disappearance of the tumour followed by reappearance at the original site because the microscopic excision was not a total success. For there to be recurrence at the original site, some tumour cells must have been left behind without being detected by the microscope.

## **Chapter 7 : Radiotherapy and Radiosurgery**

### Radiation therapy

7.1. This chapter shall discuss the use of radiation physics in treating and managing tumours. This process involves the application of ionizing radiation as a therapeutic or prophylactic agent. The term "irradiation" refers to the process by which "radiation therapy" is achieved.

7.2. The radiation that is of immediate concern in this case is radiation by X-rays which are used for medical purposes. These are short wave penetrating rays, artificially produced by electrical equipment. It is high-energy radiation. The high energy X-rays are produced by a linear accelerator, or "linac", for short. The linac is a device for accelerating charged sub-atomic particles so as to cause the particles to travel in straight lines and not in closed orbits. The linac produces electrons which are then converted to photons. The photon energy produced by a linear accelerator is used for treating

various pathological conditions in general, and also for treating malignant neoplasm in particular.

### Radiation therapy and radiosurgery

7.3. In relation to the management of tumours, there are two modalities of irradiation techniques : (a) radiation therapy or radiotherapy and (b) stereotactic radiosurgery. Radiation therapy (more commonly known as radiotherapy) has been in use for many a decade. It is a common form of treatment for *cancer*. About half of all people with cancer undergo radiation therapy as part of their overall treatment plan. Sometimes it is used as the primary form of treatment. Often it is used as an adjuvant or additional treatment to conventional surgical removal of the tumour.

### Rads and centigray

7.4. The basic measure of radiation is in rads. A more common form of measurement is centigray (cGy) (one-hundredth of a gray). One gray (Gy) equals 100 rads. One centigray is one rad. Hence  $20 \text{ Gy} = 2000 \text{ rads} = 2000 \text{ cGy}$ .

### Objective of radiation

7.5. The goal of radiation therapy is to cause the death of tumour cells. Radiation produces significant changes in nuclear DNA. Although irradiation may cause immediate death of some tumour cells due to direct effect, the therapeutic objective is to damage the chromosomes and the DNA of the rogue cells so much so that they can no longer divide. The advantage of the latter is that it causes very little, if any, death or damage of the viable cells. This is achieved by divided or fractionated dosage of the recommended amount of radiation. The fractionated administration of radiation has the advantage of avoiding or alleviating radiation sickness, that is, adverse reaction of radiation.

7.6. The next important feature of radiation therapy is that the radiation is diffused. There is no focus or concentration on a small area or volume. It is administered over a relatively wide area. In the case of the brain, radiation treatment is usually given to the whole brain. Because of this, it is called whole brain radiation.

7.7. Dr Bengt Karlsson, of Sweden, an expert witness called by the defendants, explains the biophysics of radiation. The following are excerpts from his evidence. He was responding to my questions :

Q What happens when [radiation] hits the non-tumour (normal cells). ...

A The hypothesis has always been that you strike the DNA which is the substance making, allowing, the cells to divide. ...

Later science however shows that that is most likely inaccurate because, just as a short background, it has been said that malignant cells that divide much faster than benign cells are more radio sensitive. We started to give doses far below what was previously considered as biological effective at all, and yet it worked. So even if less than one percent of the cells are in dividing phase which is considered to be the radio sensitive phase, you still have an effect of radiation. And the present research suggests that is another or that is responsible for the radiation, response, but this is for the future to be verified. But it's much more complex than we previously assumed. That is absolutely sure. ...



From a physical point of view, the only thing that matters is the density, how much mass, because the absorption is depending on the density. So lead absorbs much more radiation than water, for instance. ...

Lead, the metal lead, absorbs much more dose than water because it's much denser.

It absorbs much more radiation because it's much denser. ...

So the radiation itself is absorbed, the energy absorbed depends on the mass and mass only. ...

And whether it's a cancer cell or a normal cell, there's no difference in that sense of the word. So the effect of the cells is assumed to be the same, with the exception that cancer cells divide faster than normal cells and therefore they're supposed to be more radio sensitive. [NE 2720-2722]

#### Dr Tsao on radiation therapy

7.8. Dr Tsao Shiu Ying, an expert witness called by the plaintiff, explained the concept of fractionation with admirable succinctness. He said :

Fractionation is the golden principle of our whole speciality. In other words, without fractionation, the whole of our speciality would collapse. I can tell you that 99% of our patients are treated with fractionated radiation therapy. Fractionation is important because there is a good recovery of normal tissues between two fractions. In other words, during the 24 hours or so, between two fractions, the normal tissues as directed by the brain I mean, our brain is our director – so it would direct all the cells to recover as fast as it could. But, unfortunately, the tumour has no brain, so they would not be able to grow as fast as the normal tissues in that 24 hour gap. So, in other words, the more 24 hour gaps you build in, then the more exploitation of this phenomenon of fractionation and repair and so on, then the battle would be the protection of the normal tissue. [NE 87]

#### Dr Robert Smee on radiation therapy

7.9. Dr Robert Smee, an expert witness called by the defendants, made the same point. A recast of his evidence on this position was this :

The way we practice radiotherapy – there is very little outright death of tissue. What happens is that we cause reproductive death. Radiation affects the DNA. It can affect the DNA of normal tissue we treat. That normal tissue has better reparative capabilities to recover from that particular share. So radiotherapy does not affect normal tissue. [NE 803-805]

#### Cameron & Pauling on radiotherapy

7.10. The following excerpts from **Cancer and Vitamin C** by Ewan Cameron & Linus Pauling, at pp 59-61 provide a simple and succinct explanation on radiotherapy :

Although these high-energy rays differ somewhat from one another, their effect on the tissues is about the same, and for simplicity we may talk about radiation (meaning high – energy radiation). The effect of radiation on tissues is mainly *to damage and destroy dividing cells*. There is also another effect, which may be almost as important in the treatment of cancer. This *is to damage the ground substance* (the intercellular cement) of the whole field that is irradiated, leaving a scarred and much more resistant local environment for the tumour cells that have survived the initial assault [Author's Italics]

Because many tumour cells are dividing at a higher rate than the cells of the normal tissues, the radiation inflicts more damage on the tumour than on the normal tissues. *Also, the more rapidly proliferating, the more anaplastic (primitive, embryonic), and the more undifferentiated the tumour, the more likely will it be to respond to radiation. It seems paradoxical that it is the most malignant tumours that respond best to treatment with high-energy radiation. Slowly growing tumours respond poorly to radiotherapy; they are said to be radiation-resistant. To inflict sufficient radiation damage on such a tumour would result in intolerable damage to the normal tissues.*

Radiotherapy may be employed in certain situations as the only form of treatment, or as an adjunct to surgery, given either pre-operatively, to shrink the main tumour and to limit the spreading tendency of peripheral cells, or post-operatively, to mop up any tumour cells left behind at surgery, or it may be used in combination with chemotherapeutic regimes. It may be radical, with use of high doses in the hope of effecting a cure, or palliative, with use of smaller doses given to achieve some symptomatic relief.

The general side-effects of radiation therapy depend upon the volume of the tissue that is irradiated.

We conclude that high-energy radiation therapy is the second most valuable member of our conventional therapeutic armory. Used alone it can cure a variety of tumours, and used as an adjunct to surgery or to chemotherapy it can improve the chances of cure for many more. The side effects are rarely overwhelmingly severe and can be controlled by competent doctoring. It is true that some common tumours, such as cancers of the stomach and colon, are virtually unaffected by radiotherapy, but this fact serves to emphasize its value in the treatment of cancer at many other sites.

It is important to note that the above explanations apply to cancers in general. Their specific application to brain tumours must be considered by radiation oncologists with adequate knowledge of and experience in the treatment of brain tumours.

#### Adverse reaction to radiation therapy

7.11. The next point that is noteworthy is the patient's adverse reaction to radiation therapy. The treatment itself is painless. Adverse side effects, however, do occur later. Edema, nausea, vomiting, headaches and loss of ability to fight infection are possible side effects. These side effects are of general application in that it may not be restricted to radiation of the brain or part of it. When it happens in the brain, however, it is more painful and difficult to manage.

### Radiosurgery explained

7.12. Radiosurgery is an extreme form of tumour treatment by stereotactic irradiation. It is especially useful in the management of brain tumours of small size. It is radiation therapy with a difference. Unlike in conventional radiation therapy, the target in radiosurgery is a sharply delimited volume. Optimists consider radiosurgery as equivalent to resecting the targeted volume by irradiation with concentrated collimated beams and as a substitute for surgical resection.

7.13. The radiosurgery under consideration is a high-tech form of high-dose irradiation with a high-risk factor. The word "stereotactic" signifies that the surgery is founded on a three-dimensional survey of the brain.

7.14. According to a publication by **Korolinska Gamma Knife Centre** (May 1996) :

Stereotactic surgery destroys or affects small intracranial targets. The term radiosurgery describes a concept where ionizing radiation is used, as a neurosurgical tool, to destroy circumscribed volumes of tissue or to induce a desired biological effect in the target volume in a single session. Radiosurgery differs from radiotherapy in principle and technique. *Radiotherapy relies on the difference in biological radiosensitivity between the cells of the pathological and the surrounding normal tissue. In radiosurgery, the accurate stereotactic localization and the fields or radiation with steep gradients make such biological differences to irradiation less critical.*

7.15. Dr Tsao Shiu Ying, a medical expert who gave evidence in this case, threw light on the concept of radiosurgery as follows :

Radiosurgery is the only example that is exceptional. There is only one fraction. In other words, there is no fractionation in radiosurgery. [NE 871 – L 17-19]

### Gamma Knife and XKnife

7.16. Radiosurgery is offered under two methods : (a) the Leksell *Gamma Knife* and (b) the *XKnife*. Both are trade-names. *Gamma Knife* uses gamma rays which naturally occur. They are emitted by radiation compounds, it is radioactive, in this case, cobalt-60. They are shorter than X-rays. The *XKnife* uses artificially produced X-rays. Dr Karlsson, the defendants' expert witness, explained that both *Gamma Knife* and *XKnife* use photon beams. But *XKnife* beams carry shorter wavelengths. *Gamma Knife* carries one wavelength only – one specific wavelength.

### XKnife Protocol

7.17. The *XKnife* is made and marketed by Radionics Inc of USA. The *XKnife* procedure needs elaboration. Radionics Inc in 1996 published a user's manual called "**XKnife Radiosurgery for Brain Metastases**" ("the **Radionics XKnife** Protocol"). It was written as a monograph by Paul W Sperduto MD, Radiation Oncologist and President of the XKnife Society; Philip Gildenberg, MD PhD, Clinical Professor in Radiation Oncology; and Hanne M Kooy PhD. The last of the three authors was, presumably, not a doctor, but a radiation physicist.

7.18. The **Radionics XKnife** Protocol opens with these introductory paragraphs :

The purpose of this monograph is to provide a step-by-step description and

explanation of the clinical and technical aspects of stereotactic radiosurgery for patients with brain metastases.

The goals of radiosurgery are to : (1) define a small, three-dimensional, intracranial target volume, (2) deliver a high dose of radiation to the target volume, and (3) deliver no clinically significant dose to the adjacent normal tissue.

7.19 The **Radionics XKnife** Protocol explains the use of *XKnife* radiotherapy in these words :

Without treatment, brain metastases can be fatal within one month, and the cause of death is usually central nervous system (CNS) failure. Patients who receive whole brain radiation therapy (WBRT), the current standard of palliative care, have a median survival of three to six months. Patients with a solitary brain metastasis who undergo surgical resection and WBRT have better local control, longer survival, and longer functional independence than patients treated with radiation alone.

#### *Stereotatic radiosurgery*

(SRS) is a one-day, noninvasive, outpatient procedure that *delivers a high dose of radiation therapy to a small intracranial target while minimizing the dose to the surrounding normal brain.*

#### The gold standard ?

7.20.The **Radionics XKnife** Protocol proclaims that "Radionics is the Gold Standard for LINAC-based Stereotactic Radiosurgery and Stereotactic Radiotherapy". In response to this proclamation Dr Karlsson said :

I would definitely disagree with that. I think Gamma Knife is a gold standard. That's for sure. ...

(Radionics' claim) means that they want you to buy it. They want you to buy it, that's what it means. [NE 2709-2710]

#### Importance of learning

7.21.The Introduction in the **Radionics Xknife Protocol** states :

It is important for the reader to understand that the approach described here represents only the methods of the authors' institutions and should not be interpreted as the only way to deliver radiosurgery for brain metastases. While this monograph is intended to provide general guidelines, no two patients are identical and good clinical judgment is essential to the appropriate use of this exciting new technology. It is, of course, the responsibility of the individual clinician to decide on the applicability of any aspects of the technique described here. It is not the province of this monograph to substitute for proper clinical judgment by a clinician for a specific patient's needs.

The team approach is essential in stereotactic radiosurgery. The neurosurgeon, radiation oncologist, radiation physicist, and support staff must work together in

order to develop and maintain a high quality program in radiosurgery.

### Importance of training

7.22.A later part the **Radionics XKnife Protocol** says that "*the key members of the XKnife clinical team should be fully trained*". In the USA, there is a legal precept called "the captain of the ship doctrine". This doctrine makes the surgeon in charge of operation liable for negligence of all those under him even though the assistants are also employees of the hospital. Leaving aside the legal aspect of the doctrine, the doctrine is an excellent management principle. Someone must assume responsibility for the procedure that is being undertaken. Members of the radiosurgery team cannot shunt responsibility to each other.

### The role of XKnife in brain metastases

7.23.Section 2.2 of the **Radionics XKnife Protocol** says, inter alia, that :

Recent reports have suggested a role for stereotactic radiosurgery (SRS) in the treatment of metastatic brain tumors. The recent development of linear accelerators modified to deliver focused irradiation has expanded the availability of SRS. Advantages of SRS are ease of administration from the patient's viewpoint (one-day treatment), the ability to treat metastases located in areas of the brain not amenable to complete surgical resection, and the potential to decrease neurosurgery and radiation related morbidity and mortality. SRS allows delivery of a high dose of focal irradiation in a single fraction to the tumor from multiple geometric directions. *Brain metastases are ideal targets for SRS because the majority are small (< 3cm in diameter), most are spherical with distinct tumor margins on contrast enhanced imaging studies, and most displace rather than infiltrate normal brain.* SRS minimizes the amount of radiation received by the nontarget regions of the brain and the area targeted generally does not include functional brain.

Retrospective analyses show that brain metastases originating from a large number of different types of malignancies, including less radioresponsive malignancies such as colon cancer, renal cell carcinoma, and melanoma, respond to SRS.

Metastases to the cranium and intracranial contents are the most common malignancy affecting the brain.

7.24.Section 2.3 of the **Radionics XKnife Protocol** says, inter alia, that :

SRS has become part of the standard therapy for eligible patients with brain metastases. Standard treatment for brain metastasis(es) also includes glucocorticoids and external beam whole brain irradiation (WBRT) which effectively relieve symptoms and restore neurological function in most patients. *Untreated patients have a median survival time of less than seven weeks.*

The most common cancers to metastasize to the brain are lung and breast, 34% and 30%, respectively.

7.25.Section 4.1 of the **Radionics XKnife Protocol** says, inter alia, that :

## Eligibility Criteria

*Histologically confirmed systemic malignancy with the presence of 1 to 3 intraparenchymal brain metastases*

. Patients with solitary metastasis are eligible only if they have refused surgery or surgical resection is deemed inappropriate by the patient's physician. (The role of surgical resection may change as SRS becomes better established.) In the absence of histologically confirmed systemic malignancy, the diagnosis of the cerebral metastasis must be histologically demonstrated.

*A diagnostic contrast enhanced MRI performed within two weeks prior to registration demonstrating the presence of 1 to 3 unresected brain metastases*

.

Contrast-enhancing tumors must be well circumscribed and must have a maximum diameter of < 4.0 cm in any direction on the enhanced scan. If multiple lesions are present and one lesion is at the maximum diameter, the other(s) must not exceed 3.0 cm in maximum diameter.

*No previous radiation to the head and neck area if radiation ports included the central neuraxis*

Age  $\geq$  18 years

Karnofsky Performance Score  $\geq$  70.

Neurologic function Status 0, 1, or 2.

Patients may have extracranial sites of primary metastatic disease but no clinical or radiographic evidence of progression within one month prior to registration." "Central Neuraxis" means central nervous system.

7.26. Section 5 of the **Radionics XKnife Protocol** contains these important statements :

Viable tumor, by definition, grows and if the lesion is stable in size (no change) on serial scans, the tumor is controlled. They should not expect the tumor(s) to disappear, but this does occasionally happen, particularly adenocarcinomas.

The patient and family should sign an informed consent form which clearly explains that they understand the clinical rationale for the procedure along with its possible side effects.

7.27. Section 8 of the **Radionics XKnife Protocol** under the heading "Dose Selection" contains, inter alia, these extracts :

The recently completed RTOG 90-05 phase 1 dose escalation study of patients with previously irradiated recurrent brain metastases or *gliomas* represents the best available guide to dose selection. That study accrued 162 patients. The radiosurgery dose was sequentially escalated according to tumor size in 3 Gy increments, as tolerated. Table 4 outlines the preliminary findings of phase one for the RTOG 90-05 study.

Table 4. Maximum Dosage by Tumor Diameter

Maximum Tumor Diameter	Maximal Tolerated Dose
<2.0 cm	24Gy
2.1 – 3.0 cm	18 Gy
3.1 – 4.0 cm	15 Gy

Lesions larger than 4.0 cm in maximal dimension are often associated with mass effect and surgical resection is the preferable treatment if the lesion is located in an operable location. In general, SRS is not used for lesions greater than 4.0 cm in maximum dimension.

Perhaps the most important component of dose selection in radiosurgery is an understanding of the normal tissue tolerance of brain (particularly the sensitive areas, the so-called eloquent brain) to a single high dose of radiation. Fundamental principles of radiobiology show that the relative biologic effect of a single large dose is far greater than the same total dose split (fractionated) into many smaller doses. Accordingly, normal tissue dose tolerance for radiosurgery is much less than that for conventional radiation therapy.

The use of the word "*glioma*" in Section 8 of the **Radionics Protocol** the most relevant point of the RTOG 90-05 study. For the dosages in the study to apply there must be :

- First: a recurrent *glioma* or brain metastasis  
Second: in the case of gliomas the recurrence must have been preceded by conventional fractionated radiotherapy

The two requirements are condition precedents to the dosage prescription.

#### Radiation sickness and side-effects of XKnife radiosurgery

7.28. Section 10 of the **Radionics XKnife Protocol** contains these paragraphs on radiation sickness and other side-effects of XKnife radiosurgery :

There are always two categories of side effects from any type of radiation therapy: short-term and long-term. The short-term side effects are those that may occur on the treatment day or in the first one to two weeks after treatment and the long-term side effects are those that may occur thereafter. A list of reported complications is shown in Table 9.

The short-term side effects include **pin-site soreness**, (meaning soreness at the site of the Head Ring Screw placement); this is generally not too bothersome and resolves within two days. Acetaminophen usually provides adequate analgesia for pin-site soreness. **Headaches** may represent increased intracranial pressure and thus can often be controlled with dexamethasone.

#### **Hemiparesis**

has been reported when the target involves the motor cortex. It occurs within 36 hours of SRS and often resolves within 24 hours of onset, with or without corticosteroids.

Late complications may include **radiation necrosis** of brain and tumor as well as

**cranial neuropathies.** It is, of course, the goal of SRS to achieve radiation necrosis of the tumor but not to cause symptoms.

Table 9 List of Reported Complications

<u>Short-Term</u>	<u>Long-Term</u>
Headache	
Nausea and Vomiting	
Seizures	necrosis
Hemiparesis	Cranial
Pin-site soreness	neuropathies
Herniation	Hemiparesis
Edema	Edema
Focal alopecia (subacute)	

**Hemiparesis** may be permanent, but it is often difficult to discern if this is caused by the underlying disease or the treatment. Edema may also be a permanent side effect of SRS and may require corticosteroids which should be tapered to the minimum effective dose.

**WARNING : Every effort should be made in treatment planning to minimize the dose to the cranial nerves**

. Cranial neuropathies may be transient or permanent. The variables of dose and volume are responsible, but the exact relationship remains incompletely understood.

7.29. Section 11 of the **Radionics XKnife Protocol** headed "**Conclusions**" contains, inter alia, these comments :

The management of patients with brain metastases is an issue of increasing clinical and economic importance. *There is now persuasive evidence that whole brain radiation therapy (WBRT) plus stereotactic radiosurgery (SRS) is the gold standard of therapy for many patients with brain metastases.*

This step-by-step description and explanation of the clinical and technical aspects of XKnife stereotactic radiosurgery for patients with brain metastases is intended to be a *valuable tool but is not a surrogate for sound clinical judgment regarding the applicability of these concepts for a specific patient. A team approach incorporating input from the neurosurgeon, radiation oncologist, radiation physicist, and support staff is essential to the development and maintenance of a high quality program in stereostatic radiosurgery.*

#### Importance of experience

7.30. Finally comes the important Section 12 of the **Radionics XKnife Protocol**. The heading of this section is "General Warnings and Precautions"

As described in this monograph, stereotactic radiosurgery is indicated, clinically effective, and cost-effective for certain brain metastases and other indications.



*However, it is a very critical procedure, by its nature. Close attention to the accepted clinical methods and experience of years of clinical radiosurgery are essential for proper use of this technique. In every case, good clinical judgment for the particular patient being treated is paramount.*

This monograph represents the method used by the authors at the time of writing and should not be interpreted as the only way to deliver radiosurgery for brain metastases. The monograph provides general guidelines for the use of XKnife radiosurgery, but since no two patients are identical, specific care and judgment for each patient is essential. It is the responsibility of the individual clinicians treating the patient to decide on the appropriateness of any aspect of the technique described in this monograph, or indeed radiosurgery in general. This monograph should in no way substitute for the use of such proper clinical judgment by the caring physician for the patient's specific needs.

It is the basic philosophy of the monograph authors and Radionics that the team approach is essential for good stereotactic radiosurgery. A competent and well trained neurosurgeon, radiation oncologist, radiation physicist, and support staff must work together in order to develop and maintain a high quality program in radiosurgery.

The XKnife System represents careful design of stereotactic instrumentation, software, and quality assurance processes that have evolved over many years of work in collaboration with practicing clinicians. These procedures have been designed for the purpose of avoiding the possibility of errors and providing the maximum information and security for this technique. *The user should follow, at all times, the Radionics' recommendations for use of this equipment and the protocols for use of the quality assurance methods associated with it.*

Radionics has established a procedure for installation of its XKnife instrumentation and software at the user site and extensive training of the users themselves at Radionics, at clinical sites, and at their own site, so that they can use the equipment confidently. The key members of the XKnife clinical team should be fully trained in this manner, and that training subsequently propagated among their colleagues who may use the system. Competent and trained physics/engineering support should be associated with each XKnife site so that proper use and maintenance of the XKnife equipment will be carried out.

As part of the training and support material, Radionics has prepared an extensive user's manual for the XKnife System. This manual should be read and understood by all of its users and followed carefully for proper use of the XKnife System for radiosurgery.

In general, awareness of proximity of radiation to critical structures is mandatory. Every effort should be made in treatment planning to minimize the dose to cranial nerves, the optical system, the brain stem, and other such vital and critical structures. Cranial neuropathies may be transient or permanent. The variables of dose and volume are responsible, but the exact relationship remains incompletely understood.

7.31. Even in the case of simple gliomas, the evidence of Dr Karlsson (the defendants' expert) was this

:

In all my teaching, I say that it's not really justified to treat any gliomas with radiosurgery because I don't think it helps. [NE 2693 – L 11-13]

As to whether it helps to treat a central neurocytoma with radiosurgery he gave this answer :

Future will answer that question more specifically ... .

I have seen data that suggests that radiosurgery is efficient against this tumour. This not the future this is today. [NE 2693-2694]

Dr Karlsson did not disclose the contents of the paper he relied on but his answer was in respect of a viable tumour. He did not clarify whether radiosurgery was the sole primary treatment or in addition to previous radiotherapy. He was asked for the dosage he would give. His answer was :

It depends on the size, of course, of the lesion. But personally, I say I will give around 15, 13 to 15 Gy to that lesion. [NE 2694]

#### Dosage according to Dr Karlsson

7.32. Dr Karlsson gave the above evidence with reference to the primary radiosurgery dosage, and not in addition to conventional fractionated radiotherapy (which was what happened in this case). Dr Karlsson was asked about a lesion with the size of 12 x 11 x 6 mm. His answer :

If it's one cc lesion ... it's a lot of factors that's involved, but just a guesstimate, one cc lesion would be about 15 Gy. About 5 cc would be 13 Gy roughly. [NE 2695]

#### Dosage according to Dr Robert Smees

7.33. On the point of dosage, there is another document which must be referred to. This is the lecture notes taken down and transcribed by Dr Khor. The entire document is reproduced as Appendix II. According to this document, the dosage for gliomas is given as follows :

### **I Malignancies**

#### **Glioma**

(i) SRS boost after conventional RT. Reported series biased as SRS probably given to younger patients, those with better performance status and smaller lesions. More definite role in treating small recurrence. Dose – 54 Gy conventional RT followed by 10-15 Gy SRS boost.

7.34. It must be stressed that the specific indication for the above prescription is recurrent glioma – that is, established malignancy. Indeed the dosage for glioma appears under the main-heading of "malignancies".

#### Free for all at Mt E Hospital

7.35. There is one final matter to be mentioned. The present director of the Singapore Gamma Knife Centre gave evidence in this case. He was Dr Yeo Tseng Tsai. He said this :

*In the early years of Gamma Knife radiosurgery, which would be in 1996/1997, there weren't many guidelines on what could and what could not be done; very much a free for all*

. And it was the opinion of the Ministry of Health at that time that there was a lot of Gamma Knife being done for very spurious indications, so they got Dr Bengt Karlsson to come out and audit the first 400 cases done. This is very unusual because it never happened in the history of medical practice in the Ministry of Health, as I understand it. So he audited these cases and he gave a report to the Ministry of Health which was confidential, I do not have access to that confidential information and based on that, he made certain recommendations and one of them was an appointment of a Medical Director of the Gamma Knife Centre, the first Medical Director of the Gamma Knife Centre, and subsequently, the Ministry of Health, after he had left, based on his report, the Ministry of Health appointed me the Medical Director and gave me, well, the job description was to tighten up Gamma Knife radiosurgery to make sure we had very strict audits and that we will --- we are doing things by the book and what was internationally accepted and hence I came forth with these guidelines which were partially based on consultation with Professor Bengt Karlsson because he's an internationally well-known and, to my mind, a very objective Gamma Knife radiosurgeon. [NE 3862-3863]

7.36. It appeared that at Mt E Hospital, it was very much a free for all in 1997. Dr Chua Eu Tiong was a medical expert called by Dr Khor. He is a radiation oncologist practising both *Gamma Knife* and *XKnife* radiosurgery. He is also Chief of the Department of Radiation Oncology at the National University Hospital. He is a visiting consultant at both the *Gamma Knife* Centre as well as Tan Tock Seng Hospital. He said that in 1998 a protocol was developed by the Singapore *Gamma Knife* Centre. That has been accepted for Linac radiosurgery since 1998. He said that at the time he was giving evidence in this case, the Radiological Society and the Ministry of Health had asked him to draw up some guidelines for the use of Linac-based radiosurgery. He did not reveal that what he had done on that request. His evidence was that while there was a requirement for formal training, as well as clinical experience with a number of patients, before a doctor accredited to the *Gamma Knife* Centre could use it, there was no such requirement for *XKnife* users in Singapore. Such experience, of course, could be gained by being an adjunct of the radiosurgery team. At one point he said that there was a protocol for *XKnife* users in the USA. I then pointed out to Dr Chua Eu Tiong that although there was no written law in Singapore mandating the users of *XKnife* to undergo training, the manufacturers insisted that its users underwent training. He replied that it was so in the USA but not Singapore. And so it was free-for-all at Mt E Hospital. I then asked Dr Chua Eu Tiong whether he had seen the **Radionics XKnife Protocol**. He said he had not seen it before the present case. Even then he had not seen the entire manual but only part of. Dr Khor had shown parts of it to him. The **Radionics XKnife Protocol**, it is to be remembered, contains very vital and substantial information and warnings. It is in fact a protocol for *XKnife* radiosurgery. It gives much useful information and guidance for a regime of *XKnife* radiosurgery. I found it most disturbing that Dr Chua Eu Tiong had not seen the entire monograph. It even contains precise stipulations about how an informed consent should be obtained. Yet Dr Chua Eu Tiong, a specialist who had been asked to assist by the Radiology Society and the Ministry of Health had not even read the manufacturer's manual of a potentially dangerous medicine. Dr James Khoo later said in evidence that neither the law of Singapore nor Mt E Hospital required him to follow the dictates of the *XKnife Protocol*. How amazing! And so it was free for all at Mt E Hospital.

#### Dosage selection

7.37. In relation to the dosage of radiation, it is necessary to refer to a clinical investigation by the

Radiation Therapy Oncology Group in 1989. It published a report called RTOG Protocol 90-05. The full title of the report was "Simple Dose Radiosurgical Treatment of Recurrent Previously Irradiated Primary Brain Tumours" The purpose of the investigation was :

To determine the maximum tolerated dose of single fraction radiosurgery in patients with recurrent previously irradiated primary brain tumours and brain metastasis.

7.38.The catch notes of the report were :

Stereotactic radiosurgery, Recurrent *glioma*, recurrent brain metastasis.

7.39.It is a first and fundamental principle of medicine that a given prophylactic, therapy or procedure should be prescribed only when the possible risks and complications potentially faced by the patient are outweighed by the potential benefit of giving the prophylactic, therapy or procedure. This is particularly so where the adverse side effects are known to cause death or dire damage or disability. Only extreme malady can justify extreme medicine. In this case it will be noted in that according to RTOG 90-05 a high single maximum dose of 24 Gy or above is justified only for a previously irradiated recurrent malignant tumour with maximum diameter of 2 cm or less or brain metastases (See 7.27 above). According to the learning of Dr Khor, that is according to the teaching of Dr Robert Smee, only a malignant glioma will justify a "dose of 54 Gy of conventional RT followed by 10-15 Gy SRS boost. (See 7.32 above). According to the Radionics *XKnife* manual the maximum tolerated dose of 24 Gy was for brain metastasis. Dr Khor had noted it down in his typescript with a reminder. According to RTOG Protocol 90-05, the maximum tolerated radiosurgery dose (single fraction high-dose) of 24 Gy was reserved for previously irradiated recurrent *gliomas* and brain metastases. Everything else in the brain would be contraindicated. Even then, the justification for such high dose is not curative but palliative. It was meant for patients whose life-span was very limited and measured only in months. The purpose of radiosurgery was as a last-ditched attempt to extend life a little and lessen the patient's agony.

#### Informed consent

7.40.The next caveat to note is that the **Radionics XKnife Protocol** stipulates a protocol to be followed prior to the execution of radiosurgery. It issues the following adjuration :

It is essential that the patient and family understand the potential risks and benefits of the procedure. *Expectations are often too high*. It is important to explain that since the lesions are metastases, the patient cannot be "cured" of the entire disease and that the hope is to stop the growth – (achieve local control) of the brain tumour(s). It is also important to explain that appropriate expectations should be preservation of current neurologic function for an undefined period of time, rather than recovery of already lost neurologic function. ... The patient and family should sign an informed consent form which clearly explains that they understand the clinical rationale for the procedure along with its possible side effects.

(Section 10 gives very important additional information on possible complications, perspectives on risk, clinical judgment, and informed consent counselling).

7.41.The third point for emphasis is that the entire team must have adequate knowledge, skill and experience before they recommend and execute radiosurgery. The **Radionics XKnife Protocol** adjures

that "close attention to the accepted clinical methods and experience of years of clinical radiosurgery are essential for proper use of this technique." If the members of the team do not have such experience, radiosurgery will become a free-for-all practice – an ill wind that blows nobody any good.

## **Chapter 8 : Bad Biology Needs Good Physics – The Protocols**

### The Sydney Protocol

8.1. Apart from the **Radionics XKnife Protocol** (namely the Radionics *XKnife* monograph), there are two more documents that must be examined for the purposes of this case. They are what I call the "Sydney Protocol", the "Gamma Knife Protocol".

8.2. As mentioned previously, Dr Khor went to Sydney for a learning and training session on the use of *XKnife*. It was organised by the makers of **XKnife**, Radionics Inc of the U.S.A. The teacher and trainer was Dr Robert Smee, who gave evidence in this case as an expert in radiosurgery. The teaching session was conducted at Prince of Wales Hospital, Sydney, for 4 days from 11 to 16 October 1996. The first day was a Friday. The last was a Monday. Whether there was any lecture or training relating to radiosurgery on Saturday and Sunday was not revealed to the Court. Dr Robert Smee in his report or his oral evidence in Court did not even reveal the fact that he was in charge of the teaching and training on behalf of Radionics.

8.3. Following the learning and training session, Dr Khor prepared a summary of the lectures for his future use, and perhaps the use of his support team in the radiosurgery department of Mt E Hospital. It was a manual and an aide-memoire at once. That is what I call the *Sydney Protocol* (See Appendix II). It gave the particulars for patient selection and dosage for *XKnife* radiosurgery. It was a vital document which surfaced only when Dr Khor was being re-examined. Dr Khor revealed it.

8.4. The document was divided into two parts. Dr Khor elucidated that the first and the principal part of the document contained the knowledge which Dr Robert Smee had imparted to those who went to Sydney in October 1996. The *Sydney Protocol* placed the relevant pathologies under two "Indications" as follows :

The first :

1. Benign

- (i) AVM
- (ii) Cavernous Hemangioma
- (iii) Meningioma
- (iv) Vestibular Schwannoma (acoustic neuroma)
- (v) Pituitary Tumours

The second set of indications read as follows :

2. Malignancies

(i) Glioma

SRS boost after conventional RT. Reported series biased as SRS probably given to younger patients, those with better performance status and smaller lesions. More definite role in treating small recurrence. Dose – 54 Gy conventional RT followed by 10 – 15 Gy SRS boost.

(ii) Metastases

POW Hospital policy SRS for not more than two lesions and no lesion larger than

3 cm. WBRT + 10 Gy SRS boost. If previous WBRT given, single fraction 15 – 20 Gy.

(iii) NPC

Usually fractionated SRT as boost for residual disease or local recurrence.

8.5. The last part was recorded as follows :

XKnife Radiosurgery for Brain Metastases

Table 4 Maximum Dosage by Tumour Diameter

Maximum Tumour Diameter	Maximal Tolerated Dose
< 2.0 cm	24 Gy
2.1 – 3.0 cm	18 Gy
3.1 – 4.0 cm	15 Gy

8.6. The first group of indications are remarkable in two respects. First, some of them are not tumours. Next, some of them are tumours but by Dr Smee's and Dr Khor's characterisation, they are benign brain tumours. They are not relevant to this case.

8.7. Under the heading of "Malignancies", Dr Khor included "Metastases", and "NPC". The dosages prescribed here are important. For malignant gliomas, the maximum dosage is 15 Gy. Dosages in excess of 20 Gy are excluded even for the extreme indications of metastases.

8.8. The *Sydney Protocol* was available to Dr Khor in October 1996. The information contained in it was not available to Dr James Khoo, for he did not go to Sydney, and he did not have sight of Dr Khor's notes.

8.9. Then came the important part. Dr Khor lifted "Table 4" from the ***Radionics XKnife Protocol*** and included it in the *Sydney Protocol*. Going by Dr Khor's document, radiosurgery after excision and conventional radiotherapy is neither proper nor established nor practised for *benign* tumours in the brain. There is no warrant to perform radiosurgery on a patient with a benign tumour in the brain. A fortiori when there is no tumour at all. Using the plaintiff as a guinea pig would be an unpardonable act.

#### The Gamma Knife Protocol

8.10. The plaintiff placed before the Court a "protocol" produced by the Singapore Gamma Knife Centre. I shall call it the *Gamma Knife Protocol*. There was a covering letter to it dated 29 May 1998. The letter was signed by Dr Yeo Tseng Tsai, who had been "recently appointed Medical Director of the Singapore Gamma Knife Centre". The letter carried this relevant sentence :

Evidence-based medicine is very much the buzzword nowadays, and that is very much what I have been guided by in formulating the medical policy for radiosurgery at the Singapore Gamma Knife Centre.

8.11. Page 2 of the document carried this heading : "Protocol for Deciding on Suitability of Cases for

Gamma Knife Radiosurgery" The following extractions are the keynote of the protocol page :

All cases that are booked for gamma knife radiosurgery by the neurosurgeon intending to do the case will have to have the diagnosis and size of the lesion (diameter in cm) told to the SGKC staff taking the booking. No case will be allowed to proceed without my being aware of what the diagnosis and approximate size of the lesion is.

8.12.The next two pages elaborated the two determinants. It began with this sentence :

With regard to deciding on suitability for gamma knife radiosurgery, I have deemed it best to separate lesion diagnosis from lesion size in order not to confuse the two issues too much, since a lesion that is very suitable (eg acoustic neuroma) may be too big in terms of size, and conversely a lesion that is small may not be the most suitable indication for gamma knife radiosurgery.

### Three categories of the Gamma Knife Protocol

8.13.The paper, relying on Dr Karlsson's input, proposes three categories which "conforms roughly (not exactly) to the format in Evidence-based Medicine".

- (i) Category A (Standards)
- (ii) Category B (Guidelines)
- (iii) Category C (Options).

### Category A

8.14.The paper elaborates Category A as follows :

These are generally well-accepted indications for gamma knife radiosurgery (but not all indications here are proven in a randomised controlled trial, hence it is not exactly equivalent to Standards).

### Category B

8.15.There is a brief explanation of this category :

These are indications that are less well accepted but with enough scientific evidence to support the use of gamma knife.

Trigeminal neuralgia  
Pituitary adenoma

8.16.Dr Yeo Tseng Tsai commented that "Category A and B lesions are in my opinion fairly non-controversial, and cases falling into this category will be permitted to proceed without any problems (if it is not large lesion)".

8.17.The important point for our purpose is that neurocytoma is entirely excluded from the non-controversial Category A and Category B which pass and permit radiosurgery to be performed on lesions coming within their compass. Even malignant glial tumours (gliomas) do not come within Category A and Category B.

### Category C

#### 8.18.Of Category C, Dr Yeo Tseng Tsai said :-

Category C lesions are in my opinion controversial or unproven indications, and will require a formal research protocol before gamma knife radiosurgery will be allowed to proceed in these cases. Only under *extremely extenuating circumstances* will a waiver of a research protocol be granted for Category C patients. This protocol will have to be approved by an Ethics Committee or IRB-type committee.

I think it is important to be strict about Category C lesions because patient numbers are usually small in this category. The onus is on us, as objective medical scientists, to prove that gamma knife radiosurgery really works for these lesions or indications. Doing ad hoc random cases based on anecdotal reports in the literature is never going to give us the correct answer. In this day and age of evidence-based medicine, the only way to do this is in the setting of a protocolised controlled trial with sufficient patient numbers, which probably means we have to be part of a multi-centre study. I will try very hard for us to be part of these multi-centre trials, for only then would it be really meaningful and worthwhile to treat some of these Category C lesions, as we would be helping to provide definitive answers as to whether or not radiosurgery works for some of these lesions.

#### 8.19.The document stated the following under Category C :-

In this category would lie unproven, experimental or controversial indications for gamma knife radiosurgery. (NB: This list is not exhaustive).

- Malignant glial tumours
- Cavernous angioma
- Solid craniopharyngioma
- Hemangioblastoma
- Ependymoma
- PNET
- Pineal tumours
- Chordoma
- Chondrosarcoma
- Pallidotomy and thalamotomy for Parkinson's disease
- Thalamotomy for essential tremor
- Thalamotomy for pain
- Cluster Headache
- Cingulotomy/anterior capsulotomy for psychosurgical indications or cingulotomy for pain
- Amygdalo-hippocampectomy for epilepsy

#### 8.20.Malignant glial tumours (i.e. gliomas) come under Category C, but not neurocytoma.

#### 8.21.The *Sydney Protocol* was superior to the *Gamma Knife Protocol* in an important aspect. The *Sydney Protocol* gives the guidelines for patient selection as well as dosage selection for the indications, whereas the *Gamma Knife Protocol* does not.



### The XKnife Protocol

8.22.As I have already shown in Chapter 7, the *Radionics XKnife Protocol*, sets out in great detail the essential knowledge which must be acquired by the *XKnife* radiosurgery team.

8.23.The *Radionics XKnife Protocol* is limited to the use of *XKnife* radiosurgery on brain metastases (i.e. aggressive malignant secondary tumours). In that respect it provides invaluable guidelines on patient selection, dosage selection and advice and consent. Because of its reference to the RTOG 90-05, the *Radionics XKnife Protocol* can be adopted for previously irradiated recurrent gliomas. The dosage guidelines in the RTOG 90-05, however, do not apply to indications other than brain metastases and previous irradiated recurrent gliomas.

8.24.In summing-up, the *Radionics XKnife Protocol* concerns itself with all the essential knowledge required for the use of *XKnife* radiosurgery for a given indication – namely brain metastases. It can be adopted for previously irradiated recurrent gliomas. The *Gamma Knife Protocol* concerns itself with patient selection for three wide categories of indications but omits dosage selection. The contents of the *Sydney Protocol* combines the other two protocols in a summarised and simplified form. It covers a wide variety of indications for *XKnife* radiosurgery and the dosage applicable to each category of indications. Those who do not study it closely are bound to make category errors.

8.25.Dr Tsao Shiu Ying, an expert witness called by the plaintiff, described radiosurgery as a disruptive procedure [NE 872 – L 5]. It is a procedure where "a bad biology is being made better by good physics" [NE 1110 – L 25, 1111 – L 26]. He said he was trained in radiosurgery in many places. It was not from the books. He remembered his friend from UCLA, Tim Solberg, who said to him :

Look, this thing called radiosurgery, you must be very careful because it's got very bad biology. So you must do very good physics. So this is the golden rule number one. [NE 1111]

8.26.So the purpose of the protocols is to teach "the bad biology and the good physics" to those doctors before they place their patients under the Knife. *It would be an irresponsible act for any doctor to advice, offer or perform radiosurgery without studying the applicable protocol and acquiring adequate knowledge and training.* If radiosurgery is performed without a clear understanding of "the bad biology" and "the good physics" things can go wrong. And anything that can go wrong will go wrong.

### A recap

8.27.The following is a recap of the relevant guidelines for dosage prescription.

(a) According to the ***Radionics XKnife Protocol*** (the monograph) read with RTOG 90-05, for a previously irradiated brain metastases and gliomas with a diameter of 2 cm or less, the maximum tolerated dose is 24Gy. This is only a guideline. No two patients are alike. Individual judgement must be applied on a case by case basis. The *XKnife Protocol* contains this cautionary note to dosage selection :

Perhaps the most important component of dose selection in radiosurgery is an understanding of the normal tissue tolerance of brain (particularly the sensitive areas, the so-called eloquent brain) to a single high dose of radiation.

Fundamental principles of radiobiology show that the relative biologic effect of a single large dose is far greater than the same total dose split (fractionated) into many smaller doses. Accordingly, normal tissue dose tolerance for radiosurgery is much less than that for conventional radiation therapy.

(b) According to the *Sydney Protocol* for a malignant recurrent glioma, the prescription is "54 Gy conventional RT followed by 10-15 Gy SRS boost". For a metastatic malignancy of a diameter of 3 cm or less, the dosage recommendation is WBRT + 10 Gy SRS boost. (If previous whole brain radiotherapy has already been given, then the maximum single fraction to be given is 10-20 Gy). According to Dr Khor, the "boost" dosage does not apply if there is an interval of more than three months after previous irradiation. In this case, because there was a long interval after the previous conventional RT, the recommendation in the RTOG 90-05, according to Dr Khor would be appropriate even though what Gunapathy had was not a recurrent glioma or brain metastasis. To repeat, it is the previously irradiated glioma, and not a macroscopically excised indolent neurocytoma, that indicates high-dose radiosurgery.

8.28. Before Dr Khor discovered the *Sydney Protocol* to the Court and counsel, he said in evidence that he was taught in Sydney that *XKnife* radiosurgery was suitable for "low-grade gliomas" [NE 2554]. When I perused the *Sydney Protocol*, I found no reference to low-grade gliomas. There was no dosage selection recommendation for a glioma other than previously irradiated recurrent gliomas. Dr Robert Smee who was the leading trainer at the course in Sydney said nothing about radiosurgery being suitable for low-grade gliomas when he gave evidence in this case. Indeed, his evidence in Court indirectly stressed the requirement for a malignant, recurrent tumour. That was clear from his attempt to describe "*this*" neurocytoma, as "malignant", "recurrent", "aggressive", and "resistant to radiosurgery". To confuse an indolent neurocytoma with a malignant glioma would be an egregious category error.

## Chapter 9 : Res Ipsa Loquitur

9.1. Before embarking on the law on medical negligence, I will first deal with the doctrine of "Res ipsa loquitur". Since there was much disputation and protestation on that applicability of the doctrine to this case. There can be no doubt that it avails a patient in appropriate medical negligence cases, but it was not necessary on the facts of this case.

### The swabs case

9.2. **Mahon v Osborne** [1939] 2 KB 14 was a medical negligence case where the doctrine of *res ipsa loquitur* was applied. In that case, surgical swabs had not been removed after an abdominal operation. The swabs caused an abscess which led to the death of the patient. It was held by the English Court of Appeal that the doctrine of *res ipsa loquitur* applied. Goddard LJ, in what has now become a classic declaration of the law, said at p 50 :

The surgeon is in command of the operation, it is for him to decide what instruments, swabs and the like are to be used, and it is he who uses them. The patient, or, if he dies, his representatives, can know nothing about this matter. There can be no possible question but that neither swabs nor instruments are ordinarily left in the patient's body, and no one would venture to say that it is

proper, although in particular circumstances it may be excusable, so to leave them. If, therefore, a swab is left in the patient's body, it seems to me clear that the surgeon is called on for an explanation, that is, he is called on to show not necessarily why he missed it but that he exercised due care to prevent it being left there.

### Two fingers and four fingers

9.3. The English Court of Appeal in **Cassidy v Ministry of Health** [1951] 2 KB 343 said the same. The plaintiff, a general labourer, suffered from a pathological condition called Dupuytren's contracture. Part of his palm became thicker because of the nature of his work and the third and fourth fingers of his left hand had contracted. He could not hold them straight. So he went to Walton Hospital in Liverpool and sought treatment. When it was all over it was found that his hand had been rendered useless. He went in with two stiff fingers and came out with four stiff fingers. So he brought an action seeking damages for negligence. Sreatfield J gave judgment for the defendants on the ground that the plaintiff failed to prove negligence on the part of any of the hospital staff. The plaintiff appealed the decision. His counsel opened the appeal with this poignant statement :

At the outset only two of the plaintiff's fingers were affected; all four are now useless. There must have been negligence – *res ipsa loquitur*.

The Court of Appeal agreed. The onus lay on the hospital authority to prove that there had been no negligence on its part or on the part of anyone for whose acts or omissions it was liable, and that onus had not been discharged. Denning LJ said at pp 365-6 :

If the plaintiff had to prove that some particular doctor or nurse was negligent, he would not be able to do it. But he was not put to that impossible task : he says, "I went into the hospital to be cured of two stiff fingers. I have come out with four stiff fingers, and my hand is useless. That should not have happened if due care had been used. Explain it, if you can".

I am quite clearly of the opinion that that raises a *prima facie* case against the hospital authorities: see *per* Goddard, L.J., in *Mahon v. Osborne*. They have nowhere explained how it could happen without negligence. They have busied themselves in saying that this or that member of their staff was not negligent. But they have called not a single person to say that the injuries were consistent with due care on the part of all the members of their staff. They called some of the people who actually treated the man, namely Dr. Fahmi, Dr. Ronaldson, and Sister Hall, each of whom protested that he was careful in his part; but they did not call any expert at all, to say that this might happen despite all care. They have not therefore displaced the *prima facie* case against them and are liable to damages to the plaintiff.

### No doctor on duty

9.4. **Bull v Devon Area Health Authority** [1993] 4 Med LR 117 is a recent case on the doctrine. Mrs Bull, who was 20 years old at the material time, was admitted to the maternity unit of Exeter City Hospital for delivery of identical twins at 4.30 pm on 21 March 1970. She was seen by a senior house officer who was new to the job and by a registrar with five years' experience. At about 7.30 pm the first twin was born. The senior house officer asked for the Registrar on call to be summoned. By then brisk vaginal bleeding indicated an emergency. The hospital's gynaecology department was over a mile

away. Time ran and the Registrar had not arrived. So the consultant was summoned. He came as quickly as he could. An hour had run out by the time the second twin (to be named Stuart) was born. Stuart seemed pale for lack of blood and his veins were dark for lack of oxygen. At 18 months he was diagnosed with mental disability and spastic quadriplegia. Mrs Bull commenced court action on her own behalf and on behalf of her son. Her claim for her own damages was dismissed as time-barred. Tucker J found in favour of Stuart. The hospital authority appealed. The Court of Appeal agreed with the trial judge that the doctrine of *res ipsa loquitur* applied and affirmed his decision. The health authority was negligent for leaving the mother unattended for an excessive period of time. Its fault was its failure to provide and to implement an efficient system for alerting suitably qualified medical practitioners on call to the impending medical emergency. Counsel for the plaintiffs submitted that "this was a case where on the evidence the delays in summoning and securing the attendance of the registrar or consultant were so substantial as to place the burden of justifying them if it could, under the *res ipsa loquitur* principle."

9.5. The Judge accepted the submission and further held that the Health Authority failed to exonerate itself. The Judge said at p 131 :

The plaintiff's counsel submits that there was a failure by the hospital to get a doctor of at least registrar status to the mother for one hour after the birth of the first twin and, as I find, 40 minutes after the bleeding, the onus must be on the defendants to show that the situation arose without any failure to exercise reasonable care and that the defendants have not done so. In other words counsel submits that this is a *res ipsa loquitur* situation. In any event he submits that the plaintiff has on the balance of probabilities established either that there was not a proper system for summoning a registrar or that the system broke down.

The Health Authority appealed to the Court of Appeal. The appeal was dismissed.

Slade LJ, with whom Dillon LJ agreed, referring to the principle of *res ipsa loquitur* said at p 131 :

This principle is succinctly summarised in one sentence in "Cross on Evidence" (6<sup>th</sup> ed) at p 136 as follows :

Where the plaintiff suffers damage in consequence of one or more things which were under the exclusive control of the defendant or his servants getting out of control, reliance may be placed on the maxim '*res ipsa loquitur*' in lieu of further evidence on negligence.

Megaw LJ in *Lloyde v West Midlands Gas Board* [1971] 1 WLR 749 stated it thus :

... It means that a plaintiff *prima facie* establishes negligence where : (i) it is not possible for him to prove precisely what was the relevant act or omission which set in train the events leading to the accident; but (ii) on the evidence as it stands at the relevant time it is more likely than not that the effective cause of the accident was some act or omission of the defendant or of someone for whom the defendant is responsible, which act or omission constitutes a failure to take proper care for the plaintiff's

safety.

9.6. Slade LJ then reviewed the evidence and at p 132 concluded as follows :

In my judgment, however, all the most likely explanations for this failure point strongly either (i) to inefficiency in the system for summoning the assistance of the registrar or consultant, in operation at the hospital in 1970, or (ii) to negligence by some individual or individuals in the working of that system. This is, in my judgment, accordingly a case where the *res ipsa loquitur* principle had to be applied, whatever hardship this may cause the Authority at this late date. The onus fell on the Authority to explain satisfactorily the hospital's failure to secure the attendance of Dr Golding or Mr Jefferiss before about 8 25 pm and to call Dr Golding's back-up, Mr Jefferiss, by about 7 45 pm. It did not discharge this onus. A breach of duty has in my judgment therefore been established and the judge was right so to decide.

#### Res ipsa loquitur in U.S.A

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9.7. The law of United States harmonizes with what has been outlined above. The following basic principles may be gathered from **Prosser and Keeton on Torts**, 5<sup>th</sup> Edition :

Negligence like any other fact may be proved by circumstantial evidence. This is evidence of fact, or if a set of facts, from which the existence of the fact to be determined may be inferred on. One type of circumstantial evidence is that which is given the name of *res ipsa loquitur*. The conditions usually stated in America as necessary for the application of the principle of *res ipsa loquitur* were derived originally from the first edition of Wigmore on Evidence. They are as follows : (1) the event must be of a kind which ordinarily does not occur in the absence of someone's negligence; (2) it must be caused by an agency or instrumentality within the exclusive control of the defendant; (3) it must not have been due to any voluntary action or contribution on the part of the plaintiff. Some Courts have at least suggested a fourth condition, that evidence as to the true explanation of the event must be more readily accessible to the defendant than to the plaintiff.

#### Application of the doctrine to cardiac arrest and brain damage cases

9.8. In **Saunders v Leeds Western Health Authority** [1993] 4 Med LR 355 it was successfully invoked to give judgment against the defendants. The plaintiff, Nicola Saunders (aged four), underwent an operation to correct a congenital dislocated left hip. The doctrine was applied in relation to cardiac arrest. In **Coyne v Wigan Health Authority** [1991] 2 Med LR 301, it was held that *res ipsa loquitur* applied in relation to the brain damage caused by a failure to intubate the patient.

#### Disapplication of doctrine

9.9. The doctrine of *res ipsa loquitur*, however, has no application where all the facts are known. In **Bolton v Stone** [1951] AC 850 Lord Porter, referring to the doctrine of *res ipsa loquitur* said at p 859 :

Where the circumstances giving rise to the cause of the accident are unknown that doctrine may be of great assistance, but where, all the facts are known, it cannot have any application.

9.10. In **Bull v Devon Area Health Authority**, Mustill LJ declined to apply the doctrine on the ground that all the facts were adduced to prove negligence.

#### Burden of proof

9.11. Finally, an important point to note is that the burden of proving a case of negligence remains on the plaintiff at the end as it was at the beginning. This is so even when the doctrine of *res ipsa loquitur* applies. When applicable, the doctrine puts the evidential burden on the defendant, who must reveal everything within his knowledge. This important aspect of the doctrine is contained in s 108 of the **Evidence Act** (Cap 97).

When any fact is especially within the knowledge of any person, the burden of proving that fact is upon him.

9.12. In relation to a charge of negligence the defendant, in general, must adduce sufficient evidence, consistent standard of professional skill accepted in law to show how the damage complained of resulted and that it was not due to any fault on his part.

#### A pleading point

9.13. The rules of pleading do not require a plaintiff to plead the doctrine of *res ipsa loquitur* because it is a rule of procedure. It is, however, prudent to do so. It was indeed included in the statement of claim in this case and rightly so. The defendants had not discovered their clinical notes and other documents at the time the statement of claim was filed. The disabilities of the plaintiff made it most difficult for her say how she came to be in the state she was in. Much of the relevant evidence was in the possession of the defendants. After discovery, however, the plaintiff and her advisers became aware of the circumstances. The invocation of the doctrine in the pleadings had a salutary effect of informing everyone that the defendants had to make a full and frank disclosure of everything. In the result, I received sufficient evidence to decide the case without resorting to the technical doctrine of *res ipsa loquitur*. Most of the evidence came from the expert witnesses. Accordingly nothing more will be said about it.

## **Chapter 10 : The Law of Medical Negligence**

### Medical negligence defined

10.1. A charge of medical negligence against physicians and surgeons must show a breach of two important questions : Whether the medical man possessed (a) a standard minimum of special skill, knowledge and training to tackle a particular illness or disorder he undertakes to handle, and (b) a standard minimum of care in the performance of the task he has undertaken. See : **Antonio Dias Caldeira v Frederick Augustus Gray** [1936] AIR PC 154. Often the two are fused into one.

10.2 Those two elements are succinctly expressed in **Prosser and Keeton on Torts**, 5<sup>th</sup> Edition, at p

Professional persons in general, and those who undertake any work calling for special skill, are required not only to exercise reasonable care in what they do, but also to possess a standard minimum of special knowledge and ability. Most of the decided cases have dealt with surgeons and other doctors, but the same is undoubtedly true of dentists, pharmacists, psychiatrists, veterinarians, lawyers, architects and engineers, accountants, abstractors of title, and many other professions and skilled trades.

### Skill and knowledge

10.3. The first requirement of a standard minimum of special skill, knowledge and training is of special significance in this particular case, for it is imperative that there be strict insistence on, full, extensive training and competence of the radiosurgery team comprising of the neurosurgeon, radiation oncologist, radiation physicist and the supporting staff. A radiation oncologist is not a brain specialist. Hence the need for a neurosurgeon who understands the location of the various brain parts of the brain anatomy and their sensitiveness to mega-dose or radiation. Only this could ensure the development and maintenance of a high quality program of radiosurgery. It would be disastrous if this high-tech, experimental and potentially dangerous medical procedure is freely practised by anyone who does not fully understand its intricacies. See the **Radionic XKnife Protocol**, in particular, Section 12, quoted in Chapter 7.

### Duty of care : civil and criminal standards

10.4. Now I move to the nature and the extent of the duty of care. An understanding of the duty must begin with the case of Dr Percy Bateman : **Rex v Bateman** (1925) 19 Cr. App Rep 8. It was a criminal case. He was charged with three counts of manslaughter by negligence.

#### *Civil standard in criminal case*

10.5. On 23 July 1924, the doctor in the **Bateman** case was called to assist at the birth of a baby. The woman he went to assist was Mrs Harding, the wife of a labourer. When he arrived, he found a very unusual and difficult presentation. He administered chloroform and attempted to effect delivery by the use of instruments. He did not succeed. He then proceeded to use his hands to perform the operation. He worked at this operation for an hour, applying considerable force and finally delivered the child. It was dead. In removing the placenta, he, by mistake, removed along with it a portion of the uterus. The patient was very exhausted. The doctor did not expect her to live. Although requested by the husband and the mid-wife to have her removed to the infirmary, he did not remove her until the 28<sup>th</sup>. On admission to the infirmary she was found unfit to undergo an operation. She grew gradually weaker, and died on the 30<sup>th</sup>. On a *post mortem* examination her bladder was found to have ruptured. Her colon was crushed against the sacral promontory. There was a small rupture of her rectum. And her uterus was almost entirely gone.

10.6. Three charges of manslaughter by negligence were made against him : (1) causing the internal ruptures in performing the operation, (2) removing part of the uterus along with the placenta, and (3) delay in sending the patient to the infirmary. The case was tried before Shearman J. The Judge was asked to withdraw the first and second charge from the jury on the ground that there was no evidence to support them. The Judge declined to do so. Dr Bateman was convicted on all three charges and sentenced to six months' imprisonment. The doctor appealed on the ground that the wrong standard of care was applied.

10.7.His counsel submitted that the judge had misdirected the jury on the law and on the evidence, and had wrongly admitted inadmissible evidence, and also that the verdict was against the weight of evidence. The judge's summing-up might have been unexceptionable in a civil action against an appellant for damages for negligence, but it contained no direction on, or definition, of criminal negligence. Based on this, the submission was that the Judge had failed to appreciate the difference between the criminal and civil standard of negligence.

10.8.The Court of Criminal Appeal analysed the Judge's summing-up to the jury. It, however, concluded that looking at the summing-up as a whole there was no misdirection. Nonetheless, there was no evidence to support the first charge. Since the first charge had not been withdrawn from them, it was impossible to say that they would certainly have convicted him. For that reason the conviction could not stand.

#### *Two standard of care*

10.9.The importance of the *Bateman* case lies in the definition of the civil and criminal standards of negligence. Lord Hewart CJ drew a clear-cut distinction between the two standards. He said at p 16 : "there is a difference in kind between the negligence which gives a right to compensation and the negligence which is a crime."

#### *The civil standard*

10.11.Lord Hewart LCJ described the criteria of civil liability at pp 12-13 :

If a person holds himself out as possessing special skill and knowledge and he is consulted, as possessing such skill and knowledge, by or on behalf of a patient, he owes a duty to the patient to use due caution in undertaking the treatment. If he accepts the responsibility and undertakes the treatment and the patient submits to his direction and treatment accordingly, he owes a duty to the patient to use diligence, care, knowledge, skill and caution in administering the treatment. No contractual relation is necessary, nor is it necessary that the service be rendered for reward. It is for the judge to direct the jury what standard to apply and for the jury to say whether that standard has been reached. The jury should not exact the highest, or a very high, standard, nor should they be content with a very low standard. The law requires a fair and reasonable standard of care and competence. This standard must be reached in all the matters above mentioned. If the patient's death has been caused by the defendant's indolence or carelessness, it will not avail to show that he had sufficient knowledge; nor will it avail to prove that he was diligent in attendance, if the patient has been killed by his gross ignorance and unskilfulness. No further observation need be made with regard to cases where the death is alleged to have been caused by indolence or carelessness. As regard cases where incompetence is alleged, it is only necessary to say that the unqualified practitioner cannot claim to be measured by any lower standard than that which is applied to a qualified man. As regard cases of alleged recklessness, juries are likely to distinguish between the qualified and the unqualified man. There may be recklessness in undertaking the treatment and recklessness in the conduct of it. It is, no doubt, conceivable that a qualified man may be held liable for recklessly undertaking a case which he knew, or should have known, to be beyond his powers, or for making his patient the subject of reckless experiment. Such cases



are likely to be rare. In the case of the quack, where the treatment has been proved to be incompetent and to have caused the patient's death, juries are not likely to hesitate in finding liability on the ground that the defendant undertook, and continued to treat, a case involving the gravest risk to his patient, when he knew he was not competent to deal with it, or would have known if he had paid any proper regard to the life and safety of his patient.

10.12. At p 16 he gave an additional elucidation to this effect :

A line must be drawn between mistake or error of judgment on the one hand, and carelessness or incompetence on the other hand. If there was only mistake or error of judgment there is no liability, but if there was any falling short of a fair average degree of care or competence, then there is liability. Such a distinction would be complete and accurate on the trial of an action for damages for negligence.

#### *The criminal standard*

10.13. Lord Hewart LCJ explained the criminal standard at p 13 :

To support an indictment for manslaughter the prosecution must prove the matters necessary to establish civil liability (except pecuniary loss), and, in addition, must satisfy the jury that the negligence or incompetence of the accused went beyond a mere matter of compensation and showed such disregard for the life and safety of others as to amount to a crime against the State and conduct deserving punishment.

#### *Criminal standard in a civil case*

10.14. In the **Bateman** case, the complaint was that the trial judge had applied the civil standard to a criminal charge. In **Hunter v Hanley** [1955] S C 213 it was the reverse. Mrs Jemima Hunter was the plaintiff and, to use the Scottish expression, the pursuer. She was receiving the last of a series of penicillin injections on 24 November 1951. The injection was being administered by the defendant, Dr John Hanley. He used a hypodermic needle, that is, a short needle to inject drugs beneath the skin. The needle broke and the end of it remained embedded in the plaintiff's hip. She took Dr Hanley to court claiming damages in the sum of 2500 for the injury she suffered. It was contended for her that Dr Hanley should have used a stronger needle. Her case was tried with a jury. In his direction to the jury the Judge said, inter alia, that "there must be such a departure from the normal and usual practice of general practitioners as can reasonably be described as *gross negligence*. ... a serious departure from a normal practice, if that normal practice has been proved, and the serious departure must involve a substantial and serious fault". The jury returned a verdict in favour of Dr Hanley. The plaintiff moved for new trial on the ground objecting to the reference to "*gross negligence*".

10.15. It was the first case of medical negligence in Scotland. This is understandable, for Scotland had enjoyed a high reputation for quality medical service, to the envy of other nations. It was the role model for superior standard and performance. As Lord President Clyde remarked, "It is a tribute to the high standard in general of the medical profession in Scotland that there are practically no decisions on this question in the reported cases." "Gross negligence" or "crassa negligence" was an archaic concept which was in common use before the 20<sup>th</sup> century. It was understood to mean "intentional failure to perform a duty in reckless disregard of the consequences as affecting the life or of another." It was a lot more than ordinary breach of duty of care. It had a criminal connotation. The plaintiff

argued for the ordinary common law standard. The Court of Session agreed with the plaintiff and ordered a retrial. It also defined the meaning of medical negligence. Lord Clyde LP first made the following observations on "gross negligence" at p 217 :

In relation however to professional negligence I regard the phrase "gross negligence" only as indicating so marked a departure from the normal standard of conduct of a professional man as to infer a lack of that ordinary care which a man of ordinary skill would display. So interpreted the words aptly describe what I consider the sound criterion in the matter, although strictly viewed they might give the impression that there were degrees of negligence.

As for negligence Lord Clyde LP said at p 204:

To succeed in an action based on negligence, whether against a doctor or against anyone else it is of course necessary to establish a breach of that duty to take care which the law requires, and the degree of want of care which constitutes negligence must vary with the circumstances. – (*Caswell*, supra, per Lord Wright at p. 175). But where the conduct of a doctor, or indeed of any professional man, is concerned the circumstances are not so precise and clear cut as in the normal case. In the realm of diagnosis and treatment there is ample scope for genuine difference of opinion and one man clearly is not negligent merely because his conclusion differs from that of other professional men, nor because he has displayed less skill or knowledge than others would have shown. The true test for establishing negligence in diagnosis or treatment on the part of a doctor is whether he has been proved to be guilty of such failure as no doctor of ordinary skill would be guilty of if acting with ordinary care (*Glegg on Reparation*, p. 509). The standard seems to be the same in England.

As to deviation from ordinary professional practice Lord Clyde LP said at p 206:

In regard to allegations of deviation from ordinary professional practice – and this is the matter with which the present motion is concerned – such a deviation is not necessarily evidence of negligence. Indeed it would be disastrous if this were so, for all inducement to progress in medical science would then be destroyed. Even a substantial deviation from normal practice may be warranted by the particular circumstances. To establish liability by a doctor where deviation from normal practice is alleged, three facts require to be established. First of all it must be proved that there is a usual and normal practice. Secondly it must be proved that the defender has not adopted that practice, and thirdly (and this is of crucial importance) it must be established that the course the doctor adopted is one which no professional man of ordinary skill would have taken if he had been acting with ordinary care – there is clearly a heavy *onus* on a pursuer to establish these three facts, and without all three his case will fail. If this is the test then it matters nothing how far or how little he deviates from the ordinary practice. For the extent of deviation is not the test. The deviation must be of a kind which satisfies the third of the requirements just stated.

What happened on retrial in ***Hunter v Hanley***, if there was one, is not reported

*The Bolam case*

10.16. **Bolam v Friern Hospital Management Committee** [1957] 1 WLR 582 came close on the heels of **Hunter v Hanley**. **Bolam** was a case of extreme medicine for extreme malady – high-risk treatment for high risk malady. The defendant in that case was not an individual physician but the management committee of a mental hospital. The committee as such probably knew little about the malady or the medicine. The malady that the plaintiff, John Hector Bolam, suffered from was a morbid mental illness – acute depression with suicidal propensities. McNair J, the trial judge, described the malady as : "One of the most terrible ills from which a man can suffer. He had very little hope of recovery. In most cases he could only expect to be carefully and kindly treated until in due course merciful death released him from his sufferings." Conventional medical science had no cure for it. It was in those circumstances that physics came up with a radical remedy. It was ECT – an abbreviation for electro-convulsive therapy. It was called electric treatment. It was a remedy of last resort. McNair J described it as follows : "ECT was carried out by placing electrodes on each side of the head and allowing an electric current to pass through the brain (the voltage was 120 volts AC). One of the results of passing the electric current through the brain was to precipitate violent convulsive movements in the form of a fit in the patient, and muscular contractions and spasms." This, of course, brings before the eyes the violent motor disturbances seen during epileptic fits. One adverse side-effect of the treatment was the possibility of a fracture caused by the convulsions. It was an extremely rare possibility. An expert witness told the jury that he was aware of just one instance of a fracture of the cavity (acetabulum) which holds the head of the thigh bone. That was one in 50,000 cases involving 250,000 treatments. Bolam suffered that result. He sustained fractures of the pelvis on each side caused by the head of the femur being driven through the acetabulum or cup of the pelvis. It was on account of the resultant injuries that Bolam took the hospital management committee to Court. He blamed them on the basis that : (i) no muscle relaxant drug was administered prior to the passing of the electric current through his brain; (ii) they failed to provide him with adequate manual restraint or control; and (iii) they failed to give to him warning of the risks involved in the treatment, so that he might have a chance to decide whether he was going to take those risks or not. The plaintiff lost his case. Although there were varying methods of administering ECT, the method adopted in relation to him was in accordance with one responsible body of medical opinion skilled in that particular form of treatment. Further, he had not shown to the satisfaction of the court that, had he been warned of the risk, he would not have undergone the treatment.

10.17. The test laid down in the **Bolam** case and its reasonable standard have become the mantra of medical defence lawyers. And it is the front-line defence of the defendants in this case. McNair J in **Bolam** referred to what Lord Clyde LP said in **Hunter v Hanley** and formulated three propositions :

- (a) On each of the complaints made by the plaintiff, the real question was whether a doctor, in acting in the way he did, was acting in accordance with the practice of competent respected professional opinion.
- (b) The doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art.
- (c) Putting it the other way round, a man is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion who would take a contrary view. At the same time, that does not mean that a medical man can obstinately and pig-headedly carry on with some old technique if it had been proved to be contrary to what is really substantially the whole of informed medical opinion.

10.18. It is to be noted that skill, knowledge, competence and a sense of responsibility have all been

dexterously weaved into the propositions set out above.

#### *Bolam standard and professional service*

10.19. The essence of the propositions made by McNair J in **Bolam** has been enacted into written law. The English Supply of Goods and Services Act 1982, by s 13, in effect provides that a person providing professional services is in general under an obligation to possess reasonable care and skill, that is, such care and skill as he professes in the carrying on of some calling for which a given standard of competence is required. It has, for example, been applied to valuers : see **Kua Kok Kim & Ors v Ernst & Young** [2000] 1 SLR 707.

#### *The American standard*

10.20. The essence of the law stated in **Hunter v Hanley** and **Bolam** is widely applied. The law of the United States harmonizes with English law. **Prosser and Keeton on Torts**, 5<sup>th</sup> Edition, at p 186-187 summarises the law in the United States with admirable clarity :

A doctor may, although he seldom does, contract to cure a patient, or to accomplish a particular result, in which case the doctor may be liable for breach of contract when he does not succeed. In the absence of such an express agreement, the doctor does not warrant or insure either a correct diagnosis or a successful course of treatment, and the doctor will not be liable for an honest mistake of judgment, where the proper course is open to reasonable doubt. But by undertaking to render medical services, even though gratuitously, a doctor will ordinarily be understood to hold himself out as having standard professional skill and knowledge. The formula under which this usually is put to the jury is that the doctor must have and use the knowledge, skill and care ordinarily possessed and employed by members of the profession in good standing; and a doctor will be liable if harm results because he does not have them. Sometimes this is called the skill of the "average" member of the profession, but this is clearly misleading, since only those in good professional standing are to be considered; and of these it is not the middle but the minimum common skill which is to be looked to. If the defendant represents himself as having greater skill than this, as where the doctor holds himself out as a specialist, the standard is modified accordingly.

The courts have been compelled to recognize that there are areas in which even experts will disagree. Where there are different schools of medical thought, and alternative methods of acceptable treatment, it is held that the dispute cannot be settled by the law, and the doctor is entitled to be judged according to the tenets of the school the doctor professes to follow. This does not mean, however, that a quack, charlatan or crackpot can set himself up as a "school," and so apply his individual ideas without liability. A "school" must be a recognized one within definite principles, and it must be the line of thought of a respectable minority of the profession. In addition, there are minimum requirements of skill and knowledge, which anyone who holds himself out as competent to treat human ailments is required to have, regardless of his personal views on medical subjects. Furthermore, the physician is required to exercise reasonable care in ascertaining the operational facts upon which his diagnosis is based, and will be liable if he fails to do so.

*Bolam and the Privy Council (No. 1)*

10.21. The next case for mention is a Privy Council appeal from Malaysia, namely, **Chin Keow v Government of Malaya and Another** [1967] 1 WLR 813 As in **Hunter v Hanley** [1955] S C 213, this case arose from the administration of procaine penicillin. This time the needle did not break. The drug killed the patient. It happened in 1960 in a Government Clinic. The patient, Chu Wai Lian, was a 25 year old female attendant employed in another clinic. She sought treatment for an ulcer on her right ankle and swollen glands in the thigh. The physician, Dr Devadason, instructed the staff nurse to "give her 2 c.c. procaine penicillin". The nurse gave her the injection. That was all Dr Devadason said and did. She had received the drug before and in April 1958 she had been found to be "allergic to penicillin" and those words were endorsed in block letters on her outpatient card. She died of anaphylactic shock. Her mother brought a dependency claim against Dr Devadason and his employers, the Government of Malaya. Ong J tried the case : see **Chin Keow v Government of the Federation of Malaya & Anor** [1964] 30 MLJ 322. Dr Devadason was cross-examined. He gave these answers :

I had made no investigations into her history. Staff nurse had told me about her. I knew of the possibility of a person developing hypersensitivity to penicillin after having penicillin before. In such cases there was remote possibility of danger. Knowing that, I carried on because I had had no mishaps before. Hypersensitivity to a person could prove fatal.

I agree that Ex.1 is consistent with the doctor having been put on guard. Not as a rule do I give choice of treatment to the patient. I realise now – after the event – it was dangerous to have given the injection without the test.

In addition, another doctor, Dr Pillay gave evidence for the defence. He agreed that "the history of the patient should have been taken before injection". In the result, Ong J gave judgment for the plaintiff. See **Chin Keow v Government of the Federation of Malaya & Anor** [1964] 30 MLJ 322. He did so by applying the test in **Hunter v Hanley** and **Bolam v Friern Hospital Management Committee**. Ong J also referred to the judgment of Denning LJ in **Roe v Minister of Health** [1954] 2 QB 66. The nucleus of the judgment was in these four sentences :

The essence of the negligence here was the failure to take the simple, elementary precaution of asking a few questions. Had he done so, the mishap would not have happened. Some probing at least into every patient's history was the very first thing any doctor would start with on seeing a patient. The doctor here was guilty of negligence by his omission to do so.

The Federal Court overturned the decision : see **Government of Malaysia & Anor v Chin Keow** [1965] 2 MLJ 91. The quest for justice took the case to the Privy Council, which overturned the decision of the Federal Court and restored the decision of Ong J. The Privy Council had this to say about the decision of the Federal Court at p 817 :

The Federal Court seems, however, to have thought that evidence should have been forthcoming from medical witnesses of the highest professional standing or that such evidence as there was should have been supported by references to the writings of distinguished medical men. Their Lordships do not agree. The test is the standard of the ordinary competent practitioner exercising ordinary professional skill, and on this the evidence was all one way. Further, from a detailed analysis of the written record the Federal Court concluded that in speaking of the obligation to make due inquiry the medical witnesses were

speaking from hindsight and not of what they considered to have been the reasonable requirement at the material time - in April, 1960. But Ong J. made it abundantly clear that he did not view "this 1960 case through 1964 spectacles.

10.22.The case is authority for the proposition that the test of negligence is the standard of the ordinary competent practitioner exercising ordinary professional skill, so that evidence from witnesses of the highest professional standing or reference to writings of distinguished medical authorities is unnecessary. More importantly this case is a classic illustration that the **Bolam** criteria can be used by the patient as a sword against medical men. If there is a special procedure which the profession is required to follow, then the defendant ignores it at his own risk. In that instant case, the procedure was to ascertain if the patient was allergic to penicillin.

#### Special prescriptions

10.23.I must now cross the boundary from the medical profession to the engineering profession and consider **Greaves & Co v Baynham Meikle & Partners** [1974] 1 WLR 1261 (Kilner Brown J) and [1975] 1 WLR 1095 CA. It concerned the construction of a warehouse under a novel kind of building contract called a "package deal". Under the contract, the building owners entrusted everything to the contractors, so that the contractors were to employ their own architects and engineers. The plaintiffs, Grease & Co, were the contractors. They engaged the defendants, Baynham Meikle & Partners as the expert structural engineers to design the structure of the building and, in particular, the first floor of it. The proposed method of construction was governed by the British Standard Code of Practice, C.P. 117 (1965). After construction the floors began to crack and they were getting worse. So much so that experts were called in to investigate and advise. It was found that the cracks were due to excessive vibration. The trial judge found, inter alia, that the defendant expert structural engineers owed a duty of care, which was a higher duty than that which the law in general imposes on a professional man, and that they had breached it. This calls for elaboration. The defendants said that they must be judged by the test formulated by McNair J in **Bolam v Friern Hospital Management Committee** which had been approved by the Privy Council in **Chin Keow v Government of Malaysia & Anor**. That is to say, all that was required of them was "the ordinary skill of an ordinary competent man exercise a particular art". The Judge found that the expert evidence, taken as a whole, indicated a divergence of opinion. There was a strong body of opinion in favour of the engineer. However, the Judge found that the engineer had appreciated that the design of the floor in that particular project must specifically be suitable to carry heavily laden trucks, that he had been warned about the dangers of vibration and that he did not take these matters sufficiently into account. Then he at p 1269 concluded as follows :

This means, in my view, that the principle in *Bolam's* case is not strictly applicable. In the special circumstances of this case, by his knowledge of the requirement and the warning about vibration, it can be said that there was a higher duty imposed upon him than the law in general imposes on a medical or other professional man. In my judgment, the duty to a client or patient or employer is not necessarily a matter of general principle stated in objective terms. Thus the courts have repeatedly taken the view that a doctor should not be inhibited by anxiety as to legal consequences when trying to cure illness or save life. It seems to me that it is a different situation where an engineer fails to design properly what he is specifically engaged to design. Counsel for the defendant has asserted that such a finding is a finding of negligence and that the plaintiffs bring their claim in breach of contract. If it be necessary to allot a category for the breach of duty which I find to have occurred I would say that, not only was there here a breach of duty, as I have described, but there was a

breach of an implied term that the design should be fit for the use of loaded stacker trucks. There was an implied term on warranty here and it was broken.

10.24. It is to be noted that the Judge, having remarked that the engineer owed a higher duty than the minimum standard, eventually grounded his decision on an implied warranty.

10.25. The defendants appealed to the Court of Appeal which affirmed the decision of the trial judge. Lord Denning MR adverted to the "higher duty" mentioned in the court by Kilner Bown J and said at p 1101 :

It seems to me that in the ordinary employment of a professional man, whether it is a medical man, a lawyer, or an accountant, an architect or an engineer, his duty is to use reasonable care and skill in the course of his employment. The extent of this duty was described by McNair J. in *Bolam v. Friern Hospital Management Committee* [1957] 1 W.L.R. 582, 586, approved by the Privy Council in *Chin Keow v. Government of Malaysia* [1967] 1 W.L.R. 813 at 816. ...

In applying that test, it must be remembered that the measures to be taken by a professional man depend on the circumstances of the case. Although the judge talked about a "higher duty," I feel sure that what he meant was that in the circumstances of this case special steps were necessary in order to fulfil the duty of care.

Lord Denning MR cited in support ***Readhead v Midland Railway Co.*** (1869) LR 4 QB 379. It was a personal injury case of a passenger in a railway carriage. The case was based on an allegation of failure to carry the passenger safely. The claim was dismissed. The Court of Exchequer Chamber consisting of six judges affirmed the decision. Montague Smith J delivering the judgment of the Court said at p 393 :

Due care however undoubtedly means, having reference to the nature of the contract to carry, a high degree of care, and casts on carriers the duty of exercising all vigilance to see that whatever is required for the safe conveyance of their passengers is in fit and proper order. But the duty to take due care, however widely construed or however rigorously enforced, will not, as the present action seeks to do, subject the defendants to the plain injustice of being compelled by the law to make reparation for a disaster arising from a latent defect in the machinery which they are obliged to use, which no human skill or care could either have prevented or detected.

10.26. Geoffrey Lane LJ too referred to the same point and said at pp 1102-3 :

No great issue of principle arises in this case. The judge came to the conclusion that the defendants were in breach of two duties which they owed to the plaintiffs. The first is cast by law on every professional man holding himself out as an expert in any particular field, namely, the contractual duty as described by McNair J. in *Bolam v. Friern Hospital Management Committee* [1957] 1 W.L.R. 582, 586: "... it is sufficient if he exercises the ordinary skill of an ordinary competent man exercising that particular art." The second duty was cast upon the defendants not by law but by virtue of a warranty to be implied from the facts of the case - namely, that the parts of the building for which the defendants were responsible for designing would be fit for the purpose required,

namely, storing oil drums and for stacker trucks loaded with oil drums to travel thereon.

So far as the former duty is concerned - that implied by the law - the difficulty has arisen very largely from the way in which the judge expressed his finding. The material passage has already been read by Lord Denning M.R. At first sight he does appear to be saying that there is implied by law a higher form of duty than that set out in *Bolam's* case, a duty which is nevertheless lower than a warranty. If the judge indeed had said that, it would have been wrong; because there is no such duty. We are told by counsel that neither side at the trial advanced such a proposition, and I do not believe that the judge was intending to say that there was such a duty. What he was intending to convey was that there may be special circumstances in any particular case which require the reasonably careful expert to take special steps before his duty under *Bolam's* case can be said to have been discharged. The judge is saying that this is just such a case, because the defendants knew what the requirements of the plaintiffs were in respect of this building; knew that the type of building (that is to say, a composite construction building) was new; knew or ought to have known from the publication *British Standard Code of Practice*, C.P. 117: Part 1 (1965), that in a building of this sort there might very well be grave problems caused by vibration. The judge is saying that in those particular circumstances the defendants should have taken extra steps by way of precaution. The fact that they did not do so meant that they had not measured up to the requisite standard.

10.27. The ratio of this decision was that special circumstances of a particular case may require the reasonably competent and careful expert to take special steps or follow special procedures before his duty under *Bolam's* case can be said to have been discharged. If special prescriptions and descriptions are stipulated as in *Chin Keow* and *Readhead* cases, in respect of a particular remedy the reasonably competent and careful specialist must adhere to them. That was what responsible men in the profession would do under special circumstances. It tells how the *Bolam* principle can be used as a sword.

#### Privy Council on professional negligence

10.28. In *Edward Wong Finance Co Ltd v Johnson Stokes & Master* [1984] 1 AC 296, the Privy Council ruled that the respondent-solicitors were negligent, even though they had followed a practice which was in accordance with a body of professional opinion. The appellants, a finance company, had agreed to lend \$1.355 m to enable a company to purchase certain premises in Hong Kong. The advance was to be secured by a mortgage of the premises to the appellants, and the respondents were the appellants' solicitors in the mortgage transaction. The prevalent and customary conveyancing practice in Hong Kong at that time, called the "Hong Kong style of completion", was for the purchaser's solicitor to forward the purchase money to the vendor's solicitors on undertakings by the latter to subsequently hand over the executed documents of title. In line with this practice, the respondents forwarded the mortgage proceeds to the vendor's solicitor in reliance on the latter's undertakings. Unfortunately, the vendor's solicitor failed to honour his undertakings and decamped with the proceeds. The appellants brought an action against the respondents for negligence. The case went all the way to the Privy Council. In the judgment delivered by Lord Brightman, the Privy Council stated at p 306 :

... in assessing whether the respondents fell short of the standard of care which



they owed towards the appellants, three questions must be considered; first, does the practice, as operated by the respondents in the instant case, involve a foreseeable risk ? If so, could that risk have been avoided ? If so, were the respondents negligent in failing to take avoiding action ?

10.29. It was held that the "Hong Kong style of completion" was inherently flawed, for there was an obvious and foreseeable risk of embezzlement by the vendor's solicitor, and furthermore, that the risk could have been readily avoided if the respondents had, prior to parting with the mortgage proceeds, taken simple precautions to ensure that the appellants would have an unanswerable claim for specific performance against the vendors. In the event, it was held that the respondents were clearly negligent in not foreseeing and avoiding such risk. This was so even though they had abided by the customary conveyancing practice that was almost universally adopted by the legal profession in Hong Kong.

10.30. The principles enunciated by the Privy Council in the **Edward Wong** case parallel the application of the **Bolam** test by the Privy Council in **Chin Keow v Government of Malaysia & Anor** (supra), although neither the **Bolam** case nor the **Chin Keow** case were specifically cited in the written judgment of the **Edward Wong** case. The Singapore Court of Appeal recently followed **Edward Wong** in **Yeo Yoke Mui v Ng Liang Poh** [1999] 3 SLR 529. L P Thean JA, delivering the judgment of the Court of Appeal, pointed out that the mere fact that the respondent lawyer had complied with the standard conveyancing practice in Singapore did not preclude a finding that he had not done enough to advise the appellant and had breached his duty of care towards her, for evidence on standard conveyancing practice was only a general guideline of what was expected of a reasonably competent lawyer - the exact ambit of the respondent's duty as a lawyer was dependent on his retainer and the particular circumstances of the case, and "[t]he question is not really what the practice is or what a particular solicitor would have done in a particular situation but the extent of the legal duty in a given situation, which is a question of law." These cases, of course, involved an implied duty of care in a contractual rather than tortious relationship, but the standard and duty of care in contract and tort are the same.

#### The Bolitho case

10.31. The Edward Wong decision was further commented on by the House of Lords in **Bolitho v City and Hackney Health Authority** [1998] AC 232. The **Bolitho** case concerned a two year-old child (Patrick Nigel Bolitho) suffering from breathing difficulties. He was admitted into St Bartholomew's Hospital on 16 January 1984. The following day, his condition became catastrophic. His respiratory system was entirely blocked and he was unable to breathe. As a result he suffered a cardiac arrest. It took some nine to ten minutes before the respiratory and cardiac functions could be restored. In consequence he suffered severe brain damage. He and his mother sued the hospital for non-attendance to the boy by a doctor and failure to intubate him. On 15 February 1991, Hutchinson J dismissed the claim. The boy died two days later. His mother appealed to the Court of Appeal. The appeal was dismissed on 15 December 1992. The mother appealed to the House of Lords which dismissed the appeal on 13 November 1997. It took 13 years from the time of the injury to the resolution of the case by the House of Lords. The decision of the House of Lords is important on two points of law.

#### Bolitho on Bolam and findings of fact

10.32. The first point was on causation. The hospital admitted negligence, that is, breach of duty in that a doctor failed to attend to Patrick on time. However, the hospital argued that even if a doctor had arrived, he would not have intubated the boy and accordingly there was no causal connection. It

was argued for the plaintiff that the **Bolam** case had no application to questions relating to causation. It was settled law, established by the House of Lords long before the **Bolitho** case that the **Bolam** test has no proper place where the Court is confronted with matters of fact. The **Bolam** test applies when the Court is considering the question of law of whether the conduct is negligent on the basis of opinion evidence. In this regard, evidence of medical experts play a very vital role in the trial on liability. Causation, on the other hand, is a question of fact. See **Loveday v Renton** [1990] 1 Med LR 117, **Cavangh v Bristol & Weston Health Authority** [1992] 3 Med LR 49, **Joyce v Wandsworth** [1996] 7 Med LR 1. The House of Lords agreed that issues as to causation were not governed by the **Bolam** propositions of law, held that on the facts of the case, causal connection had not been proved because the doctor would not have intubated Patrick.

10.33. This point was affirmed by the English Court of Appeal recently in **Penney v East Kent Health Authority** [2000] PNLR 323. Lord Woolf MR said at 330-331 :

The **Bolam** test has no application where what the Judge is required to do is to make findings of fact. This is so, even where those findings of fact are the subject of conflicting expert evidence.

*Bolitho on Bolam and expert evidence (a sense of responsibility)*

10.34. The next question in the **Bolitho** case related to the weight and value of the opinion of the defendants' expert witnesses. It was argued for the plaintiff that : "the views of the defendant's experts were simply not logical or sensible". It was unreasonable and illogical. It was further argued that it was "ultimately for the court, not for medical opinion, to decide what was the standard of care required of a professional in the circumstances of each case". The House of Lords agreed with the principle of the submission. It was held that *a doctor could not escape liability for negligent treatment or diagnosis just because he leads evidence from a member of medical experts who are genuinely of the opinion that the defendant's treatment or diagnosis accorded with sound medical practice. The defendant's experts must constitute a competent, reasonable, respectable and responsible body of medical men. The opinion of the defendant's witnesses must be founded on logic and good sense. They must not adopt and implement a practice which carried an obvious risk.*

10.35. Lord Browne-Wilkinson, with whom the other Lords agreed, commented on the **Edward Wong** decision, and pointed out that in that case, "the body of professional opinion, though almost universally held, was not reasonable or responsible". He went on to apply the **Edward Wong** dicta in the medical negligence context, and at p 243 added this gloss to the principles established by the **Bolam** decision :

These decisions demonstrate that in cases of diagnosis and treatment there are cases where, despite a body of professional opinion sanctioning the defendant's conduct, the defendant can properly be held liable for negligence (I am not here considering questions of disclosure of risk). In my judgment that is because, in some cases, it cannot be demonstrated to the judge's satisfaction that the body of opinion relied on is reasonable or responsible. In the vast majority of cases the fact that distinguished experts in the field are of a particular opinion will demonstrate the reasonableness of that opinion. In particular, where there are questions of assessment of the relative risks and benefits of adopting a particular medical practice, a reasonable view necessarily presupposes that the relative risks and benefits have been weighed by the experts in forming their opinions. But if, in a rare case, it can be demonstrated that the professional opinion is not capable of withstanding logical analysis, the judge is entitled to

hold that the body of opinion is not reasonable or responsible.

I emphasise that, in my view, it will very seldom be right for a judge to reach the conclusion that views genuinely held by a competent medical expert are unreasonable. The assessment of medical risks and benefits is a matter of clinical judgment which a judge would not normally be able to make without expert evidence.... it would be wrong to allow such assessment to deteriorate into seeking to persuade the judge to prefer one of two views both of which are capable of being logically supported. It is only where a judge can be satisfied that the body of expert opinion cannot be logically supported at all that such opinion will not provide the bench mark by reference to which the defendant's conduct falls to be assessed.

10.36. What is stated above, is part of the law on the expert evidence. It requires that expert medical evidence, like all expert evidence, be subject to the scrutiny of the court and to be discarded if found to be unsupported by sound reason or logic.

#### Informed consent

10.37. In **Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital**, with regard to the duty of disclosure of the risks inherent in the proposed treatment procedure, Lord Bridge said the same thing at p 900 :

But even in a case where, as here, no expert witness in the relevant medical field condemns the non-disclosure as being in conflict with accepted and responsible medical practice, I am of opinion that the judge might in certain circumstances come to the conclusion that disclosure of a particular risk was so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it.

See also **Chatterton v Gerson** [1981] QB 432; **Hills v Potter** [1984] 1 WLR 641. These cases affirmed the principles that "the cause of action to base a claim for failure to inform of risks and implications is negligence, not trespass."

American Law is no different in this respect **Prosser and Keeton on Torts** at p 189-190 states the American Law :

A rapidly growing form of medical malpractice litigation involves the doctrine of "informed consent," which concerns the duty of the physician or surgeon to inform the patient of the risks involved in treatment or surgery. The earliest cases treated this as a matter of vitiating the consent, so that there was liability for battery. Beginning around 1960, however, it began to be recognized that the matter was really one of the standard of professional conduct, and so negligence has now generally displaced battery as the basis for liability.

10.38. Where, therefore, negligence is alleged in connection with a failure to furnish adequate and accurate information prior to the obtaining of the consent of the patient, a court can reach its own view independent of expert medical witnesses as to what is reasonable and responsible medical practice.

#### Consent is useless where there is no prophylactic reason

10.39. ***Doughty v North Staffordshire Health Authority*** [1992] 3 Med LR 81 is an important case. The plaintiff was born with a birthmark. After a plastic surgeon had worked on it over a period of 12 years the foundation of her life was ruined by the disfigurement of her face. Mrs Doughty was born in April 1957 with a pinkish lesion involving the skin of the right eye, right cheek, upper lip and right half of her nose. In medical parlance it was a capillary haemangioma. Its popular parlance in English was port wine stain. It was a quite benign lesion with smooth skin and did not necessarily have to be removed because it posed no danger to her life. Her parents contacted Mr Growcott, a plastic surgeon. In July 1957 Mr Growcott in a letter to the plaintiff's GP wrote as follows :

The port wine stain is amenable to surgery. She will need grafting but I prefer to let this wait until the child is very much older. Grafts at this stage do not do very well [- and these are the important words - ]. This type of lesion does not extend. It is the raised type which is dangerous and may extend rapidly. I would like to see her again in twelve month's time.

10.40. There were no prophylactic reasons for surgery. They were dealing purely with a cosmetic disability. All the same, Mr Growcott decided that it was a suitable case for surgery. He did a first operation in 1962 when she was five years old. He performed a second operation when she was six. He then performed on her face about 10 additional operations including skin grafting. The final operation was done in 1974 when she was 17. When Mr Growcott completed his job, the plaintiff's face was cosmetically in a worse condition than before he started. But for his professional services her appearance could have been improved by cosmetic make-up. Even that was made impossible by the condition caused by Mr Growcott. In 1978 she consulted a solicitor intending to sue Mr Growcott. The solicitors obtained an expert opinion and concluded that she had no case of negligence against Mr Growcott. On their suggestion she sought counsel's opinion. Counsel confirmed that there was no case. The next year she watched a television programme "That's Life". It dealt with medical accidents and how the law dealt with them. It prompted her to seek the help of a support group for victims of medical accidents. In the result an action was brought in 1997. By then she had become a divorcee mother. The charges made by her against the hospital and the surgeon were : (a) her skin condition should have been left alone why operate at all? (b) the consent of her parents to the operations was obtained without proper information and advice. In short they were misled by Growcott.

10.41. On the question of consent, Henry J found for the defendants. On the issue of the surgery, the Judge found for the plaintiff – Growcott was guilty of negligence in embarking on the surgery procedures. There were no prophylactic reasons calling for the surgery and no cosmetic benefit either when she was only five years old. The Judge said at p 92 :

I am unable to accept that there was a body of reasonable competent medical opinion in 1962 or 1963 that would have exposed this five year old child to that course of surgery to deal with her port wine stain. Accordingly, I am of the opinion that it was negligent to have embarked on this surgery.

10.42. ***Jackson & Powell on Professional Negligence***, Fourth Edition (1997) in paragraph 6-133 cite the case in support of this illuminating proposition of law :

With the growing panoply of available medical treatments, cases sometimes arise where medical practitioners attempt to treat the incurable or embark on treatment which is worse than the original disability. Thus before considering whether the method of treatment was negligent, it must sometimes be asked whether medical intervention can be justified at all.

10.43. In the next chapter I have summarised in point form the essential principles of the law relating to medical negligence.

## **Chapter 11 : The Ten Commandments**

11.1. This is a summary of the essence of the law of medical negligence :

(1) A medical practitioner who holds himself out as ready to give medical advice or treatment or is consulted by a patient or a prospective patient impliedly undertakes that he possesses the requisite skill, experience, training and knowledge for the purpose. He must not undertake to treat any disease or disorder that he is not knowledgeable on or experienced in. He must not embark on any treatment or medical procedure and in particular any radical treatment that he is not knowledgeable on, trained or experienced in (see : ***Hunter v Hanley; Bolam v Friern Hospital Management Committee***).

(2) A medical practitioner also owes his patient a duty of care in diagnosing the disease or disorder, advising on the therapy or prophylactic, and in the administering of the treatment (see : ***Hunter v Hanley; Bolam v Friern Hospital Management Committee***).

(3) The practitioner must bring to his task a reasonable degree of skill, knowledge and competence. He must also exercise a reasonable degree of care in the diagnosis, advice and treatment, in the light of the particular circumstances of the patient before him (see : ***Hunter v Hanley; Bolam v Friern Hospital Management Committee***).

(4) The very highest degree of competence and care is not required of him. He will not be permitted a very low degree of care and competence. The test is the standard of the ordinary competent specialist practitioner (see : ***Hunter v Hanley; Bolam v Friern Hospital Management Committee***).

(5) Where medical opinions diverge or where there is no usual and normal practice in place yet, the "reasonable standard" means that a medical practitioner must act in accordance with a practice accepted as proper by a responsible, competent and respected body of medical men ordinarily skilled in that particular art, even though a body of contrary opinion also exists among medical men (see : ***Hunter and Hanley; Bolam v Friern Hospital Management Committee***). In doing so, he must ensure that the practice he has adopted stands on the ground of logic and sense and that he has the support of reputable and responsible experts who will support him with logic and sense (see : ***Edward Wong Finance Co Ltd v Johnson Stokes & Master; Bolitho v City and Hackney Health Authority***).

(6) If there is a special requirement or accepted practice with regard to the diagnosis, advice or treatment, he must comply with it. This is over and above the ordinary reasonable standard and depends on the particular circumstances of the case (see : ***Chin Keow v Government of the Federation of Malaya & Anor; Greaves & Co v Baynham Meikle & Partners; Readhead v Midland Railway Co***).

(7) If a proposed treatment carries with it a high magnitude of risks and adverse side effects, he must ensure that the disease or disorder is serious enough to warrant such high-risk treatment procedure to be undertaken. The law in all cases exacts a degree of care commensurate with the risk (see : ***Doughty v North Staffordshire Health Authority***).

(8) Where high-risk measures are to be undertaken, the medical practitioner, when circumstances permit, must give adequate and unambiguous information, explanation and warning to the patient in the presence of those close to the patient and give the patient ample opportunity to make the decision and give his informed consent in response to the advice (see : ***Chatterton v Gerson; Hills v Potter; Sidaway v Governors of the Bethlem Royal Hospital and the Maudsley Hospital***).

(9) When a treatment or surgical procedure involves a team, someone must take responsibility as the team leader and ensure that everyone in the team understands his function and responsibility and the precaution each is required to take.

(10) Finally, the practitioner must make and preserve adequate, accurate and unambiguous notes as circumstances warrant. This is particularly so in high-risk and novel treatment cases.

### The Authorities

11.2. The summary of the essential principles are extracted from cases discussed in the previous chapter, other cases, the evidence of the expert witnesses in this case and ***Halsbury's Law of England***, Fourth Edition, Vol 30 and 2001 ***Cumulative Supplement*** on the Medical Profession and Medical Practice Paras 35-41. ***Jackson & Powell on Professional Negligence***, 4<sup>th</sup> Edition, and its ***Third Cumulative Supplement*** (2000) bore the torch all the way. Its help was immense.

## **Chapter 12 : The Law of Expert Evidence**

### Expert evidence

12.1. As in every complicated medical negligence case, expert evidence played a crucial role in the trial on liability. Before examining the evidence of the many expert witnesses in this case, I shall, in this chapter, state and elaborate the vital principles and propositions relating to expert evidence and witnesses.

12.2. The ***Evidence Act*** (Cap 97) by s 47 provides, inter alia, that "When the Court has to form an opinion upon a point of science or art, the opinions upon that point of persons *specially skilled* in such science or art are relevant facts". Such persons, says the section, are experts. The Court must receive all relevant evidence. Any evidence is admissible if it enables the Court to discover the truth or if it is relevant to the facts in issue, but it need not be exclusively relevant to those facts. See s 11 of the ***Evidence Act***. An expert's opinion evidence is relevant and admissible because it is impossible to do justice without a proper understanding of the facts and reasons for a correct decision. The great American Judge and Jurist, Benjamin Cardozo, once said "Assume that the judges know the rudiments of the law". To that I would add : "Assume that judges will take judicial notice of general knowledge and knowledge of the common affairs of life which men of ordinary intelligence possess." See s 58 of the ***Evidence Act*** and ***Peart v Bolckow, Vaughan & Co*** [1925] 1 KB 399. On

matters outside those areas, a Judge cannot justly and fairly make a decision without help from men with specialist knowledge, skill and experience in a given subject, simply because he is not knowledgeable in them. The justification for this rule is to be found in **Folkes v Chadd** (1782) 99 ER 589. Lord Mansfield said at p 590 "In matters of science, the reasonings of men of science can only be answered by men of science". Lawton LJ in **Reg v Turner** [1955] 1 QB 834 at p 841 added this gloss to Lord Mansfield's statement :

The opinion of scientific men upon proven facts may be given by men of science within their own science. An expert's opinion is admissible to furnish the court with scientific information which is likely to be outside the experience and knowledge of a judge or jury. If on the proven facts a judge or jury can form their own conclusions without help, then the opinion of an expert is unnecessary. In such a case if it is given dressed up in scientific jargon it may make judgment more difficult. The fact that an expert witness has impressive scientific qualifications does not by that fact alone make his opinion on matters of human nature and behaviour within the limits of normality any more helpful than that of the jurors themselves; but there is a danger that they may think it does.

#### Court decides the issue

12.3. The opening words of s 47 of the **Evidence Act** (supra), "When the Court has to form an opinion," make it clear that opinion evidence when accepted becomes the decision of the Court. It is the Court that finally forms the final opinion and makes the decision. The section also dictates that in matters of science and art the Court must receive the findings and reasons of experts and only then determine the issues and decide the case. The responsibility of making the conclusion and decision at all times, however, rests solely with the Court. Accordingly, experts, however eminent, must never be allowed to usurp the functions of the Court and decide an issue or, still worse, the case. The Court must never shunt that responsibility to witnesses.

12.4. In this regard the dictum of Cooper LJ in **Davie v Magistrates of Edinburgh** [1953] SC 34 at p 40 is very pertinent :

Expert witnesses, however skilled or eminent, can give no more than evidence. They cannot usurp the functions of the jury or Judge sitting as a jury, any more than a technical assessor can substitute his advice for the judgment of the Court – *S.S. Bogota v S.S. Alconda*. Their duty is to furnish the Judge or jury with the necessary scientific criteria for testing the accuracy of their conclusions, so as to enable the Judge or jury to form their own independent judgment by the application of these criteria to the facts proved in evidence. The scientific opinion evidence, if intelligible, convincing and tested, becomes a factor (and often an important factor) for consideration along with the whole other evidence in the case, but the decision is for the Judge or jury. In particular the bare *ipse dixit* of a scientist, however eminent, upon the issue of controversy, will normally carry little weight, for it cannot be tested by cross-examination nor independently appraised, and the parties have invoked the decision of a judicial tribunal and not an oracular pronouncement by an expert.

#### Opinion must be based on sound facts and reason

12.5. It being the Court, and not the expert witness, that ultimately decides the issue and the case, the opinion of the expert must always be accompanied by the proven facts and findings upon which it

is premised. The court must know the premises on which the expert's opinion is founded, so as to judge the strength of that opinion. The **Evidence Act** by s 48 of the **Evidence Act** provides that "facts not otherwise relevant are relevant if they support or are inconsistent with the opinions of experts when such opinions are relevant." The underlying jurisprudential basis of this provision is that unless an opinion is based on proven facts and findings it would be speculative and useless.

12.6. In scientific decisions, as in judicial decisions, there cannot be correct conclusions without correct evidence of facts. There can be no proof without evidence. As Sir Arthur Conan Doyle said : "It is a capital mistake to theorize before one has data." An eminent scientist, Richard Dawkins, the author of **Selfish Gene**, says that the sole basis of sound belief is sound reason. He equates good evidence with sound reason. The stronger the evidence the sounder the proof. The basis of s 48, of the **Evidence Act** is a long-established judicial axiom apposite to judicial process : witnesses may lie, but circumstances cannot lie. "Circumstances" here mean those facts which with the aid of reason lead to the right inference, that is, right opinion.

12.7. Lawton LJ put it pointedly in the judgment of the Court in **Reg v Turner** [1975] 1 QB 834 at 840 :

Before a court can assess the value of an opinion it must know the facts upon which it is based. If the expert has been misinformed about the facts or has taken irrelevant facts into consideration or has omitted to consider relevant ones, the opinion is likely to be valueless.

Thus, expert evidence has two components : (i) facts and (ii) opinion. Some expert evidence may be confined to facts alone. For example when a chemist makes a statement as to the contents of a prohibited drug, or a surveyor ascertains the area of a piece of land, it is a statement of fact. But opinion or belief must be founded on accurate facts. S 48 of the Evidence Act stresses the importance of facts from which opinion emerges. The Rules of Court recognizes this dichotomy between facts and opinion. See O 40 r 1 (1).

12.8. The **Evidence Act** by s 53, provides that "whenever the opinion of any living person is relevant, the grounds on which such opinion is based are also relevant." The grounds are relevant because without them the opinion is utterly useless. Evidence and reason are two indispensable pillars of justice. As it is incumbent on the Court to make reasoned conclusions, the opinions of experts, *ex necessitate*, must be based on reasons.

12.9. The proposition was elegantly stated by Washington J in **Harrison v Rowan** (1820) 11 F. Cas. 658 :

the mere opinions of the witnesses are entitled to little or no regard, unless they are supported by good reasons, founded on facts. ... If the reasons are frivolous or inconclusive, the opinions of the witnesses are worth nothing.

Another American Judge, Duncan J, said the same in **Rambler v Tryon** 7 S & R 94 (as quoted in **Sarkar On Evidence**, 15<sup>th</sup> Edition (1999) at p 960 :

Opinion is no evidence, without assigning the reason of such opinion.

12.10. **Sarkar On Evidence**, Fifteenth Edition (1999) at p 960 explained the substance of s 53 of the **Evidence Act** in these words :



The soundness or otherwise of the opinion expressed must depend to a large extent on the reasons on which the opinion is held. If the grounds are known, the value of the opinion may be increased or lessened. An expert whose special knowledge on a subject is derived from a study only of standard authorities is not incompetent to testify, but if it is found that that study was made solely for the purpose of deposing in the case in question, and that it was not in the line of his profession, he becomes incompetent to testify. Or, if it is found that his opinion is not based solely on the study he had to make in the pursuit of his calling or profession, but also on his own experience or actual observation, that opinion necessarily acquires a higher value. Persons who pretend to be experts without any special skill or experience may be exposed by questioning him about the grounds of his opinion.

### The rule against hiding and siding

12.11. It will be readily appreciated that the provisions of the Evidence Act mentioned above constitute the rule against hiding and siding. The expert witness is under an obligation to assist, and not mislead the Court. Accordingly the expert witness must not hide any relevant material from the Court. And he must not side with any party, not even the party who calls or pays him. Lord Langdale MR said in **Langley v Fisher** (1843) 49 ER 650 at p 651:

Generally speaking, a witness has no business to concern himself with the merits of the case in which he is called on to give evidence or whether, when given, it will be material to the cause.

12.12. The sense of detachment stated by Lord Langdale MR applies with greater force to expert witnesses. So the law imposes two important duties and responsibilities on the expert witness :

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|-----------|---|
| First,    | expert evidence presented to the Court should be, and should be seen to be, the independent product of the expert uninfluenced as to form or content by the expediciencies of litigation – <b>Whitehouse v Jordan</b> [1981] 1 WLR 246.   |
| Secondly, | an expert witness should provide independent assistance to the Court by way of unbiased opinion in relation to matters within his expertise. See <b>Polivitte Ltd v Commercial Union Assurance Company PIC</b> [1987] 1 Lloyd's Rep 379 and <b>National Justice Compania Naviera SA v Prudential Assurance Co Ltd</b> (The <i>Ikarian Reefer</i> ) [1993] 2 Lloyd's Rep 68. |

12.13. In practice, however, the above norms were almost always never observed. The dissatisfaction of the Court with expert evidence is succinctly summarised in **Sarkar On Evidence**, 15<sup>th</sup> Edition (1999) at pp 929-930 :

Perhaps the testimony which least deserves credit with a jury is that of *skilled witnesses*. These gentlemen are usually required to speak, not to facts, but to *opinions*; and when this is the case, it is often quite surprising to see with what

facility, and to what extent, their views can be made to correspond with the wishes and interests of the parties who call them. They do not, indeed, wilfully misrepresent what they think, but their judgment becomes so warped by regarding the subject in one point of view, that, when conscientiously disposed, they are incapable of expressing a candid opinion. Being zealous partisans, their belief becomes synonymous with faith as defined by the Apostle, and it too often is but "the substance of things *hoped for*, the evidence of things *not seen*". To adopt the language of Lord Campbell "skilled witnesses come with such a bias on their minds to support the cause in which they are embarked, that hardly any weight should be given to their evidence" [*Tracy Perrage Case* (1843) 10 Cl&F 154, 191; *Tay s 58*]. In *Middlings P Co v Christian*, 4 Dillon, 448, 459, Miller J, said :-

My own experience both in the local courts and in the Supreme Court of the United States is that, whenever the matter in contest involves an immense sum in value, and when the question turns mainly upon opinions of experts, there is no difficulty in introducing any amount of them on either side.

The infirmity of expert evidence consists in this that it is mostly matters of opinion and is based on facts detailed by others or assumed facts or opinion against opinion and experts are selected by parties by ascertaining previously that they will give an opinion favourable to the party calling them.

12.14. Lord Jessel MR in ***Thorn v Worthing Skating Rink Company*** (1876) 6 Ch D 415 mentioned that in one case a party had commissioned 68 expert's reports until a favourable one was obtained.

#### Duty to court and not party

12.15. In order to remedy this malady in the judicial process and remind lawyers and expert witnesses of the latter's duties and obligations, the **Rules of Court** by O 40A r 2 provides that :

(1) It is the duty of an expert to assist the Court on the matters within his expertise.

(2) This duty overrides any obligation to the person from whom he has received instructions or by whom he is paid.

12.16. Furthermore, Order 40A rule 3 (2)(h) requires the expert witness to state in his report that he understands that his duty is to the Court and that he complies with that duty. The expert must not only be impartial but must also appear to be so. The expert should avoid being the witness of a party with whom he has a special relationship. If that is unavoidable he must disclose the relevant facts. On this point there must be absolute transparency from the expert witness and their legal advisers for they are both officers of the Court.

12.17. In conclusion, where expert witnesses, and the lawyers who use them, adhere and follow the above dictates faithfully, their talent will flourish. Otherwise it will perish.

## **Chapter 13 : A New Case for the Defence**

A positive case must be pleaded

13.1. It is necessary to begin this chapter with a point of law relating to procedure and evidence. Stated in a sentence : When a defendant has an affirmative case of his own in answer to the plaintiff's assertions he must specifically state it in the defence. He cannot content himself with a mere denial. As Buckley LJ said succinctly "reasons of practice and justice and convenience require the party to tell his opponent what he is coming to prove". See ***In Re Robinson's Settlement, Gant v Hobbs*** [1912] 1 Ch 717 at p 728

13.2. It is a positive requirement that a defendant must state his positive case. He is not permitted to insinuate his after thoughts into a bare denial. The purpose of a denial is to dispute and force the plaintiff to prove his case. A denial does not entitle the defendant to cast about and come up with justifications at the trials. Such conduct cannot be condoned particularly when his new defence negatives a positive case framed before the close of pleadings. Should he do so he will crush his own credibility. See generally ***Davie v New Merton Board Mills Ltd*** [1956] 1 WLR 233.

13.3. The point arose in ***Regina Fur Company Ltd v Bossom*** [1958] 2 Lloyd's Law Rep 425. Lord Evershed MR at p 427 made the point with great flair and force :

A defendant – whether he is an underwriter or any other kind of defendant – is entitled to say, by way of defence, "I require this case to be strictly proved, and admit nothing". Where such is the defence, the onus remains throughout upon the plaintiffs to establish the case they are alleging. Where such is the form of the pleading, it is not only not obligatory upon the defendants but it is not even permissible for them to proceed to put forward some affirmative case which they have not pleaded or alleged; and it is not, therefore, right that they should, by cross-examination of the plaintiffs or otherwise, suggest such an affirmative case.

Lord Evershed MR added that the trial Judge will watch carefully that the defendants :

- First, do not attempt by evidence or cross-examination, to establish some affirmative case of which no proper notice has been given by way of pleading to the other side;
- Second, do not attempt to lead evidence solely directed to the credit of witnesses.

13.4. In this case the defendants were in flagrant breach of the rules I have mentioned. They pleaded one case and presented another case which went against the pleaded case. They made a U-Turn on many a point. Nonetheless, I permitted them to proceed because I did not wish to adjudicate on the basis of procedural flaws. In this regard I remembered the words of Buckley LJ in ***In Re Robinson's Settlement, Gant v Hobbs***. Referring to a situation where the defendant is in breach of the rule he said :

If he does not do that the Court will deal with it in one of two ways. It may say that it is not open to him, that he has not raised it and will not be allowed to rely on it; or it may give him leave to amend by raising it, and protect the other party if necessary by letting the case stand over. The rule is not one that excludes from the consideration of the Court the relevant subject-matter for decision simply on the ground that it is not pleaded. It leaves the party in mercy and the Court will deal with him as is just.

### Tumour diagnosis

13.5. In tumour diagnosis practice, there is no substitute for biopsy and histopathological examination. That is the study of the anatomy of tissue cells and minute cellular structure with a microscope after the cells have been stained. In a case where biopsy is not possible or advisable, or where it has already been established that the growth is a benign tumour, determination of the rate of growth of the lesion becomes crucial and essential. Dr Esther Tan had emphasised a follow-up after the February 1996 MRI to ascertain whether there was growth or spread. Dr James Khoo, adhering to the advice of Dr Esther Tan, advised a follow-up and eventually commissioned a follow-up MRI 10 months later. He did not deem it advisable or necessary to do a biopsy. After all, a biopsy had been done just three months earlier and it was accepted by all concerned – histological examination of the tumour removed by surgical resection demonstrated that it had none of the markers of a malignant tumour.

13.6. The adjectival phrase "low grade" was appended by Dr Anjula Thomas to the earlier diagnosis of "primary glial tumour". Dr Carol Kwan did not append it to the neurocytoma as it had none of the features of malignancy. The ascertainment of whether there was a rapid or significant growth of the lesion to warrant a prophylactic or therapeutic radiation or laser treatment was the sole reason for the follow-up MRI 10 months later in December 1996.

13.7. Dr Esther Tan in her report of 27 December 1996 stated with clarity that the nodule protruding from the roof of the left lateral ventricle did not change significantly when compared with the previous study of 26 February 1996. The report was made by Dr Esther Tan without prior knowledge of the previous histological finding of neurocytoma or the radiotherapy performed on Gunapathy. She assumed that there might have been a remnant tumour in the sense that the excision was incomplete.

### The defendants' case before Dr Robert Smee

13.8. Both Dr James Khoo and Dr Khor accepted and adhered to Dr Esther Tan's finding of no significant change. In any event they did not dispute it before the radiosurgery was advised and performed. In their letters to Michael Khoo & Partners they did not postulate any growth or change in the lesion. Their defences did not assert that there was a perceivable growth or change in the lesion between February 1996 and December 1996.

### Histologically benign but clinically aggressive tumour

13.9. The idea of a "histologically benign but clinically aggressive tumour" made its advent in this case when defence counsel, Mr Karuppan Chettiar, cross-examined Dr Prem Pillay, Gunapathy's witness. As that time I had difficulty in understanding the concept. Later I understood its meaning.

13.10. The neurocytoma before the resection supported and illustrated the idea distinctly. The neurocytoma housed in Gunapathy's left ventricle before resection was histologically benign but clinically morbid. It had grown downwards, touched and obstructed the foramen of Monroe and caused hydrocephalus. When it was discovered, it had become a life-threatening growth which had to be removed or shrunk by a surgical or other medical procedure. Once it was removed by surgery the idea of a clinically aggressive tumour became inapplicable to Gunapathy. It was not this idea that made Dr James Khoo and Dr Khor offer radiosurgery to her. According to their original defence, Gunapathy had insisted on undergoing radiosurgery so that she could proceed with her plans to conceive. It was raised by Dr Smee after the trial began. It was a lifeline which Dr Robert Smee threw to rescue the doctor defendants. I shall now consider the new theory of Dr Robert Smee.

Dr Robert Smee introduces a new case

13.11. Dr Robert Smee had lectured on *XKnife* radiosurgery to a group of people in October 1995. Dr Khor and Dr Ho Kee Hang had attended the lectures. The lecture notes kept by Dr Khor included a prescription of high-single dose radiosurgery to a previously irradiated recurrent glioma (a high-grade malignant glial tumour). A publication by Radionics, the manufacturers of *XKnife* radiosurgery equipment, read with a study called RTOG 90-05 suggested the same prescription – high-single dose radiosurgery for a previously irradiated recurrent glioma. The line of defence conceived by Dr Robert Smee was an attempt to bring the radiosurgery done to Gunapathy with the parameters of his lectures and RTOG 90-05 study – a high-single dose radiosurgery to a previously irradiated recurrent tumour (a high-grade tumour).

13.12. By way of expert evidence, Dr Robert Smee introduced a positive case for the defence which was not the pleaded case of the defendants. Dr Robert Smee's expert opinion emerged after the trial had commenced. Before he revealed his opinion the doctors' defences were: (a) it was on the insistence of Gunapathy that they had carried out the radiosurgery; and (b) the nodule could not be a scar because it was on the roof, and the site of previous surgery was the floor and not the roof. Before Dr Robert Smee came to give evidence, the defendants relied on Dr Esther Tan's reports without qualification. At the trial, the new point shaped by Dr Robert Smee took centre stage. The defence team did not even realise this until I pointed it out.

13.13. The first time it was suggested or asserted that the nodule had changed and that it behaved malignantly was after the defendants' experts came into the case. Dr Robert Smee, a radiation oncologist attached to Prince of Wales Hospital, Sydney, was the leader of the defendants' team of experts. He was also a promotor of the *XKnife* system, a fact which he chose not to reveal to the Court. He produced a report which he signed in the witness stand.

13.14. Dr Robert Smee in his report postulated a new theory. Relying on the CT scan done five days after the surgical removal of the neurocytoma, he said :

Here we have on the one hand the confidence that there is no residual disease post macroscopically complete resection.

13.15. Having satisfied himself that there was no residual tumour, he took note of the radiotherapy done after the surgery in December 1995 and January 1996. He then relied on the appearance of the nodule in the February 1996 and drew this conclusion :

Thus in February 1996 we have the demonstration of a "recurrent" nodule.

The decision was made to proceed through to radiosurgery, and at that procedure with imaging performed on the day the maximum diameter nodule of 19 mm was noted. One interpretation of this is the nodule had actually increased in size between the scan of December 1996 and treatment procedure of 31.1.97. The alternative and more likely option is that much finer slices are performed for the radiosurgery procedure, and thus it is more easy to accurately assess the true size of this lesion.

13.16. Dr Robert Smee's evidence that the nodule had grown to 19 mm by January 1997 was a statement of great consequence. Prima facie, it purported to demolish Dr Esther Tan's report in December 1996 and made her report appear utterly unreliable. Dr James Khoo took the cue and pronounced Dr Esther Tan as an incompetent brain MRI radiologist. Thus Dr Robert Smee's newfangled

theory radically changed the colour and character of the defendants' case.

13.17. Based on the above postulate of 19 mm diameter, Dr Robert Smee presented a proposition and a justification fused into one. He said :

*Although neurocytomas can be regarded as histologically benign, their behaviour is variable*

. The enclosed articles indicate that recurrences do occur. I have certainly in my own practice had occasions to treat recurrent neurocytomas. Although various proliferative markers indicate a very low mitotic index for these types of tumours, one has to put that into context of the circumstances relating to this particular patient. ...

*This patient presented with neurological findings entirely consistent with a central neurocytoma*

. Neurosurgical excision of this is certainly an appropriate option. The documentation I have is that a macroscopically complete resection took place, and *her post operative CT scan was reported as demonstrating no evident residual disease*. A post operative pre radiotherapy MR scan was not performed. I note she proceeded onto a course of fractionated radiotherapy receiving a dose of 5400 rads in 27 fractions to the 90% isodose curve by a 3 field technique, the maximum field diameter being 4.5 cm. These fields could certainly not be described as large volume. She was well subsequent to that, however her progress MR scan (the first post surgery) in February 1996 suggested a well defined lesion within the roof of the left lateral ventricle. In the report of 26.2.96 mention is made that it may have been difficult to know with certainty whether this represented scar tissue post surgery, or tumour. It should be noted that this scan was performed 3 months after surgery and the likelihood of this being representative scar tissue would be very low. *It would be more appropriate clinically thus to regard this as residual tumour*. The option was then taken of repeating the scan ten months later and the nodule was still persistent. It was reported as having not increased in size but on the MR scans forwarded to me (copies) the nodule appeared to be more enhancing on that later scan. It is thus appropriate that some concern be recorded regarding this feature. Here we *have on the one hand the confidence that there is no residual disease* post macroscopically complete resection, and then a nodule becoming apparent three months later following surgery and radiotherapy. Surgical resection of that would carry with it some morbidity, and thus the concept since the lesion appeared to border the lateral ventricle, that stereotactic radiosurgery was an appropriate option. I have certainly treated lesions in this manner by similar procedure.

Central neurocytoma are quite uncommon, with any individual treating brain tumours only likely to see personally less than 10 throughout their working lifetime. A larger centre may accumulate a greater number however this would be over a considerable time frame. On reviewing MEDLINE, to January 2001 there are only 256 articles published on neurocytomas. Approximately 120 of these have been since this patient first presented, many of the preceding ones were in non clinical journals. Two of the more recent text books on "brain tumours" devote less than a page to a description of the pathology and clinical behaviour. Enclosed are a number of articles published during mid 1996 that have appeared in the clinical literature (as opposed to the pathology or radiology literature that may not be easily accessible to a practicing clinician). Although the articles stress the more favourable prognosis, there is a mixture of treatments provided, with radiotherapy included as a component of treatment in some of the articles,

even institutions such as Massachusetts General Hospital in Boston. Up to 1995 I was certainly using radiotherapy as part of the treatment approach in patients with neurocytomas. Thus it was certainly "reasonable" to consider the addition of radiotherapy post operatively, despite the perception of a macroscopically complete removal. The question thus is not whether it is absolutely advisable that the patient should have had treatment, rather that it was "reasonable" to provide it. On the basis of the literature to that date this patient's management was not a deviation from accepted medical care.

*Thus in February 1996 we have the demonstration of a "recurrent" nodule*

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The fact that this tumour had become more prominent (ie progressed) indicates that this is a somewhat more biologically aggressive lesion, growing in the face of what was previously a quite reasonable dose. One would thus aim to give an adequate dose to achieve local control of that tumour. The determinant size on the imaging performed on the day was 1.9 cm, and thus a dose of 2000 rads to the 85% isodose curve using a 2.25 cm cone would seem reasonable under that circumstance.

13.18. Notably, that in one breath Dr Robert Smee said that "it would be more appropriate to clinically regard this tumour as *residual tumour*". In the next breath he said : "Here we have the confidence that there is no *residual disease*". And then he asserted : "thus in February we have the demonstration of a *recurrent nodule*". It is also notable, that his concept of a *recurrent tumour* is postulated to depend on a complete excision of the neurocytoma from Gunapathy's brain, and a negative CT scan. These two premises were later proven to be false premises and unfounded.

#### Faults and flaws of Dr Robert Smee

13.19. Dr Robert Smee's perception of the existence of a 19 mm tumour in January 1997, and his two propositions were inherently flawed in more than one way. First, in order to see whether there was a change in the nodule's size, from February 1996 to December 1996, and then January 1997 the comparison must be done with MRI slices of the same intervals. In other words, before there can be a proper comparison of the scans, the variables must have been kept constant. The 1996 MRIs had not been done with the same intervals as the January 1997 images, because the January 1997 images had been done solely in preparation for the radiosurgery itself. In fact, the decision to proceed with radiosurgery, had already been made, and that decision was not the result of the January 1997 images.

13.20. Next, the imaging for radiosurgery in January 1997 was not done by Dr Robert Smee. It was done by the radiation physicist at Mt E Hospital. I did not have the benefit of his evidence. Nor did Dr Robert Smee. Dr Robert Smee was speculating on the imaging. It therefore became necessary to examine the January 1997 images closely to test the truth of Dr Robert Smee's assertions.

13.21. When he took the witness stand, Dr Robert Smee made a major modification to his perception of a 19 mm tumour. One day before he took the witness stand, he went to Mt E Hospital and viewed the actual XKnife planning images of January 1997 stored in the computer. He said in evidence :

I based my assessment of the size on my own evaluation of the (axioemaslysis) and not on something that was marked out. The 19 mm is a transverse diameter, which is the maximum diameter – to encompass this lesion, not an anterior,

posterior, medial lateral transverse diameter. [NE 724 – L 15-19].

In view of this new evidence, there was no common basis for comparison of the January 1997 computer image with Dr Esther Tan's December 1996 MRI image. Dr Esther Tan's dimensions did not give the transverse diameter which will be much greater than the length of lesion. The maximum diameter is the diagonal measurement of the lesion. In crude terms it reflects the Pythagoras' theorem  $L^2 + B^2 = H^2$ .

13.22. The matter did not end there. I asked to view the images of 31 January 1997 which purportedly demonstrated a tumour of 19 mm. I was told that it was in Mt E Hospital. So I went to the computer room of the radiation oncology department of Mt E Hospital. This was days after Dr Robert Smee had completed his evidence and had left Singapore. The visit to the hospital was an enlightening experience in more ways than one. Dr James Khoo and Dr Khor were there. Dr Esther Tan and Dr Tsao were there. So was Dr Prem Pillay, who perceived Dr Robert Smee's assertions with very strong scepticism. And of course, the physicist who did the January 1997 imaging was the central person at the session. After viewing the computer scans and Dr Esther Tan's 1996 MRIs, and having heard the various comments, I directed Dr Esther Tan to be recalled to give evidence in Court.

#### Dr Esther Tan's evidence – the second appearance

13.23. Dr Esther Tan was recalled. In the course of receiving her evidence, the Court also received inputs from the others. In the result the following points were clearly established. On the [January 1997] radiosurgery imaging, unlike the diagnostic MRIs [in 1996, scales or measurements were not available. The mouse did the measurement of the lesion. The XKnife software, unlike the MRI device, did not have the tools to measure the dimensions of the tumour. More importantly, the [January 1997] radiosurgery image was something created or drawn by the radiosurgery team. It was a graphic simulation by the XKnife software. It was shaped and somewhat magnified by the XKnife software. It was not a representation of the real lesion in the plaintiff's brain. It was a modified and magnified image for radiosurgery treatment purpose.

13.24. It was Dr Prem Pillay who alerted the Court to the flaws in the evidence of Dr Robert Smee. Dr Khor was obviously aware of the flaws and to his credit he readily confirmed the truth. But it must be remembered that Dr Robert Smee had visited Mt E Hospital before he gave evidence and modified his evidence about the 19 mm diameter of the lesion. It should also be mentioned here that Dr Khor in his defence and affidavit of evidence-in-chief had revealed that the maximum diameter of 19 mm was a component of radiosurgery planning. He did not assert in his pleading that the nodule had grown from 12 mm to 19 mm during the brief period between 27 December 1996 to 31 January 1997 (35 days).

13.25. Dr Prem Pillay explained it as follows :

When we draw for a radiosurgery case, it's actually quite different from when the radiologist does measurements. When the radiologist does measurements, they will measure from one tip of the lesion to another tip of the lesion. But when we draw with a mouse, we actually draw with a slight margin around a lesion or a nodule. ... Again the angle is also quite different because this measure is obtained not directly as the radiologists do in a diagnostic MRI but obtained of the printout is made. [NE 1467-68].

13.26. It became clear that a collimator, which has a fixed diameter, was used to measure the diameter of the simulated target on the screen. The purpose of this was simply to determine which of the different sized collimators should be used in the radiosurgery. Dr Prem Pillay added :



The 19 mm was not a measured dimension of the supported tumour on 31 January 1997. It was an artificial construct made by a neurosurgeon on that for the purpose of radiosurgery planning. It is not used for the purposes of comparing it with other diagnostic MRIs. It is a MRI used for therapy. [NE 1468 – L 14-24].

13.27. Dr Esther Tan, with characteristic impartiality, frankness and clarity, said :

I don't have the (radiosurgery) scans from February, we only have diagnostic scans from February 1996. If we had similar radiosurgery type scans from February 1996, then we could try and compare those with these to see if there has been any change in size. But because we don't, I cannot tell you whether there's actually been a growth in this particular abnormality between December 1996 and January 1997 (one month) or whether it is just purely a difference in the way, in the technique of acquiring the image that could explain the change. It appears bigger but I don't know whether that is because the scan is done differently ... because the scans were done differently, it is very hard to actually compare them. Because the techniques used for both, the two examinations were different ... . I can't tell you whether it's actually grown or not unless we actually had 3 mm scans from December 1996 to compare. [NE 1511-1513]

13.28. On the question of whether the nodule had dramatically grown from 12 mm to 19 mm in the short time between 27 December 1996 and 31 January 1997, my conclusions are as follows :

(a) It is an issue of fact and accordingly not governed by the **Bolam** principle. The Court must determine the issue based on all the evidence and in particular the expert evidence.

(b) The onus of establishing that it had grown so aggressively was on the defendants. On the totality of evidence, the defendants had not established it. In fact it was not actually asserted by any of the defendants. It was not in their pleaded case. It was a theory conceived by Dr Robert Smee for the purpose of giving evidence for the defence. Even he abandoned it when he gave evidence.

#### Tumour recurrence theory

13.29. I now advert to another aspect of Dr Robert Smee's expert evidence. This was the theory that the nodule was a tumour *recurrence*. It went like this :

... a macroscopically complete resection took place and her post operative CT scan was reported as demonstrating no evident residual disease. A post operative pre-radiotherapy MR scan was not performed. I note she proceeded onto a course of fractionated radiotherapy receiving 5400 rads in 27 fractions to the 90% isodose curve. ...

... her progress MR scan (the first post surgery) in February 1996 suggested a well defined lesion within the roof of the left ventricle. ...

... the likelihood of this being representative scar tissue would be very low. It would be more appropriate clinically thus to regard this as residual tumour. ...

Thus in February 1996 we have the demonstration of a "recurrent" nodule. ...

... If the radiological interpretation is consistent with residual/recurrent disease then I would certainly not be persuaded away from further action despite a negative biopsy.

13.30. The labels "residual" and "recurrent" actually appear in his written opinion. His conclusions of the a recurrent nodule is founded on the assumption of total excision of the neurocytoma from Gunpathy's brain in the November 1995 operation and negative CT scan. He categorically concluded that it was a recurrent tumour. Then, on the assumption of a recurrent tumour with 19 mm diameter he said that the radiosurgery dose of 2000 rads to the 85% isodose curve using a 22.5 mm cone (collimator) would seem "reasonable under that circumstance". His answer begs the question. Since it is undisputed that such a CT scan cannot reveal any residual tumour or nodule or scar, and there is no way to prove conclusively that the November 1995 operation achieved total excision. His expert evidence was based on unfounded assumptions and facts, which, once exposed, had no leg to stand.

13.31. Dr Tsao and Dr Prem Pillay later measured the diameter of the lesion as 14 mm as against Dr Robert Smee's assumed 19 mm.

13.32. When Dr Robert Smee was cross-examined, he said that personally he would override the findings and report of Dr Esther Tan that the nodule was a scar and no further action need to have been taken without any further investigation, inquiry or second opinion. I asked Dr Tsao Shiu Ying, the medical expert called by the plaintiff, to comment on Dr Robert Smee's comment that he would override Dr Esther Tan and proceed to perform the radiosurgery without further ado. Dr Tsao Shiu Ying said : "I think it would be irresponsible". Dr Tsao ShiuYing rightly said so.

13.33. Having tested both the facts and reasoning upon which Dr Robert Smee based his expert opinion, I conclude that Dr Robert Smee was irrational and irresponsible, for the evidence considered as a whole established beyond doubt that there was no tumour recurrence, and that the diameter of the lesion had not increased from 12 mm in December 1996 to 19 mm in January 1996. This was the false foundation on which he formulated his theory that the "histologically benign tumour" was "clinically malignantly". This theory was necessary to justify the high dosage of radiation administered with a 22.5 mm collimator.

13.34. I have grave doubts about his claim that he had handled a neurocytoma case which was relevant to this present case. So I directed him to send them to me. He never did.

#### Dr Karlsson on growth of lesion

13.35. Dr Karlsson, another medical expert witness, called by the defence also subscribed to the theory there was an aggressive growth of the nodule. In his report, he stated as follows at p 2 :

The enhancing nodule was visualised in February 1996, one month after radiotherapy was given. The lesion did not decrease in size in 10 months' time, and if any changes between the MR images in February and December 1996, the lesion is bigger rather than smaller.

13.36. The above statement glossed over the question of growth in size. Later, it became clear that his narration of facts had been supplied to him and he assumed them to be true. Dr Karlsson's oral evidence on recurrent tumour will be discussed later.

13.37. After the issue of growth became a burning issue, he returned to Sweden and had a look at the MRIs with the guidance of his radiologist. He even came up with a report from his radiologist. The radiologist was not called as a witness. The report therefore was hearsay and thereafter inadmissible and cannot be relied on. I excluded it for that reason.

13.38. Dr Karlsson said in evidence that the nodule was a recurrent tumour. He did not want to concern himself with the previous histological reports on the neurocytoma. The histological reports were not in favour of his postulates. He relied on the defence's allegations of total excision and negative CT scan which other witnesses of the defendants were not in favour of. Based on this, he concluded that the nodule was a recurrent tumour that was growing. It could not be ignored. It had to be treated by radiosurgery. His opinion was in essence the same as that of two other defence witnesses, Dr Robert Smee and Dr Chua Eu Tiong. For the reasons to be given later I reject Dr Karlsson's evidence and Dr Robert Smee's evidence that there was a viable recurrent tumour in December 1996. This is a finding of fact. His evidence on treatment will be considered elsewhere.

## **Chapter 14 : Location of the Tumour**

### Dr James Khoo states the location of tumour

14.1 Dr James Khoo in his original defence postulated that *the nodule was in the roof of the left ventricle* and therefore it was less likely to be a scar because the location of *the dissection of the tumour was in front and attached to the floor of the ventricle*. In other words, the sites of the nodule and the removed tumour were antipolar.

### The company states the location of the nodule

14.2. The company defendant asserted that the nodule was relatively small and sited in the posterior lateral wall of the ventricle. The nodule was not, as Dr James Khoo said, in the roof but in the wall. The tumour site was the anterior floor of the ventricle.

The assertion, that the dissected tumour and the nodule had diagonally opposite positions, prima facie had a sinister implication. By definition, the nodule was a metastasis or secondary tumour within the brain. It was an aggressive new growth. Such a condition if true would be an indication for radiosurgery.

14.3. On 8 January 2001 (the opening day of trial) an opening statement for Dr James Khoo and Dr Khor was tendered. It made the assertion that the site of the nodule and the tumour were different : Note that this time the assertion was made by both doctor defendants. Para 29 of the opening statement asserted as follows :

It is the 1<sup>st</sup> and 3<sup>rd</sup> defendant's case that they had considered the plaintiff's history and severity of her condition fully, and that they have carried out the necessary investigations and examinations to ascertain that the nodule noted in the MRI scan in December 1996 could not have been a post surgical scar but a recurrent neurocytoma as the dorsal lateral aspect of the lesion in the ventricular wall site was not the site of the previous surgical dissection, which was anterior (in front) and attached to the floor of the ventricle.

### Translated, the doctor defendants were saying:

(a) Both doctors carried out the necessary investigations and examinations.

(b) The nodule was noted in the December 1996 MRI.

(c) The nodule presented a dorsal aspect (i.e. the back, upper part, namely the roof) in the ventricular wall. The nodule was attached to the wall and the roof. (This was a repetition of what Dr Esther Tan said – that is, it was protruding from the roof).

(d) The site of the previous surgical dissection, namely the site of the tumour, was the anterior (i.e. front) and attached to the floor of the ventricle.

#### *It was a new point*

14.4. The point, that the tumour and the nodule were located in diagonally opposite positions, was first raised by Dr James Khoo in his defence and repeated in the opening statement of both doctor defendants. He did not say so anywhere in the records in February or March 1996 when he had sight of Dr Esther Tan's first MRI report dated 26 February 1996. There was nothing about that in Dr James Khoo's contemporaneous clinical notes. There was no letter from him to Dr Devathasan to that effect. Even after Dr Esther Tan's second MRI report dated 27 December 1996, he did not say that the nodule and the tumour had antipolar positions. His clinical notes in January 1997 were silent on that. Dr Esther Tan's reports clearly suggest that they occupied a common site. Dr James Khoo failed to state that the nodule and tumour were at the antipolar positions in any letter to Dr Devathasan.

14.5. Then came Dr James Khoo's letter of 19 August 1997 to "The Physician Concerned": Once again he did not say that the nodule and the dissected tumour were at different locations. That was also the position when he wrote to Michael Khoo and Partners in November 1999.

14.6. The absence of any mention of this fact in the records and contemporaneous letters is very telling – if Dr James Khoo had really believed that the dissected tumour and the nodule were in different locations, and that the nodule was thus less likely a scar and very possibly an aggressive brain metastasis, that fact must have been foremost in his mind and logically the first thing he would indicate in his records.

#### *Purpose of the point*

14.7. The reason why Dr James Khoo mentioned the point was to convince the Court that it was absurd of Dr Esther Tan to suggest the nodule could be a scar. How could there be scar at the back of the roof (top) when the site of his operation was there but at the front end of the floor (bottom). Additionally and more importantly, Dr James Khoo's assertion of the positions of the nodule and tumour helped to buttress his other assertion that the removal of the tumour was total and that the post-surgery CT scan manifested no tumour.

14.8. That position remained unamended at the commencement of the trial. In fact, the pleadings contained all the assertions about the antipolar positions, total excision and negative CT scan. These documents were shown to the defendant experts who founded their expert opinion on those assertions. When I read the defences of Dr James Khoo and his company and his affidavit evidence-in-chief, I myself formed the preliminary view that if that was the true position, the plaintiff's case would be extremely tenuous. But then, Dr Esther Tan had found that the tumour and the nodule were at the same site in the roof. So my mind would not accept Dr James Khoo's assertions and I needed to investigate the point.

#### *Dr James Khoo's illustration*

14.9. In these circumstances, when the trial commenced I asked counsel for Dr James Khoo and his company to give me a pictorial representation of the left ventricle and the sites of the nodule and the neurocytoma within that ventricle. Dr James Khoo produced a colour pictorial representation. Counsel for the company, Mr Tan Beng Swee, made a copy of it gave me the original and the copy. They clearly demonstrated the antipolar positions. See Appendix III and IV.

#### Viewing the MRIs

14.10. At that time I had not viewed the relevant MRIs. Subsequently the November 1995, February 1996 and December 1996 MRIs were viewed by me in Court in the presence of all concerned. It was so clear that the site of the tumour and the nodule were the same. It was the roof of the left ventricle. It was not a matter on which there was any need for the assistance of experts. I could see that they both were located in the roof of the ventricle in an overlapping position. Dr Esther Tan gave me a very useful guided tour of the MRIs.

#### Dr Baratham debunks the defence

14.11. When Dr Baratham gave evidence as the plaintiff's expert, the location issue cropped up. By this time, Dr James Khoo had reviewed the relevant MRIs, and with the benefit of Dr Esther Tan's evidence counsel for Dr James Khoo (Ms Renuka Chettiar) had these exchanges with Dr Baratham. She said that Dr James Khoo said that the attachment of the tumour was to the septum and not the floor as pleaded. The basis of this suggestion was the operation record dated 15 November 1995. Dr Baratham was sharp. He said, in that case, Dr James Khoo would have removed the whole septum with the tumour [NE 1280 - L 6-7, 1287 - L 18-20], which was the common practice but was not what had happened in this case. Then Ms Renuka Chettiar said the tumour "was towards the roof of the ventricle, it was not attached." It just fell off.

14.12. Dr Baratham then asked Ms Renuka Chettiar : "Is there an attachment or is there not an attachment to the roof? I need to know clearly" [NE 1281 - L 11-12].

14.13. Ms Renuka Chettiar stated that there was no attachment to the roof [NE 1283]. Once again Dr Baratham was sharp. He said in surprise : "If it is not attached to the roof, and it just fell off after you took off its attachment to the septum pellucidum, then there should not be a scar in the roof, nor should there be any remnant tumour or recurrent tumour in the roof". He pointed out that if the tumour was not attached to the roof then there could not be a recurrence or remnant in the roof. For there to be a scar, remnant or residual or recurrent tumour in the roof there must be an attachment to the roof. "If a secondary attachment to the roof was dissected there would be a scar in the roof - the more trauma there is in dissection, the more likely to have a bigger scar."

#### Dr James Khoo's evidence

14.14. When Dr James Khoo gave evidence he said that the tumour was loosely attached to the roof. Later, he said :

The tumour was growing from the septum pellucidum. It was attached to the septum pellucidum in the centre. ... It had grown backwards on the floor of the ventricle tubing attached to the choroid plexus. It had grown upwards to the roof of the ventricle where it was loosely embedded on near the centre. [NE 1821]

It was loosely attached and loosely embedded to the roof. [NE 1822]

Dr James Khoo persisted that the tumour was towards the roof but not attached to the roof. He said :

It's embedded on but not stuck to the roof. [NE 1823 – L 10].

The primary attachment was to the septum and floor ... but it loosely was attached to the roof. [NE 1825 – L 19-24].

My recall was probably not as good but I do remember the tumour coming up to the roof. [NE 1826 L 8-9].

The tumour was touching the roof and loosely attached - loosely embedded in it. [NE 1827 - 1-2].

The back of the tumour was in the region of the nodule. [NE 1858 – L 1].

14.15. One can observe that on this point Dr James Khoo had no consistent or clear stand. He was wavering. Additionally, if Dr James Khoo's initial evidence that the tumour originated from the floor of the left ventricle, is to be believed, then the nodule being located on the roof could not be a "residual tumour". By definition "residual" means that the original tumour was not completely and totally resected. Yet he himself had called the nodule a residual tumour. Thus, he found himself in an impossible situation and was trying to extricate himself from that impossible position.

#### Dr Esther Tan's evidence

14.16. On the question of the location of the tumour before it was resected by Dr James Khoo, I received very useful elucidation from Dr Esther Tan. At first, she explained the features of the tumour with reference to the MRI done on 7 November 1995. She was standing outside the witness stand (before the illuminator holding up the MRI scans).

14.17. The sagittal (side) view slides presented views of the tumour hanging from the roof – that is the corpus callosum. Much of its mass was proximate to the roof of the ventricle. It represented an inverted cauliflower growing from the roof. It was obviously embedded in the roof. By embedded I mean that it was "firmly fixed in the surrounding mass". Its downward growth was proximate or touched the floor of the ventricle. Whether it was in contact with the floor was not clear. But I could deduce that it had reached and touched the foramen of Monroe and obstructed the flow of the CFS into the third ventricle. That was why there was a buildup of the CFS in the left ventricle. This deduction was confirmed by the axial (top or vertical) view slides and the coronal (front to back) view slides. The left ventricle had lost its normal shape and size. The right ventricle had shrunk. The left ventricle was dilated and disfigured. More importantly, the left ventricle had expanded its space and trespassed into the territory of the right ventricle. On the coronal plane, about one-third of the tumour shifted the ventricular septum, the mid-line structure, into the right hemisphere. Dr Esther Tan then gave evidence. She spoke with clarity and conciseness. She knew what she was talking about. As to the sites of the tumour before the resection, and the nodule after the excision, she said :

The nodule "was in the same area where the original tumour was". [NE 906 L 12].

14.18. Later Dr Esther Tan graphically illustrated the positions of the tumour before resection, and the nodule that was detected in February 1996. See Appendix V and VI. The tumour as drawn by Dr Esther Tan did not touch the floor of the ventricle, let alone stem from the floor as Dr James Khoo would have it. Her finding on this simple matter was antithetical to Dr James Khoo. If Dr Esther Tan

was right, and I will hold she was, there was nothing for Dr James Khoo to resect at the floor as asserted by Dr James Khoo. Dr James Khoo was obviously confabulating, improvising and shifting his position whenever the facts did not favour him.

Dr Ho Kee Hang's evidence

14.19. Dr Ho Kee Hang, was called as a witness by Dr James Khoo. He filed an affidavit of evidence-in-chief. As to the location of the original tumour he said this in his affidavit :

The location of the nodule was almost in the same area as the original tumour.  
Considering the surgical tract taken by Dr James Khoo a *remnant tumour (if any)*  
*was likely to be left at that location.*

This was consistent with his description of the nodule as "residual neurocytoma".

14.20. The above statement of Dr Ho sharply contradicted Dr James Khoo's statement in the pleadings that the nodule and original tumour did not have a common site. Dr Ho had seen the plaintiff on 21 January 1997 and on that day he made a clinical note that the plaintiff had a "small residual neurocytoma hanging from roof of left later ventricle" "Residual" meant something that remained after a greater part had been taken off. It meant that the first excision of the tumour was not total. When he gave evidence in Court, Dr Ho conceded that the location of the tumour was not on the floor [NE 2980 – L 10-14].

14.21. In the next breath, he said that original tumour was attached to the septum pellucidum as well as the roof. It was attached to both [NE 2980 L 17-21]. Dr Ho next clarified that as far as he could see, he did not think it was attached to the floor although the lowermost part of the tumour did approach the foramen of Monroe, which was at the floor, but that was the smallest part of the tumour. He at once proceeded to state his theory (and contradicted himself) as to why the original tumour did not come from the roof. It was his theory. It was his argument.

14.22. Dr James Khoo's counsel asked Dr Ho whether his opinion of the location was based on observation. He said it was based on the observation of the scans in 1997. He had spent all of 10 minutes viewing the MRI scans and advising Gunapathy. Amazing memory, I thought. But then, I learnt that Dr Ho had spent a whole week-end just before he gave evidence studying the scans and shaping his evidence. He even had the benefit of studying Dr Esther Tan's evidence in Court. I had directed that he should remain out of the Court and not listen to the evidence of other witnesses because I was told that he was not an expert witness. However, my intentions were defeated for he was provided with the transcript of her evidence. So his memory was not as amazing as I had earlier thought it was.

14.23. Later on, he confirmed that "I don't think it (neurocytoma) originates from the roof. This is going by the theory of it. But when we look at a tumour or a scan, very often, the tumour, it involves both the roof and the septum. And there is no way we can tell by looking at the scan what the point of origin is". He then conceded that if the theory was wrong, it could come from the roof – in which case it would be described as "neurocytoma from the corpus callosum". If it was from the wall, it would be called from the septum. It would be described by where it was attached to [NE 3427-3429]. He had not, however, come across a neurocytoma from the roof (i.e. the corpus callosum). Dr Ho was then shown an article published in ***The American Journal of Surgical Pathology*** Vol 16(2), 1992. The title of the article was : ***Central Neurocytomas, Critical Evaluation of a Small-Cell Neuronal Tumour***. The article contained a table giving the clinical features of 20 patients with central neurocytoma. The location in 10 cases was "foramen of Monroe and lateral ventricle". In 4 cases it

was the third ventricle. Two were located at the septum pellucidum. Two were attached to the corpus callosum. The location was given as corpus callosum and septum pellucidum. There was no mention of the floor (i.e. the choroid plexus). Dr Ho was asked whether he would revise his view. He agreed. So this theoretical argument that there could be no neurocytoma attached to the roof (corpus callosum) was proven wrong by empirical evidence.

14.24. Counsel for the plaintiff asked Dr Ho what he would do with the tumour attached to the roof. His answer was that "he would try to remove or rather to separate the tumour from this attachment as far as possible." He was then asked : what if it was attached to the septum pellucidum? Dr Ho's answer was : "On the septum, we – quite often, I would remove it together with the tumour because we're not aware of any specific important function of the septum" [NE 3440 – L 912]. What Dr Ho said was the same as what Dr Baratham had stated.

14.25. Next, counsel for the plaintiff asked this important question : If the primary attachment was the roof of the ventricle, then of course in trying to remove the attachment, the surgeon would probably have to remove some part of the roof. He answered :.

**Dr Ho**

: Yes.

**Plaintiff's Counsel**

: And in the process, you would leave a scarring on the corpus callosum?

**The Court**

: You'll cause surgical interference, that is all he can say.

**Plaintiff's Counsel**

: All right.

**Dr Ho**

: Yes, that's correct.

**Plaintiff's Counsel**

: And this blood brain barrier interference would probably show on a CT scan or an MRI done afterwards?

**Dr Ho**

: Yes, it will. [NE 3443-3444]

14.26. The end effect of Dr Ho's evidence on the location of the original tumour was that it was from the septum pellucidum and the roof.

14.27. I hold that his original description of "residual neurocytoma hanging from the roof" must necessarily mean that it was embedded in or growing from the roof.

#### Dr Chua Eu Tiong's evidence

14.28. Dr Chua Eu Tiong was an expert medical witness called by Dr Khor. On the question of the point



of attachment of the tumour before excision, he first said that it was the "septum and roof". Then he said he could not say whether it was attached to the septum. But there was an attachment to the roof. Later he said he assumed that it was attached to the roof. Dr Chua Eu Tiong further confirmed that if it was attached to the septum "you have to remove the septum. ... If it is just abutting against it, then you don't have to remove it". He did not even hint that the tumour was attached to the floor and Dr James Khoo had removed it from there and therefore there could be no scar in the roof Dr Chua Eu Tiong was then shown the drawing of the tumour made by Dr James Khoo on the day of the surgery on 15 November 1995. He said that he could not tell from the drawing the point of attachment of the tumour. It was abutting against the septum.

#### Dr Francis Hui's evidence

14.29. Dr Francis Hui, another expert witness called by Dr James Khoo, confirmed that the original tumour and the lesion were in the same location.

#### Dr Yeo Tseng Tsai's evidence

14.30. Dr Yeo Tseng Tsai was asked to state his understanding of the point of attachment of the tumour before the resection. He was unhelpful. There was no direct answer from him. [NE 3730-3732]

#### My conclusion on the point of attachment

14.31. As can be seen, even the expert witnesses called by the defence generally conceded that the location and point of attachment of the original tumour before excision was to the roof of the left ventricle and not the floor of the ventricle. In conclusion I hold that the point of attachment of the tumour before resection was the roof of the left ventricle. In the result Dr James Khoo's pleaded defence that the tumour was "attached to the floor of the ventricle" and that the nodule, being in the roof, could not be a scar, was contradicted and proved to be false by the real evidence. It was a disingenuous defence. It was misleading. It also established that Dr James Khoo's observation and recollection were unreliable. Further it proved the propensity of Dr James Khoo to plead a disingenuous defence disregarding the hard evidence. Finally it gave credence to the saying which his own expert witness, Dr Yeo Tseng Tsai, said in Court : "Surgeons can lie but MRI cannot."

### **Chapter 15 : Recurrent Neurocytoma**

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#### A verbal confusion

15.1. The nodule that was seen in the February 1996 and December 1996 MRIs were described in various terms by the doctor defendants and their medical experts.

15.2. Dr James Khoo in his defence made these statements :

As the plaintiff wanted to have fertility treatment ..., she was anxious to have any suspected *tumour remnant* cleared up as quick as possible. (Para 3 (e)).

There was no simple and totally safe way to verify whether the lesion was a granuloma or a *recurrent neurocytoma*. (Para 6 (1))

15.3. The company defendant made these statements in its defence :

The 1<sup>st</sup> defendant (i.e. Dr James Khoo) informed the plaintiff that the small nodule was probably a *recurrent* tumour. (Para 8 (a)).

The plaintiff gave clear instructions to "have complete clearance of all *potential gliomas/tumours* that could be aggravated by powerful fertility hormonal therapy. (Para 17)

#### Dr James Khoo's affidavit

15.4. Dr James Khoo filed his affidavit of evidence-in-chief on 22 December 2000. In his affidavit he made the following statements :

(After the February 1996 MRI) I suspected the nodule to be a *recurrent tumour* but I could not be sure if it was a post surgical granuloma or scar. (Para 4)

(After the December 1996 MRI) there was no simple and totally safe way to verify whether the lesion was a granuloma or a *recurrent neurocytoma*. (Para 5)

Recent studies show that radiosurgery is an excellent option for *residual central neurocytoma*. (Para 6)

#### Dr Khor's defence and affidavit

15.5. In his defence Dr Khor was non-committal in the categorization of the nodule. He said in his defence that the plaintiff "insisted that all *possible tumour* in the brain be controlled." In his affidavit evidence-in-chief he made these statements:

Post-operative CT head scan showed no evidence of *residual* tumour. (Para 3)

Neurocytoma is not a benign tumour but a *malignancy*. As a cancer, even of low grade, *any remnant* would almost certainly re-grow. (Para 21 (1))

CT scan and even MRI imaging may show no sign of *remnant tumour* as no gross disease is left. ... treatment in the "adjuvant" setting, where no tumour may be detected on any known test, is a major part of *cancer* treatment. (Para 21 (1))

#### Dr Robert Smee

15.6. Dr Robert Smee in his report submitted to Court at the trial made these points :

Post operative CT scan was reported as demonstrating no evident *residual* disease.

It would be more appropriate clinically thus to regard this as *residual tumour*.

Here we have on the one hand the confidence that there is *no residual disease*.  
...

Thus in February 1996 we have the demonstration of a *recurrent nodule*.

If the radiological interpretation is consistent with *residual/recurrent disease*

then I would certainly not be persuaded away from further action despite a negative biopsy.

Was the decision to give stereotactic radiosurgery an appropriate option at the time of documented *recurrence* ...

However it was evident as stated above that she developed a *progressive/recurrent nodule* and required a further management decision.

Dr Yeo Tseng Tsai

15.7. In his report dated 30 October 2000, Dr Yeo made the following statements :

The radiological appearance on MRI scan of 26/12/96 of the enhancing nodule very likely represents *tumour recurrence*.

It was reasonable to presume based on the MRI brain scan done, that the enhancing nodule was indeed *tumour recurrence* and not radionecrosis.

Treatment of a *remnant* or *recurrent* central neurocytoma with radiosurgery is presently a reasonable option in my opinion.

Dr Bengt Karlsson

15.8. In his written opinion dated 22 November 2000, Dr Karlsson makes these statements :

In spite of this (radiation therapy) treatment, a scan performed in February 1996 revealed a small contrast enhancing nodule at or close to the previously operated tumour. The contrast enhancing nodule was interpreted being either a small tumour *remnant / recurrence or scar tissue* from the operation.

The fact that the tumour *recurred* in spite of radiotherapy given suggested that this tumour may be quite radioresistant.

Dr Francis Hui

15.9. For reasons to be stated later it is crucial to determine whether the nodule noted in February 1996 and December 1996 MRIs was a recurrent tumour. Dr Francis Hui said it was recurrent tumour. He was the defendants' "star" witness on the interpretation of the MRIs. The defendants described him, as a "neuroradiologist". He also said he was a neuroradiologist. He did not produce any paper which conferred that title on him. However, Dr Francis Hui explained why he called himself a neuroradiologist. After obtaining MBBS, he qualified as a radiologist. The following extracts are from his evidence :

I'm a radiologist. A radiologist is a specialist who has to qualify as a medical doctor first – MBBS, and then undergo a further examination to pass as a radiologist and the exams that we go through is the Royal College of Radiologist exam conducted by the UK body, the degree that we get is a Fellow of the Royal College of Radiologists. [NE 3628-3629]

And then after that, I decided to specialise in neuroradiology. So what I did was, when we decide to specialise, that means we focus our efforts into doing more

of a certain subject of radiology and, that is, in this case, it is neuroradiology. And I also got a government approved fellowship to study interventional neuroradiology in Paris in 1991 to 1992.

That's a one year attachment to a hospital doing cases, and then after that, I came back. It is 12 months. [NE 3630-3631]

For the neuroradiologists, we are the ones who will interpret all the brain scans and do diagnostic interventional procedures. [NE 3633]

When I was training in Paris, I was training in interventional neuroradiology, and at the same time, I also did training in diagnostic neuroradiology during that time. Usually, you cannot really do interventional without knowing diagnostic neuroradiology. [NE 3662]

Before that, I also trained in diagnostic neuroradiology in Singapore and after that, I come back and I also do diagnostic interventional neuroradiology, and most of my work actually, greater part of my time is involved in diagnostic neuroradiology. [NE 3663]

Interventional neuroradiology is a technique of treating certain conditions of the brain, which means I can access a blood vessel in the patient, for example, put in a tube, bring it up to the brain, and I can inflate a balloon or detach a balloon, or I can inject glue to block off abnormal blood vessels in the treatment of diseases." [NE 3663]

15.10.By this, the defence sought to inject the suggestion that Dr Francis Hui was more qualified than Dr Esther Tan (a general radiologist) at interpreting MRI scans on the brain.

15.11.Dr Esther Tan gave a vivid description of Dr Francis Hui's specialisation in these words :

I think Dr Hui, he did his further training in neuroradiology but I think his interest was specific in doing interventional work. Basically, it is trying to do things like stopping blood flow to tumours in the brain and blood vessel abnormalities in the brain rather than specifically in the interpretation of MRI scans. Do you get what I mean? He's actually - his specific training, as I understand , was in interventional procedures of the brain as opposed to interpretation of MRI scans. Certainly, he probably sees MRI scans day in, day out, and he doesn't see mammograms and chest X-rays and barium meals like I would do. [NE 997-998]

Dr Francis Hui's expert evidence "report"

15.12.However, Dr Francis Hui's so-called specialisation in "neuroradiology" has very little to do with this case. Dr Francis Hui's initial expert evidence was evidenced by and contained in what the doctor defendants' counsel first called a "report". In the next breath it was called a "letter". The letter was dated 15 January 2001. His expert evidence was comprised of three sentences :

In the 26 December 1996 MRI scan, the nodule in the superior surface of the left lateral ventricle shows more prominent enhancement after IV contrast when compared to the scan done on 26 February 1996. The size of the nodule has also increased slightly. The imaging features are highly suggestive of *recurrent*

*growth of the tumour.*

15.13. Dr Francis Hui's so-called expert evidence report failed to conform to the requirements of O 40A of the Rules of Court. It was prepared and presented in a lackadaisical fashion. In particular, it failed to state the facts on which he had based his conclusions. He also failed to state the reasons for his conclusions. The report was not revealed to the Court until after the trial had begun. Counsel for the company defendant read Dr Francis Hui's conclusions to Dr Esther Tan. But he did not reveal to Dr Esther Tan the facts and reasons on which Dr Francis Hui based his conclusions. The Court, therefore, was denied the benefit of Dr Esther Tan's response to Dr Francis Hui. With that caveat, I shall now consider the substance of Dr Francis Hui's evidence.

#### Dr Francis Hui's oral evidence

15.14. Dr Francis Hui said that Dr James Khoo was his friend. So was Dr Esther Tan. "Their friendship has no bearing whatsoever in my interpretation of the images here" said Dr Francis Hui in his evidence. But what was important was that Dr James Khoo had conferred with Dr Francis Hui before he presented his "report".

15.15. The thrust of Dr Francis Hui's evidence was that the nodule in the superior surface (the roof) of the left lateral ventricle was a *recurrent* growth of tumour. More accurately he said that the imaging features of the December 1996 scans were "highly suggestive" of a *recurrent growth of tumour*. Dr Francis Hui, when he gave evidence in Court, gave reasons for his conclusion that the imaging features were highly suggestive of a recurrent tumour. He gave six reasons all told.

15.16. These reasons were not revealed to Dr Esther Tan or the Court before Dr Francis Hui gave his evidence in Court. The six reasons can be summarised as follows :

(i) The appearance of the nodule in February and December 1996 was nodular rather than a straight or linear appearance. This made it a more favourable diagnosis of a recurrence. [ see NE 3343 – L 13-19]

(ii) Between the two scans there was enlargement in the size of the nodule. An enlargement is another feature of recurrence. [see NE 3343 – L 19-21]

(iii) In the December 1996 scan there was an additional area of enhancement after intravenous contrast, adjacent to the original nodule. This was an indication of spread and growth, and another feature that would favour the diagnosis of a recurrence. [see NE 3345 – 11-16] [see NE 3346 – L 1-3]

(iv) There was a change in the enhancement pattern after intravenous contrast of this nodule in the December 1996 scan compared to the February 1996 scan. [see NE 3346 – L 3-7]

(v) In the December 1996 scan, there was enhancement of the nodule. This was an enhancement more than one year after the tumour operation. This is another feature of recurrence.

(vi) The last point was the location of recurrence. The location of the recurrence was at the site of the original tumour.

#### A flaw in Dr Francis Hui's evidence

15.17. There was a fundamental flaw in Dr Francis Hui's evidence. It was revealed when Mr Michael Khoo SC, counsel for the plaintiff, cross-examined him :

Q Now, when you used the word "recurrent" could we know what you mean by that?

A That means the tumour is growing again.

Q Growing again, meaning it had been completely excised and has re-grown?

A It has been completely excised and it has regrown, we will call it a recurrence.

Q I see. Not a residue?

A Not a residue. We have to prove that the tumour was there immediately after the operation to say that it is a residual tumour.

Q And that, you know, could not be proved?

A The most accurate way of doing that is to do an MRI scan after the surgery.

Q Which was not done in this case?

A Yes.

Q A CT scan was done.

A Yes.

Q Which showed no residue?

A The CT scan did not show evidence of residue. As I have mentioned, the MRI scan is a more accurate investigation and since we are comparing MRI scans, if we were to have a fair comparison, we would need to have an MRI scan done immediately post-operatively. That would be the best way to compare – Yes.  
[NE 3678]

15.18. It was abundantly obvious that Dr Francis Hui's conclusion that there was a recurrent tumour was based on the major premise that there was a total excision of the original tumour. It was also clear that it was Dr James Khoo who so informed him. Alternatively, he obtained that information from Dr James Khoo's clinical notes and perhaps the defences. Dr Francis Hui must have accepted that information from Dr James Khoo whom he described as his friend. It is to be remembered that Dr James Khoo in his operation record noted that "Tumour resected *totally macroscopically*." The assertion of total or complete excision was maintained by him all the way until the trial began. In para 3 (a) of his defence he asserted that the "neurocytoma was successfully excised by an anterior transcollosal *microsurgical operation*". Here he uses the word "*microsurgical*" and not "macroscurgical". In his defence Dr James Khoo spoke of a "scar or remnant tumour" and "a recurrent neurocytoma". His new theory of "recurrent tumour" was consistent with his original defence that the nodule appeared in the roof whereas he had totally resected the tumour from the floor. This meant that the nodule was a malignant tumour. It also meant that there had been metastasis – a tumour removed from the floor of the left ventricle had reappeared as a secondary tumour in the roof of the left ventricle.

15.19. At the trial, Dr James Khoo began to assert that the resection was not total. Additionally Dr James Khoo called two doctors to establish that there was no total excision. They were Dr Ho Kee Hang and Dr Yeo Tseng Tsai. Dr Ho described the lesion as "residual neurocytoma". Dr Francis Hui's major premise could no longer stand. Since there was no total excision and the basis of his conclusion was wrong, Dr Francis Hui's conclusion of recurrent tumour, by his own definition, had no leg to stand on. If the excision had been total, the appearance of the nodule in the February 1996 itself must be recurrent tumour according to the reasons advanced by Dr Francis Hui. Thereafter, it must follow that the December 1996 scan must necessarily show significant changes because a malignant tumour recurring or reappearing by definition must grow and grow substantially between February 1996 and December 1996. Dr Francis Hui would see the changes he wanted to see. But according to his own measurement the nodule had grown at the most only about 10% and there was always a margin of error 10% to 15% in such measurement. If the margin is applied to his measurement there was no growth or negligible growth between February 1996 and December 1996. There was no significant change in size. This meant that the nodule was effectively static and stabled. Dr Esther Tan had stated affirmatively in her evidence that there was no change in the size of the nodule. She said :

I thought, on the basis of what I saw, that there hadn't been a change. [NE 942 – L 20-21]

I have stated in my report that I thought that it was probably scar, rather than tumour. That's an opinion which I expressed and the basis for that was because in my opinion, the area of abnormality had not changed. [NE 970 – L 18-21]

What I saw in February of 96 and followed up in December of 96, what I saw, I thought was probably a scar rather than tumour because it had remained stable.

[NE 989 – L 21-24]

15.20. In view of the evidence of Dr Francis Hui and Dr Esther Tan, I say with moral certainty that there was no growth in the size of the lesion between February 1996 and December 1996. It therefore was not a tumour. This is also in accordance with the histopathological report that the neurocytoma did not possess the ingredient for malignant growth.

15.21. As to the alleged increased enhancement, Dr Esther Tan had demonstrated most convincingly that the enhancement was "non-specific". Additionally, the increased enhancement was due to increased and more effective application of the contrasting dye. As she explained, it was analogous to the brightening control of the television screen. Dr Esther Tan said that for the December 1996 scans she had applied greater and more effective contrast which magnified the enhancement.

15.22. Growth of the nodule between February 1996 and December 1996, and such growth alone, was the determinant that the nodule was not a scar but a viable tumour requiring treatment. Dr Francis Hui produced no evidence of such growth. His conclusions were based on the ill-founded premises of total excision and a false proposition as to greater enhancement.

15.23. Dr Francis Hui's last point on common location was non-sequitur. A scar or residue must appear in the same location as the original tumour.

15.24. Finally, Dr Yeo Tseng Tsai and Dr James Khoo took pains to emphasise that the nodule was not a recurrent tumour as defined by Dr Francis Hui. In his report, Dr Francis Hui had stated that there was a recurrent tumour in the sense of a remnant tumour. He based his opinion on the basis of the December 1996 scan alone. When he gave evidence he tried to change his evidence but it was clear

that he was just improvising.

15.25. Dr Robert Smee, Dr Chua Eu Tiong and Dr Karlsson also subscribed to the opinion of recurrent tumour as defined by Dr Francis Hui. But all three based their opinion on total excision which was a false assumption. Their opinions accordingly were wrong just as Dr Francis Hui's opinion was wrong.

## **Chapter 16 : Residual Tumour**

### Residual tumour

16.1. "Residual tumour" is a term of art. It is a technical term. The word "residue" and its cognate "residual" signify that a small part remained after the bulk of it had been removed or resected. It means the same as a remnant.

16.2. In the case of a tumour, the words residual and remnant take on a special significance. The significance is magnified in the case of malignant tumours. It is of great importance to the surgeon, whose function is to remove tumours, and to the radiation oncologist, whose principal business is irradiation of tumours in general and malignant tumours in particular.

16.3. A surgeon must do his best to remove the tumour in its entirety. Otherwise the purpose of the surgery is not fulfilled. Rapid growth, and its consequences are the pathological properties of malignant tumours. These pathologies are magnified in the case of brain tumours because of the limited space in the cranium. The tumour has no abundance of space in the brain. A tumour, and in particular a benign tumour, that grows into the lateral ventricles without invading the brain parenchyma, is relatively not so morbid as a glioma that grows into the parenchyma. A tumour in the lateral ventricle makes the task of a neurosurgeon relatively less difficult because total excision can be done with a great degree of accuracy. In such a case he need not touch the brain parenchyma. All that he may have to sacrifice are :

- (a) the septum pellucidum if the point of attachment is at the septum;
- (b) part of the ependyma and perhaps part of the corpus callosum (roof) and some blood vessels if the point of attachment is the roof;
- c) part of the choroid plexus (floor), if the tumour is attached to the floor.

16.4. In the case of attachment to the septum pellucidum, the surgeon has the privilege of throwing the baby out with the bathwater for he can remove the entire pellucidum with the tumour. In the case of the roof, removing a margin of the corpus callosum does not matter much. In every transcallosal surgery, sacrificing part of the corpus callosum is inevitable. The surgeon has to bore a hole through it to access the tumour in the ventricle. In case of the floor, the surgery will cause interference with the choroid plexus, a web of blood vessels and consequential bleeding. However, all these sacrifices do not affect the functional parts of the brain.

16.5. One must bear in mind what Wilkins and Rengachary said: "At times, even when a small amount of tumour has been left, there may be no growth for quite some time. Radiation therapy at present does not seem to have a role in treatment". (See 2.9 above). If a part of the stem is left behind and, contrary to the advice of Wilkins and Rengachary, the remnant is irradiated, the irradiation will in all probability put an end to mitosis (cell division), if there was any. If there is no mitosis there should be no re-growth of the remnant. In any event, the remnant will remain and not disappear. An analogy is the stump of a cut or felled tree which has been exposed to intense heat. Like the stump, the



necrotic remnant will roughly retain the original shape. See further chapter 18 below.

16.6. What has been stated above requires the surgeon to understand correctly the point or points of attachment of the tumour. MRI imaging techniques make this achievable without much difficulty. If the surgeon misunderstands the point of attachment he cannot do his job properly. For example, if he concludes that the tumour grew from the floor when it actually grows from the roof it will lead to consequential errors. The surgeon will conclude that a scar in the roof is a fresh growth and treat it as such. In the case of radiation-based treatments, it may cause irremediable damage to the brain – namely radionecrosis.

#### Total excision

16.7. Dr Esther Tan explained in lucid language how a surgeon can ensure that he has effected total excision. The surgeon should ask for a pathological report to check whether the margins of the excised tumour are clear of tumour cells. If so the chances of regrowth are eliminated or minimised.

16.8. There is another way of determining whether the tumour has been extricated in its entirety. That is to do an MRI examination. This is particularly useful where a possible residue is small. A CT scan for this purpose is not sensitive enough and unreliable. This view was forcefully stated by Dr Tsao Shiu Ying who was a witness called by Gunapathy, as well as Dr Francis Hui called by the defendants. It was accepted as a correct statement by all.

16.9. If a tumour after total excision returns, it is called a recurrent tumour or a relapse. Such a tumour, by its reappearance, manifests a virulent and aggressive character.

16.10. That is the theory of total removal of tumour. But life is not that simple for a diagnostic radiologist. Dr Esther Tan explained :

What happens is that when tumours are removed, the surgeon usually attempts to remove a tumour with a margin of normal tissue around it to make sure that they haven't left anything behind. But it's well known that despite what appears to have been complete removal of a tumour, there may have been microscopic spread beyond that area that nobody with a naked eye or even a microscope can see. I mean it's a little bit like having a patient who's had breast cancer and the tumours being completely removed and the breast has been removed and it appears that everything is gone, and a few years subsequent to that the patient ends up with a secondary somewhere else in the body or somewhere else. [NE 906-907]

Dr Esther Tan's explanation was with reference to a malignant tumour because benign tumours don't metastasize. Metastasis depends on the degree of malignancy and the type of tumour. Benign tumours do not metastasize. Sometimes there is a fine line between the two. Whether the neurocytoma is considered benign, or malignant, or a "low-grade malignancy", is for a pathologist to decide. This is because there is no such a thing as a typical neurocytoma.

16.11. If, after what is believed to be a total excision, a lesion appears in the same spot of the attachment of the excised tumour, it can be detected by MRI. When an MRI is done with an administration of contrast, the abnormality will appear as a bright spot. In other words, the lesion will show up as the contrast enhancement. But the enhancement itself is non-specific, because anything abnormal will enhance. A scar will enhance. A remnant tumour will also enhance. So it can be scar tissue or tumour. The abnormality by itself is something to watch, and should not be treated as a

remnant tumour at once. Treatment or management is necessary only if the lesion is a viable tumour that is to say, if it grows significantly and appreciably in size.

16.12.If a tumour remnant is established or suspected, particularly when it is a glioma, it would be prudent to irradiate the tumour volume. This is standard in the case of glioma of the parenchyma because too often it is inaccessible or too extensive to be removed by manual surgery. Radiation is thus the second most common treatment for gliomas.

16.13.Dr Khor stated in paragraph 21 (1) of his affidavit of evidence-in-chief :

Neurocytoma is not a benign tumour but a malignancy. As a cancer, even of low grade, any remnant would almost certainly re-grow. It is common practice to give radiation in such an "adjuvant" setting when the surgeon is not confident of having taken the tumour out completely. In oncologic practice there is a distinction between macroscopically (gross) complete removal and microscopic clearance – the latter demonstrating a "margin" of normal tissue enveloping the tumour. Unlike most other organs, in the brain, the surgeon is constrained in the amount of normal tissue to be sacrificed and microscopic "clearance" is often not possible. Post-operative radiation is thus commonly used to lower the risk of tumour recurring. CT scan and even MRI imaging may show no sign of remnant tumour as no gross disease is left. Such treatment in the "adjuvant" setting, where no tumour may be detected on any known test, is a major part of cancer treatment.

16.14.This was an incorrect statement. It has not been established that every neurocytoma is a cancer, that is, a malignant tumour. If anything, the typical neurocytoma is a benign tumour; it is an indolent tumour. But there are exceptions. In this case the histological examinations were done in 1995 and 2000. These examinations looked at the bottom of the cell. The first histological report admittedly established that the neurocytoma excised from Gunapathy's brain was benign and non-malignant, non-cancerous. The examination done by Dr Jennifer Teo with the eyes of the year 2000 reconfirmed that it was benign and non-malignant.

16.15.Dr Khor relied on the classification by the WHO to argue that the neurocytoma is malignant. The WHO has done a classification of tumours of the nervous system. There are four classes according to their behaviours. They are as follows :

0 for benign tumours

1 for low or uncertain malignant potential or borderline malignancy

2 for in situ lesions

3 for malignant tumours

16.16.WHO places central neurocytoma under class 1. This class signifies that its behaviour can vary. Because it falls under an uncertain class it can be a benign tumour or it can be a borderline malignancy. It all depends on the particular tumour in question that is a generalisation. But histopathological examinations can establish the true nature of a given tumour. In the case at hand, histopathological examinations were done. The determination was that it was a neurocytoma. The words "low grade" was not appended to it. In any event "low grade" means occurring near the low end of the range – that is near "0". The histological determination show no markers of malignancy

whatsoever. It was, therefore, decided to be benign tumour by histological determination. The histological determinations placed them in the "O" category. More to the point, they did not categorise this neurocytoma a "glioma". Dr Khor's evidence that he would place near class 2 is unscientific and unsupported by empirical evidence. It was mere wishful thinking.

16.17. Dr Khor made a valid point in that if there is a cancer in the brain, as gliomas often are, radiation therapy is a standard treatment to destroy possible remnant or residual tumour cells.

16.18. Now comes the keystone of diagnostic radiology. A remnant tumour that has been effectively irradiated will not disappear but will remain as scar tissue. In other words it will cease to be a viable tumour. Where biopsy is not possible or inadvisable, the sole test of a viable remnant tumour is whether there is growth – that is, significant increase in size. When one talks about a viable remnant tumour, the word "viable" is omitted because it is tautological. A non-viable tumour is not a tumour. For a mass to be called a tumour at all, it must be growing. This meaning of a "remnant tumour", as referring a growing tumour, must be in the forefront of the mind of all those who talk about a remnant or residual tumour especially after there has been radiation therapy.

16.19. Dr Francis Hui presented a book when he gave evidence – **"Neuroradiology, The Requisites"**. It summed up the concept of a tumour succinctly :

Blood resolves, granulation stays the same or decreases in size, and tumour grows.

The above passage stresses "growth".

16.20. The book also stated at pp 99-100:

Determining whether residual neoplasm is present in the postsurgical tumour bed is one of the most daunting tasks facing a neuroradiologist. What hangs in the balance are prognostic considerations for the patient, potential repeated surgeries, nonsurgical therapeutic decision-making, and the wrath of neurosurgeons regarding your analysis of their fine work. Nothing infuriates the surgeon more than a postoperative scan after a "complete resection" that is interpreted as a small biopsy. Here is how you can avoid this pitfall and why it is such a problem.

Within 72 hours after surgery, granulation tissue develops. Because this is generally fibrovascular in nature, it enhances on CT and MR. It thus becomes difficult to tell whether enhancing tissue in a surgical bed is due to granulation tissue or marginal tumour enhancement (provided that the tumour enhanced preoperatively). The granulation tissue enhancement may persist for months postoperatively, but intraparenchymal enhancement and mass effect after 1 year should be viewed with suspicion. Dural enhancement is nearly always seen even at 1 year and can persist as long as decades after surgery. Enhancement appears sooner and persists longer on MR than on CT.

The above passage talks about "enhancement". It is to be inferred from the passage that non-parenchyma tissue enhancement may persist for decades. The bed of the tumour in the present case was non-parenchymal.

16.21. It is well to be reminded of what the **Radionics XKnife Protocol** said of an irradiated tumour :

Viable tumour, by definition, grows and if the lesion is stable in size (no change) on serial scans, the tumour is controlled. They (i.e. patients and their relatives) should not expect the tumour(s) to disappear, but this does occasionally happen [See Section 5]

16.22. It is essential to note that it is the size that is stressed. Contrast enhancement is not even mentioned here. Dr Esther Tan too stressed that if the size remained stable, then it was a scar. (See for example NE 989 – L 23-24). It cannot be a remnant tumour. It was in this context that Dr Esther Tan spoke of "a scar or remnant tumour". Remnant tumour here meant a viable remnant tumour, a tumour that was still growing and not merely manifesting more enhancement. Enhancement is non-specific.

16.23. Dr Karlsson said that he and his radiologist had seen on the CT scan of 20 November 1995, five days after the surgical removal of the neurocytoma, something that should not be there. That something was located at the posterior part of the previously existing tumour. At that time they could not say what that represented. Then the February 1996 MRI confirmed its presence. Then the December 1996 MRI scan, according to him, showed that it had increased in size. They were confident that this represented "a viable tumour". "It was still alive. It was a tumour, otherwise it would not be alive. Yes, it is a tumour" he said. I have referred to his evidence merely to show the meaning of the word "tumour". Whether the interpretation of the scans by Dr Karlsson and his radiologist was correct is an entirely a different matter, to be considered elsewhere.

16.24. On the same point, Dr Chua Eu Tiong said this :

Q If it was actually a remnant, and the tumour had been treated with radiotherapy, it may take some time before the remnant of that tumour which has radiated would disappear?

A Yes.

Q And there is no fixed period of time?

A No fixed period of time.

16.25. Dr Yeo Tseng Tsai in his expert opinion given at the request of Dr James Khoo said :

The enhancing nodule was indeed tumour recurrence and not *radionecrosis*.

16.26. The point he was making was that if the nodule had been effectively irradiated it would not be tumour. It would be dead tumour cells, or "radionecrosis", which means the destruction of tissue caused by radiation. To put it another way, Dr Yeo was saying that the enhancing nodule was a viable remnant tumour and not one whose growth was controlled by radiation therapy. I have quoted Dr Yeo Tseng Tsai to explain the meaning of the expression "scar or remnant tumour". The term "remnant tumour" has been considered. Dr Yeo Tseng Tsai's "radionecrosis" was the same as Dr Esther Tan's "scar". Dr Esther Tan was not aware in February 1996 that there was radiation therapy and therefore could not speak of "radionecrosis".

16.27. In a case where the tumour has not been completely, (that is, microscopically), excised in the sense described above, there might be a remnant or residue left behind. That remnant tumour may or may not re-grow depending on its potential for re-growth. The potential depends on mitosis and proliferative propensity. If such a remnant tumour is effectively irradiated by conventional

radiotherapy, whatever potential for re-growth the remnant tumour had, would be eradicated by the irradiation. But the remnant will remain there still, as a dead tumour and no longer a viable tumour. If the remnant had been nodular it would remain as nodular. If it was shaped otherwise, it would remain so. It might disappear, but patients should not expect it to. The point to note, however, is that the mere presence of that remnant does not mean there is still a tumour. I cannot stress this more – a remnant tumour is a viable tumour. As such it must grow. If it does not grow after irradiation it is not a tumour; it is dead. There are various names for a dead remnant. "Scar" is one such name. "Radionecrosis" is just another name for it.

16.28.To repeat the point, a tumour is a viable tumour. It must be living. If it is dead, by definition it is not a tumour. Whether it could be a tumour depends on whether it is growing. If it is not evidently growing over a series of scans, it is not a tumour. It can be called a scar, fibrosis, radionecrosis, post-surgical change, granuloma or what you will. It matters not what name one gives to it. That it is not a tumour – a viable tumour, is what matters. Dr Esther Tan's finding that there was no significant change in the nodule in Gunapathy's brain between February 1996 and December 1996 established that it was not a tumour. The doctor defendants did not dispute her finding at the material time. When they disputed it at the trial, they, however failed to disprove her finding.

16.29.The question whether the nodule was growing is a question of fact. Determination of that question is not governed by the **Bolam** principle. On the basis of all the evidence it was established that it had not grown from February 1996 to December 1996. It was not a tumour. This finding was based on radiological evidence was congruent with and supported by two histological reports. More importantly, it was not in the brain parenchyma to cause any concern in December 1996 or January 1997.

## **Chapter 17 : Expert Evidence of Dr Chua Eu Tiong**

17.1.Dr Chua Eu Tiong was called because he was a radiation oncologist. He gave evidence in support of Dr Khor.

17.2.Dr Khor's main defence was that "as the plaintiff was anxious to have children and wished to embark on a program of assisted reproduction she insisted that all possible tumour remnant in the brain be controlled. She had seen the first defendant who had offered radiosurgery for this purpose". Dr Khor also sought to justify the dosage of 2000 cGy at the 85% isodose by relying on the RTOG 90-05 study. Dr Khor further asserted that the use of 22.5 mm collimator was justified as the maximum diameter of the tumour was 19 mm.

17.3.Dr Chua Eu Tiong affirmed an affidavit in which he made the following statement of conclusion :

I am of the view that radiosurgery was carried out competently according to accepted *international* guidelines.

17.4.The reasons stated for the conclusion were as follows :

(a) The tumour as reported on the MRI scan done on 27 December 1996 was approximately 11 mm x 12 mm x 6 mm in size.

(b) During the radiosurgery treatment planning on 31 January 1997 the maximum diameter of the tumour was determined by the 3<sup>rd</sup> defendant (Dr Khor) to be 19 mm. This required a collimator of 22.5 mm.

(c) The dosage was well within the dosage guideline from the RTOG 90-05 study.

17.5.Statements in (a) and (b) each contained an egregious error. First, Dr Chua should not have used the word "tumour". It was not reported in the December 1996 MRI scan that there was a *tumour*. It was reported that the opacity protruding from the roof was "probably due to *scarring* from previous surgery". Next, Dr Chua was wrong to say that the 19 mm measurement was the size of the tumour. That was the measurement of computer simulated imaging.

17.6.His errors show how careless and irresponsible he was in making his expert report. As to the first error relating to the "tumour", he admitted that he was in error and apologised. He said that he "presumed", and he "thought", it was a tumour. His "impression" was that it was a tumour. He was not a diagnostic radiologist and he did not even read and understand what Dr Esther Tan, an experienced diagnostic radiologist, had reported. Even Dr Khor had not questioned or rejected Dr Esther Tan's findings. He had accepted her findings and had used them as a basis to advise the plaintiff at the material time. That being the case, Dr Chua Eu Tiong based his conclusion on a misreading of Dr Esther Tan's report.

17.7.Later he changed his evidence. He sought to justify that it was a tumour because it was an enhancing nodule that was getting brighter. He argued that because it had enhanced it was a tumour. As I have already mentioned in the previous chapter, Dr Esther Tan had explained convincingly that enhancement by itself was non-specific. In the December 1996 MRI, there was increased enhancement because of technical factors such as those that can make a picture on the TV screen brighter. The true radiological determinant of a viable tumour is significant increase in size. Clear increase in size alone is the true marker of a tumour. In this case Dr Chua Eu Tiong did not demonstrate that, from February 1996 to December 1996, there was an increase in size signifying significant growth to justify high-single-dose radiation to Gunpathy.

17.8.As to the matter of the 19 mm diameter Dr Chua Eu Tiong fell into the same error as Dr Robert Smee – he assumed that the January 1997 imaging was MRI imaging like the 1996 MRI scans, when in actual fact they was computer simulated images for the purpose of radiosurgery. But unlike the latter, Dr Chua Eu Tiong did not correct himself. As a person who specialised in radiosurgery he ought to have known that the treatment target was a computer simulation and that one does not treat the computer image but the patient. In fact it was Dr Chua Eu Tiong who taught the physicist to measure the image with a collimator. As a last resort he said the nodule was a recurrent tumour – recurrent after radiotherapy. This was the position taken by Dr Francis Hui and Dr Robert Smee. He said it was "a glioma with a malignant behaviour. ... The clinical behaviour is malignant, it has recurred fairly early. And you have a tumour that has recurred fairly early" ... It was a "recurrence" because it is something which is no longer there and has reappeared" even though you already had a total excision initially" ... It is unlikely to be a remnant because you had a CT scan done immediately after" [see : NE 3298-3299]. All these arguments were hollow sounding and shallow in substance. They were improvised at the trial. They were not in his report. The defendants themselves did not take these points in their pleadings. They were raised by their expert witnesses – Dr Robert Smee and Dr Karlsson who had given evidence before Dr Chua Eu Tiong. He followed thus like a lemming. He was parroting the phrases and false ideas introduced by Dr Robert Smee. False ideas because they were founded on wrong premises. They were not substantiated by hard evidence. There was no proof that the nodule was clinically malignant. The bottomline is that the only relevant evidence in this case about the nodule were the February 1996 and December 1996 MRIs. They demonstrated that there were no significant changes in appearance. More importantly, the defendants had accepted Dr Esther Tan's findings at that time and advised Gunapathy on the basis of those findings. The defendants' case was changed by some of the defendants' witnesses to justify the potent dosage of radiosurgery, when there had been no cause for the radiosurgery. Dr Chua Eu Tiong in his affidavit referred to the nodule

as "tumour" in two sentences and said nothing more. Both sentences were egregiously in error. There was no empirical finding or reasoned opinion of his own. He was relying on and regurgitating the discredited evidence of Dr Robert Smee.

17.9. Moving on to another point, Dr Chua Eu Tiong agreed that if the nodule did not have a diameter of 19 mm and was in fact 14 or 15 mm he would use a collimator of 17 mm. Dr Prem Pillay and Dr Tsao gave a customary margin and came up with a maximum diameter of 14 or 15 mm. Dr Chua Eu Tiong admitted that the collimator for that sort of diameter should be 17.5 mm. On that basis, the 22.5 mm collimator actually used was 28% more than what would be appropriate and adequate, assuming of course that the nodule was a glioma.

17.10. The next matter for consideration is dosage of radiosurgery. His affidavit evidence on this point was as follows :

The dosage of 2000 cGy at 85% isodose administered to the plaintiff, in my opinion, is not excessive as it is well within the dosage guidelines from the RTOG 90-05 study in the United States and quoted in the XKnife radiosurgery monograph of 1996 (Sperduto et al). (Para 5)

17.11. I have already demonstrated that the RTOG 90-05 guidelines are applicable only to "patients with recurrent previously irradiated primary tumours and brain metastasis". I have also demonstrated that even by the teachings of Dr Robert Smee the dosage of 15-20 Gy was the prescription for brain metastasis – that is, a malignancy that has metastasized to the brain from a lower organ. According to Dr Robert Smee's teaching for previously irradiated glioma recurrences, the appropriate dosage was 10-15 Gy. The defendants carried the burden of establishing that Gunapathy carried a glioma recurrence after undergoing whole brain or even a partial radiation therapy. They woefully failed to establish that. Gunapathy, admittedly, did not have a glioma recurrence.

17.12. Dr Chua Eu Tiong at one point said that the histology said that it was a low grade tumour. Dr Chua Eu Tiong erred once again. It was the first preliminary, alternative finding of Dr Anjula Thomas which described the original excised tumour as a "low grade" glioma or a neurocytoma. The final histology report simply said it was neurocytoma. Even then the markers of malignancy were not present. It was therefore wrong to treat it as a recurrent glioma.

17.13. Dr Chua Eu Tiong practised both *Gamma Knife* radiosurgery as well as *XKnife* radiosurgery. He was asked about the functions of the radiation oncologist and the neurosurgeon in stereotactic radiosurgery. The relevant exchange was as follows :

Q Would there have been occasions where the neurosurgeon would have prepared the dose and you would have, after discussion, asked for a modification?

A Yes.

Q Either upwards or downwards?

A Yes.

Q So that ultimately both you and the neurosurgeon would be responsible for the correct dose to be administered?

A Yes.

Q And so that you would not absolve the neurosurgeon from all liability for dosimetry, that is dosage and distribution in the case of a treatment plan?

A No.

Q You wouldn't?

A No.

[NE 3090-3091]

17.14. It was also evidence of Dr Prem Pillay and Dr Tsao Shiu Ying that in Singapore the neurosurgeon in the radiosurgery team was jointly responsible for the dosage. That responsibility makes good reason because he knows the nature, location and sensitivity of the different parts of the brain. He sees the patient and advises the patient – so he must know the basics of the physics and biology of radiosurgery.

17.15. Dr Chua Eu Tiong tendered in evidence a chart made by him in 1994/1995. The chart contained particulars of the size of various lesions and the radiation dosage for each. There were four different kinds of lesions : AV Malformation, Glioma, Metastasis and Acoustic Neuromas. As to gliomas with a diameter of less than 20 mm, he stipulated the following :

2500 cGy as isocentre prescription.

2000 cGy as 80% isodose prescription.

He said in evidence that the prescription details were derived from the book *Stereotactic Radiosurgery* by Eben Alexander III, Jay S Loeffler, and L Dade Lunsford. It was Dr Prem Pillay who introduced the book to him. Counsel cross-examined Dr Chua Eu Tiong about the indications for the prescriptions. The following exchange between him and counsel:

Q Now, if you look at this D24 (the chart) itself, the glioma under section two, which you have listed there is actually in fact for malignant gliomas?

A Yes.

Q Dosage there, and not low grade gliomas?

A No, because the experience for low grade glioma is not reflected in this book.

Q Yes. So, therefore, this is only for malignant gliomas?

A Yes.

[NE 3092]

So the dosage prescription in the chart was not for a low-grade glioma, let alone a benign neurocytoma. It is well to remember that the prescription for glioma in the *Sydney Protocol* did not make mention of low-grade gliomas as claimed by Dr Khor.



## Chapter 18 : The Scar or Tumour Controversy Laid to Rest

18.1.The alternative descriptions of "scar" or "residual tumour" of the lesion were first introduced by Dr Esther Tan, a diagnostic radiologist in her report of 26 February 1996. She said : "this may represent scar tissue related to the previous surgery than residual tumour." When Dr James Khoo's clinic asked for the February 1996 MRI, the request form stated that a left intraventricular tumour had been removed. It did not state that it was a neurocytoma.

18.2.Next, when Dr Esther Tan performed the MRI of 26 December 1996, once again there was a request form from Dr James Khoo's clinic. It stated : "a left intraventricular *glioma* excised 19/11/95". Dr James Khoo later disclaimed responsibility for the description of the tumour as glioma instead of neurocytoma. It was the fault of his staff and not his, he said. He would not accept responsibility even though he was the captain of his clinic. For obvious reasons to be stated later, it was dangerous to treat the neurocytoma in Gunapathy's brain as a "glioma". Dr Esther Tan, however, went by what was stated in the request form. "I report what I see" she said. In December 1996 after studying the MRI images she concluded : "These abnormalities are probably due to scarring from previous surgery." This time she omitted all reference to a "residual tumour". Thereafter Dr Esther Tan was no longer involved with Gunapathy.

18.3.Then there was the clinical note by Dr Khor on 4.3.96 which had this entry : "? Scar at roof of (L) lateral ventricle". On 31 January 97 there was another note by Dr Khor : "Had seen Dr J Khoo – finally requested R/S to increase probability of tumour control before proceeding to conception". Dr Khor did not assign any specific pathology to the nodule.

18.4.Unbeknown to Dr James Khoo and Dr Khor at that time Gunapathy visited Dr Ho Kee Hang. The meeting was arranged by Dr Devathasan. The clinical record of Dr Ho Kee Hang made on 21 January 1997 contained these notes :

Diagnosis : (L) lat. ventricle neurocytoma

Problem: small residual neurocytoma hanging from the roof of (L) lat. ventricle

18.5.Dr Esther Tan later gave evidence. These are extracts from her evidence.

[The nodular lesion] was in the same area where the original tumour was and I wasn't sure whether this was a little bit of tumour that had been left behind or whether it was a scar. ...

What happens is that when tumours are removed; the surgeon usually attempts to remove a tumour with a margin of normal tissue around it to make sure that they haven't left anything behind. But it's well known that despite what appears to have been complete removal of a tumour, there may have been microscopic spread beyond that area that nobody with a naked eye or even a microscope can see. I mean it's a little bit like having a patient who's had breast cancer and the tumours being completely removed and the breast has been removed and it appears that everything is gone, and then a few years subsequent to that the patient ends up with a secondary tumour somewhere else in the body or somewhere else. [NE 906-907]

18.6.Dr Esther Tan's illustration was in respect of a malignant tumour. She confirmed it was so. She then added this caution :

Whether it is benign or malignant, sometimes it's a fine line between the two. I am not a pathologist, whether the neurocytoma is considered benign or malignant or a low grade malignancy is something I think they have to decide on. [NE 907]

18.7. Then came the December 1996 examination. Referring to this she confirmed that she took the measurement of the nodule as 11 x 12 x 6 mm by using the computer's mouse. She further confirmed that just because the report mentioned "sagittal, axial and coronal" it did not follow the measurements were in that order. She said that sizes in the MRI were measured on the computer monitor.

18.8. It was this statement that much later impelled me to insist on viewing the radiosurgery images done on 31 January 1997 only to be told that the *XKnife* software had no device to measure a lesion.

18.9. On a later day, Dr Esther Tan confirmed that the measurements were actually recorded on the December 1996 MRI images. There was no such recording for the February 1996 MRI scan. The imaging of November 1995 recorded the dimensions of the original tumour before excision.

18.10. Dr Esther Tan was asked later how she managed to compare the size of the nodule on the February 1996 and December 1996 scans if she did not note the measurements in the February 1996 MRI. Her answer was :

I made assessment on the basis of comparing the size of the abnormality with relation to the structures around it. [NE 1007]

And she made what she called a crude measurement in Court and came up with 10 x 10 x 7 mm. She also clarified two MRIs are bound to have some differences because of the position of the patient and the slices. It is impossible to be absolutely precise.

18.11. Dr Esther Tan in her evidence gave her reason for concluding that the nodule was a scar :

I did not think that it had enlarged. So in terms of size and appearance it appeared to be similar to the February 1996. ... The nodule was enhancing, and I also described that there appeared to be a bit of enhancement in the brain tissue next to the nodule, because the nodule was a protuberant lesion and this was on the scarring from previous surgery. On the basis that I didn't think there had been a change, on the basis that the findings were stable, I concluded that they were probably scar tissues. [NE 910-912]

18.12. Dr Esther Tan was told of Dr Robert Smee's assertion that he was 99.9% sure that this was a recurrent tumour. In response to that she commented as follows :

I think it is actually very difficult to say, just looking at the images, what the cell type is going to be. I think to be absolutely sure, you would need to have some tissue diagnosis, which is a biopsy of one form or another. [NE 912]

There was then the suggestion by the defence that in the December 1996 scans of the nodule, there was contrast enhancement. That is, in the December 1996 scans the nodule was brighter. Dr Esther Tan commented on it as follows :

OK, contrast enhancement in the brain depends on --- there are few factors which will determine whether an abnormality enhances with contrast or not. And

the key in that is whether there has been a breach in what we call 'the blood-brain barrier'. Because some of the vessels --- many of the vessels in many parts of the brain are specialised in that there is a barrier. When there's been a breach in the blood-brain barrier, the contrast, the dye that has been injected has a tendency to leak out. It's allowed to leak out. Contrast enhancement is non-specific. You can see it in a variety of situations. If the patient has an infection, if the patient has a tumour, if the patient has a scar from previous surgery or maybe a head injury or something like that. So it's non-specific finding. Now, the degree of enhancement that you see will vary with the amount of contrast that was given, the speed at which it was given, and the time between the administration of the contrast and the acquisition of the image. OK, and how bright it looks on an image will depend on some degree --- will depend to some degree on how the image has been taken. You can adjust the window level and window width to adjust the grey scale.

As you would adjust an image on a television screen, for instance, to make it slightly brighter or slightly darker. Also, some of the factors that may come into play are the technical factors in how an MR examination is done. There were slight differences between --- the technical factors between the two examinations and while we try to keep things constant when there are new developments and sequences that may improve our images, this is what we employ. [NE 914-915]

18.13. In cross-examination by counsel for the doctor defendants on the scar or tumour controversy, Dr Esther Tan lucidly stated her position :

First, if there is something abnormal in the area where the tumour appears to have been removed and the margin of resection was clear then it would be likely that there was no tumour remaining.

If the margin was not clear histologically, then there is a chance that there you have left something behind. I would say a strong likelihood that there is a tumour remnant behind.

Secondly, it appears to the naked eye that the tumour has been removed. You have done a scan after that. That shows something there. The pathologist cannot confirm to you that the margins have been clear, although it appears to the naked eye that it could be clear.

In addition the patient had radio therapy after that. Then something appears there. In that case there could be a remnant tumour. [NE 954-956]

In the above scenario the important element is that the pathologist cannot confirm that the margins have been clear. That was not the case here. There was no finding by a pathologist as to whether the margins were clear. There was no report to that effect. Dr James Khoo did not ask for such a finding. Nonetheless Dr James Khoo had stated that there was a total removal. There was no statement to that effect by a pathologist.

Thirdly, if 13 months after the surgery, she saw a distortion resulting from the surgery and that is what I would consider a scar, a distortion in the shape of what the original brain looks like. They very often will settle to some degree, but

very often it does not go away completely. The amount of scarring that you see varies greatly with how much disturbance there has been to the area ... .

You get a bad scarring, and the bad scarring would remain looking like bad scarring for years after that. But in general I would say scarring would usually become a little less obvious ... .

I wouldn't be surprised if the changes had become less obvious. But then again, if the changes had remained stable, it wouldn't be something I would be surprised about either.

We have done MR examinations 13 months later, you can sometimes follow up patients years after they have had operations done and you will still see scars, you will still see the enhancement in the tissues.

It has been known that you can follow up a patient 10 years after that, 15 years after, and you will still see enhancement,

you will see  
distortion. That is  
empirical – you  
see it – it is not  
just an opinion."  
[NE 958-959]

18.14. Counsel asked Dr Esther Tan if she in her 10 years experience, had seen enhancement, that is a scar, remaining a year in the same size after radiotherapy. Her answer was :

Same size, radiotherapy changes can remain.

OK, if a patient has radiotherapy, say, nothing else has been done, OK, we are taking a fresh brain and the patient has radiotherapy. There will be changes in the brain. Because you have actually given radiotherapy, there will be swelling and there will be some inflammation in the tumour, maybe the brain, a bit of the brain around it and so on. So it gets swollen, should I say, and inflamed. And in initial period, that's when it looks angriest. And if you say, then stop the radiotherapy and then you follow the patient up over time, the changes will settle down to a degree. In some instances, you may have the change prolonged and then it becomes a diagnostic dilemma as to now, is this just change from radio therapy or has the tumour grown back and extended? So the answer is yes, *you can have changes from radiotherapy extending for more than a year.*  
[NE 960]

18.15. At the time she did the February and December 1996 MRIs, Dr Esther Tan was not aware that Gunapathy had undergone radiotherapy. In the above extract she confirms that changes from radiotherapy may last for a long time. Changes from radiotherapy is usually called "radionecrosis", a term used by Dr Yeo Tseng Tsai.

18.16. Dr Tan then explained what she meant by the term "scar" and distinguished it from "fibrosis" :

I think fibrosis tend to be a --- to me, you are talking about a specific pathological term, and I am not sure I could see something on an MR which I would say, "this is fibrosis". When I use the term "scar", I mean that the area has been disturbed and there are some changes which I feel are the consequence of a particular form of instrumentation, surgery or radio therapy or maybe the patient had a bump to his head and had some trauma. So I use the term "scar" in some ways as a rather loose term. When you say "fibrosis", if you are talking about the pathological diagnosis that there's fibrous tissues forming down there, I don't know if I have actually seen specifically fibrosis in the brain.

I cannot tell you that I have seen a case and this has been histologically proven that it's fibrosis. If you ask me if I have seen a brain that is scarred from whatever --- surgery or whatever, yes, I have seen that.

I cannot recall that there has been a specific diagnosis made of fibrosis in the brain, because I think it's something you might want to talk with the pathologist about. [NE 961-962]

18.17. Other high-points of her evidence were these :

The size of the lesion, but what happens is that with radiosurgery, usually the scans that are done are only in one plane, usually. They are usually done in just the axial plane. [NE 967]

If I say to you that something is square, and absolutely, square, and say --- or say a cube, because it's a three-dimensional structure now, it would be quite easy to give you accurate measurements. But the lesion, not being of a regular shape, it wasn't round, it wasn't oval, it wasn't square, but it was kind of a lobulated thing. I gave an estimate because if you measure one dimension at a certain part, it may be slightly different from a dimension, maybe, in one plane slightly below it. So I gave an approximate measure.

What we normally do when we want to measure these lesions is to do it on the computer, with a cursor on the picture so that the measurements are a little more accurate. [NE 968-969]

Because of the nature of the MR examination the likelihood is that they will be at slightly different angulations and they will start at slightly different reference points, if you did it or if I did it, or even if you did it three times on the same day, the three examinations may be slightly different. So if you bear in mind that you take a lesion which is not a regular shape, and then you are prescribing manually where the slices go through it, there is going to be slight variation, depending on the operator and also even, as I have said, the same operator doing it the same time --- different times, there will be slight variations. And so you might measure the same lesion and not get the same size at each sitting. [NE 969-970]

I have stated in my report that I thought that it was probably a scar, rather than a tumour. That's an opinion which I expressed, and the basis for that was because in my opinion, the area of abnormality in question had not changed. [NE 970]

I think Dr Hui, he did his further training in neuro radiology but I think his interest was specific in doing interventional work. Basically, it's trying to do things like stopping blood flow to tumours in the brain and blood vessel abnormalities in the brain rather than specifically in the interpretation of MRI scans. Do you get what I mean? He's actually --- his specific training, as I understand, was in interventional procedures of the brain as opposed to interpretation of MRI scans. Certainly, he probably sees MRI scans day in, day out, and he doesn't see mammograms and chest X-rays and barium meals like I would do. [NE 997-998]

OK, Francis has his opinion, he's seen the films. I have explained to you that because of the difference in the way --- differences in the way the examination is done, the lesion may look slightly different. OK, so, that's one thing. There may be a more prominent --- it may appear that the enhancement of the lesion is more prominent. But as I say, in the previous exam, there was already enhancement in the lesion. The appearance of a more prominent enhancement could well explained by technical factors, rather than something significant happening in the lesion. There was already a breach in the blood-brain barrier previously. So I am not sure that I can actually read too much into a change in the perceived degree of enhancement of the nodule. Certainly, I would agree

that if a nodule has changed in size, that is something suspicious, something to sit up and take a lot more notice about. But it was, and it is my opinion that there hasn't been a change. Well, there wasn't a change between the two examinations. [NE 1002-1003]

18.18. Dr Esther Tan as an expert witness will be assessed in chapter 22.

18.19. The all important question that first attracts my attention is: What was the disease, disorder or deformity that indicated the appropriateness of high-tech radiosurgery in addition to conventional radiotherapy?

18.20. Since Dr Khor was in charge of radiosurgery in Mount E Hospital I examined his defence for his answer to the question. In other words I expected Dr Khor to say what diagnostic procedure he applied to make his own diagnosis or determination. The importance of right diagnosis or correct categorization of the disease, when it comes to the high-tech, high-dose, high-risk procedure of radiosurgery is a matter of vital importance. A wrong diagnosis or categorization may mean personal disaster to the patient. In paragraph 3 (c) the defence alleged that the plaintiff "insisted that all possible tumour remnant in the brain be controlled. She had then seen the 1<sup>st</sup> Defendant who offered radiosurgery for this purpose". This did not say what Dr Khor's diagnosis was that indicated radiosurgery.

18.21. In paragraph 5(3) Dr Khor alleged : "The tumour as reported on the MRI Scan was approximately 11 mm x 12 mm x 6 mm in size. At the treatment planning, the maximum diameter of the tumour was 19mm". This was a misleading statement. The only document that gave the dimensions of 11 mm x 12 mm x 6 mm was Dr Esther Tan's report dated 27 December 1996 and the MRI which related to it. Nowhere in the report of December 1996 did Dr Esther Tan mention the word "tumour". In that report and in the earlier report done on 26 February 1996 she discusses "the lobulated enhancing mass", "a small nodular density protruding from the roof of the body of the left lateral ventricle", and "an enhancing nodular opacity protruding from the roof". Dr Khor, thus, has plucked the word "tumour" from nowhere.

18.22. I now turn to Dr Khor's clinical notes in 1996 and 1997 when the plaintiff consulted Dr Khor. These notes have been reproduced in chapter 2. Nowhere in these notes did Dr Khor record what disease indicated radiosurgery. There was nothing in those notes to indicate that Dr Khor applied his mind to make a determination of the disease he proposed to treat.

18.23. Such was the state of affairs as of 31 January 1997. Next was Dr Khor's "confidential" letter of 8 December 1999 to Messrs Michael Khoo & Partners (See chapter 4.1). In that letter he acknowledged in paragraph 4 that "A follow-up examination was suggested as the reporting radiologist was not able to tell whether the lesion was just scar tissue or residual tumour". In paragraph 8 of his affidavit Dr Khor said : "a progress MRI on 27 December 1996 had again shown the enhancing nodular opacity protruding from the roof of the left lateral ventricle – this had not changed significantly from the finding of February 1996". In other words over the period of 10 months there was no growth of the nodule. All expert evidence before us established that radiology is the only means of determining whether a tumour is present and in particular a malignant tumour. For there to be a tumour, there must be clear evidence of growth and enlargement. This was the reason why Dr James Khoo had recommended a follow-up MRI four months later. However, he failed to get that done – in four months. He failed to carry out his own advice and recommendation. He was so unconcerned about the nature of the nodule that an MRI was only done 10 months later in December 1996 and even then there was no evidence of growth. Dr Esther Tan was satisfied that there was no significant change. The only conclusion to be drawn from that was that there was no tumour. There was no cause for

concern. The major indicator of malignancy, namely progressive growth, was not there. The doctor defendants accepted her findings and advised Gunapathy on the basis of her finding. The other main indicator of malignancy – that is metastatic or secondary growth – was totally missing. There was not an iota of scientific evidence to suggest that there was a morbid medical condition requiring any treatment let alone high-risk, high-dose radiosurgery.

18.24. Then Dr Khor sought to hide behind Dr James Khoo. On 31 January 1997 he recorded : "Had seen Dr J Khoo – finally requested R/S". Again in his letter of 8 December 1996 he said : "She saw James Khoo soon after and requested further treatment" and he agreed

18.25. I shall now consider Dr Khor's position on Gunapathy's pathology as revealed by him at the trial. In paragraph 3 of his affidavit of evidence-in-chief he conceded that the original tumour which Dr James Khoo removed was confirmed to be a neurocytoma and it did not have the markers of a malignant tumour. Post-operative CT head scan showed no evidence of residual tumour. Such being the case there was no pathology which indicated the need for any therapy, let alone radiation therapy. Nonetheless he agreed to give the *radiation* therapy. His affidavit said that neurocytoma was not a benign but malignant tumour. Following that, he agreed to give radiosurgery.

18.26. His justification is found in paragraphs 9 and 10 of his affidavit evidence :

I saw the plaintiff again on 23 January 1997 when we had long discussion regarding the implications of a pregnancy should she conceive. The plaintiff had been married for over a year and was anxious to have a child. She was assured that there was no medical contra-indication to pregnancy, but that the social aspects should be considered, as she could not be regarded at that time to be cured of her brain tumour.

Thereafter, I was informed by the 1<sup>st</sup> defendant that the plaintiff had seen him and requested further treatment to ensure that there was complete tumour control. At that time, the role of radiosurgery was discussed. The 1<sup>st</sup> defendant then telephoned me and I asked for the plaintiff to see me again before the procedure was performed. When I saw her again on or about 27 January 1997, my advice to her was to observe the lesion shown on the MRI. The implications of radiosurgery were discussed with her, including the risks and the option of continuing monitoring the abnormality shown on the MRI. However, as the plaintiff insisted that all possible tumour in the brain be controlled before she embarked on a programme of assisted reproduction, it was decided to proceed with radiosurgery.

18.27. At the trial, however, Dr Khor asserted that it was Dr James Khoo who told him that there was a tumour. It was Dr James Khoo who asked for radiosurgery for the tumour. The evidence of Dr Khor on this point is as follows :

Q Who told you that it was a tumour, Dr Khor?

A Oh, Dr Khoo told me---

Q I see.

A --- it was a tumour. As I said, he had called me up and told me.



Q And assuming Dr Khoo was wrong, what would you have been left with?

A Of course, if Dr Khoo were wrong, then we would have left with having treated something that was not a tumour.

Q I see.

A Yes, I cannot say no to that.

Q All right, so you relied entirely on Dr Khoo, I mean, his judgement or his opinion.?

A Yes, yes.

Q Did Dr Khoo tell you that radiosurgery was being indicated as a curative method or, rather, for curative purposes, or was it palliative, meaning, you know, to provide her with comfort or ---?

A No, I don't recall whether Dr Khoo said it was curative or not but my own understanding of it is that the radiosurgery was given with intent to cure. What we call a radical treatment, we hope to cure, we intend to cure. In our work, your Honour, the first thing before we---after we say we give treatment is "Am I giving it with an intent of palliation, in which case, the dose is a bit different, or am I going to treat this with intent to cure?", and the intention was to cure. [NE 2478]

## **Chapter 19 : Advice and Consent**

### The issue

19.1.The other principal issue raised in the pleadings concerns the advice given by the doctor defendants and the consent given by Gunapathy.

### The evidence of Gunapathy's husband

19.2.I shall first state the evidence of Gunapathy and her husband. Gunapathy's husband, Mr Silvere Sanchez, had accompanied her to see Dr James Khoo in early February 1996. This was after the radiotherapy. They went to see Dr James Khoo with the February 1996 MRI scan. According to him, Dr James Khoo told them that the "the small white spot" may be a scar but not a tumour because a tumour would be brighter. There was a slight possibility that it was a tumour. But it was not so bright. So he advised them to leave it alone for six months or one year. If after that it had grown "you can just zap it". The witness added that Dr James Khoo said : "it's just very simple, very safe, it is just only a half a day operation and it's quite common and you just zap it". He did not accompany his wife in relation to the consultation on the December 1996 MRI. No one told her or him about the risks of radiosurgery. This meant that his wife did not inform him that any of the doctors she had seen had advised her that there was some risk in the radiosurgery. His memory on that was poor. His impression was straightforward. To him "from the beginning it was no risk. It was a simple operation. Something common. Something very simple." He said that "Dr James Khoo explained : Just wait for a while ... , take it easy and after some time, a year, if the thing still appears, if the thing has grown or whatever, no need to be worried or frightened about. We can still just do some kind of zapping – like a laser, just to zap it. That's it, it will be gone." In view of the impression he had about the nodule and the

safety and simplicity of the radiosurgery procedure, he did not even accompany her when she went for the radiosurgery. Her brother sent her to the hospital and left. He later fetched her.

#### The plaintiff's evidence

19.3.The plaintiff gave evidence on the issue of advice and consent. She was aphasic. She had great difficulty in verbalising her thoughts. She had a poor collection of words. She tried to compensate her aphasia by writing and drawing with her left hand. She was slightly more responsive to leading questions. She did file an affidavit but as that was obviously the work of her lawyers, I decided not to place any reliance on it. I wanted to observe her under cross-examination. In her evidence, "I forgot" and "maybe" were frequent responses.

19.4.In relation to the nodule she was asked by the doctors's counsel what Dr James Khoo told her. She wrote her answer "it's simple, not fear any." She then drew the head ring used in radiosurgery.

19.5.She was asked whether in relation to the second operation (the radiosurgery), Dr James Khoo had explained to her the risks involved. She wrote her answer : "It's not risk an operation." She then did not want the "It". So it became "not risk an operation".

19.6.She agreed she saw Dr Khor before the second operation (radiosurgery). She was not so sure about seeing Dr Devathasan. In particular she could not remember Dr Devathasan's letter of 22 January 1997 stating that she "decided to undergo radiosurgery". The defendants relied on Dr Devathasan's letter but for reasons best known to themselves did not call him as a witness. Neither side called him. The impression I formed was that Dr Devathasan was being difficult and refused to assist or co-operate.

19.7.Gunapathy agreed that she had seen Dr P C Wong, a gynaecologist, and sought his expert opinion report. She remembered another gynaecologist, Dr Pritam. She wrote "Seetho Clinic – Doctor, Tanglin Shopping and Gleneagles Hospital". Asked about "fertility programme" she wrote : "No, not. No Fertility".

19.8.It appeared that she had an abortion before the marriage. That was "maybe 1990 or 1991".

19.9.No one mentioned the word "cancer" to her at any point in time. The word "lesion" was mentioned. So was the word "nodule".

19.10.Gunapathy could not remember seeing Dr Ho Kee Hang.

#### Why did the plaintiff agree to radiosurgery

19.11.The doctors' counsel asked her : "Why did you not wait and see the nodule?" She wrote her response : "Because so "simple". She agreed it was because she wanted to proceed to have a baby. Then counsel put it to her : "You wanted to have a baby, that is why you did not want to wait?" She then spoke : "I don't know, maybe, you know, but you know –". And she wrote "simple".

19.12.I interpreted her words back to her to this effect : "I've got a nodule, I want to have a baby, Dr Khoo said : "Take out simple". "So take out, I have a baby." The witness confirmed my interpretation to be correct.

19.13.She also confirmed that what was in her head was "Scar". It may also be "tumour".

19.14.She expressed herself very poorly because of her morbid condition. Often it was ambiguous.

Most of the time it was garbled. Nonetheless the substratum of her evidence was this : She and her husband wanted to have a baby, but did not want to proceed to conceive with a possible brain tumour. Dr James Khoo advised that it was a simple operation to remove the nodule, which could either be a scar or a tumour, by radiosurgery. So she agreed to have it removed and consented to radiosurgery. She consented because it was a simple operation, and no one had indicated to her that it involved any risks. Certainly no one informed her that it was a highly potent and still largely experimental technique, which, combined with her previous radiation therapy, could produce lethal and serious side effects.

#### Fertility programme

19.15. Gunapathy had consulted Dr P C Wong on 2 August 1995. There was no evidence to the effect that in 1995 or 1996 any fertility programme had been planned for her. The plaintiff's bundle of documents contained two letters from Dr P C Wong. They were dated 28 April 1999 and 20 October 2000. Dr P C Wong did not give evidence in Court. According to those letters, Gunapathy saw Dr P C Wong for a second opinion "regarding the procedure called video laparoscopy to be carried out by another gynaecologist. She had consulted the other gynaecologist for fertility treatment." After reviewing some of her test results Dr P C Wong "suggested to her that if she was not keen to proceed with the laparoscopy as yet, she may then try to conceive on her own for the next few months. She might then consider laparoscopy if she is not pregnant by then." It would appear that she tried to conceive but was not successful. In November 1995 the neurocytoma intervened and sent her to Dr James Khoo and Dr Khor. She then did not want to conceive before the "lesion" was cleared. Then came the radiosurgery and the adverse side-effects.

19.16. There was another letter from Dr Pritam Singh whom Gunapathy saw on 14 July 1997. She had seen him as Dr P C Wong was not in. He wrote a letter dated 14 October 2000 containing the following sentences :

She reported that on 31 January 1997, she had a "localisation" of "scarred tissue" or "the site of possible recurrence of previously treated brain tumour. She had earlier completed radiotherapy on 15 November 1995 for the brain tumour". (The word "radiotherapy" should be read as "surgery". It would appear that Dr Pritam Singh was informed of the radiotherapy and radiosurgery but not the duration of radiotherapy.)

#### Finding on advice and consent

19.17. Having considered all the evidence and having seen the witnesses and the clinical notes I find that the advice given by Dr James Khoo to Gunapathy and the basis of her consent to radiosurgery was in essence what I have stated in paragraph 14 of this chapter. Dr James Khoo adopted the findings of Dr Esther Tan and told Gunapathy that he was not certain about the true nature of the nodule. It could be a scar, it could be a "recurrent" or "residual" tumour. He used these terms without assigning any special technical meaning to them. He further led her to believe that she should have the nodule removed before she conceived. He led her to believe that radiosurgery was simple and safe. He did not inform her of the adverse side-effects it entailed. Dr James Khoo's letters and defence in effect confirm the substratum of her evidence. His suggestion that he did it because of her insistence is unsupported by evidence. The truth of what happened was contained in his letter to Michael Khoo & Partners : "the nodule was suspected to be a recurrent tumour. The plaintiff was keen to have a baby and not in favour of an expectant line of treatment nor any form of open surgery again." There was no mention of any side-effects. Dr Khor's position was not different significantly. Dr Esther Tan had ruled out a residual tumour but Dr Khor seems to have misunderstood her. He said in

his letter to Messrs Michael Khoo & Partners that in December 1995 Dr Esther Tan "was not able to tell whether the lesion was just a scar tissue or residual tumour". He therefore told Gunapathy that "she could not be regarded at that time to be cured of her brain tumour". Dr Esther Tan did not say that there was a tumour. Hence, Dr Khor's statement that Gunapathy "requested further treatment to ensure that there was complete tumour control before proceeding to conception" was based on his unfounded conclusion that there was in fact a tumour. There was no mention of complications or adverse side-effects.

19.18. Dr Ho Kee Hang's position was slightly different. He concluded that there was a residual neurocytoma. In such a situation she would naturally want to have it removed before she conceived. Dr Ho Kee Hang's notes do not say he warned her of the possible adverse consequences. He mentioned "pros and cons". This must relate to the choice of "conceive first or remove the tumour first". Under the circumstances the natural and reasonable choice was to have the residual neurocytoma which Dr Ho Kee Hang said was hanging in the roof, removed. She would not want a repetition of her November 1995 suffering.

19.19. Dr Ho Kee Hang attended the Sydney lectures by Dr Robert Smee. He said that "there were handouts but I do not really remember what were in the handouts now." (Dr Khor, however, said that there was no handouts; all he returned with with the notes he took down). Then there was the exchange between Mr Michael Khoo SC and Dr Ho Kee Hang :

Q All right. Now, do you recall that in the case of glioma, and I think this is where what you have told us is in accordance with what Doctor Smee had said. If you recall at this lecture, he said that the treatment for malignant glioma will be radiosurgery, stereotactic radiosurgery after conventional---with a boost after conventional radiotherapy.

A I'm not sure whether he---I don't think he said that. My understanding of the condition is perhaps stereotactic radiotherapy and not radiosurgery. I've never done that. These are two different---totally two different methods of treatment.

Q Sure, because radiosurgery would be a single dose and---

A Exactly.

Q ---stereotactic---but some doctors, we've heard in the witness box, have confused the two.

A Yes.

Q All right. Now, in this case, would you remember for treatment of the malignant glioma with stereotactic radiotherapy, the dose recommended is 54 Gy conventional RT, followed by a boost of 10-15Gy?

A I don't remember that because I'm really not involved in that aspect of treatment because I do not practise stereotactic radiotherapy, I refer the patient to the radiotherapist and he does everything, as far as the malignant glioma is concerned, I'm not in the position to comment on that. [NE 3456-3457]

19.20. Obviously Dr Ho Kee Hang did not pay attention or understand what Dr Robert Smee had said. What Dr Robert Smee said was recorded by Dr Khor in the *Sydney Protocol*. Later Dr Ho Kee Hang said

hat he had never recommended any patient for radiosurgery. He had seen one patient with low grade glioma. It was Dr Baratham's case. That patient went to Sweden. Dr Baratham arranged for consultation in Sweden. Dr Ho Kee Hang did not know what treatment the patient had in Sweden.

19.21. Then Dr Ho Kee Hang revealed the extent of his understanding of radiotherapy and radiosurgery. He agreed that for malignant glioma the suggested course of treatment would be radiotherapy of 54 Gy plus 10 to 15. Here are the material parts of his evidence :

Q That is radiotherapy plus a boost, 54 Gy plus 10 to 15?

A Yes.

Q And that's how you'd treat even a malignant glioma?

A Yes.

Q So what more---how do you then treat a low grade glioma?

A That is exactly the problem we have because the low grade glioma grows slowly, therefore, it may not be as sensitive to the fractionated treatment that you give to malignant glioma. We face the same situation with a tumour that was mentioned earlier on, a meningioma, which is a very benign tumour. And we have given, in some circumstances, fractionated radiotherapy; in other circumstances, radiosurgery. I think currently we would use radiosurgery more often than radiotherapy.

By Xknife or Gamma Knife. Similarly, the acoustic neuroma is a benign tumour, and we use radiosurgery. In fact, radiosurgery is more useful in a more benign type of tumours because benign tumours have usually got a clear-cut margin and the beauty of radiosurgery is you can give a very high dose to the tumour and yet spare the neighbouring brain whereas in radiotherapy, the area that you cover is much bigger. So my understanding of the use of the radiation is that for an infiltrating malignant tumour, we tend to use fractionated radiotherapy. For a slow growing benign tumour, we would tend to use radiosurgery. That is as a general rule, but of course it has to be tailored according to the circumstances.  
[NE 3464-3466]

19.22. Then he agreed that he was not aware of any evidence that radiosurgery would have worked for neurocytoma. "I think we do not know enough about central neurocytoma" he said. He should have advised her to go to an experienced person like Dr Prem Pillay or Dr Tsao Shiu Ying. He said that he did not know what knowledge or training or experience Dr James Khoo had acquired with regard to treating central neurocytoma with radiosurgery. Then my question and his answer went as follows :

Court	Do you think you know enough to go and recommend a radiosurgery, meaning all the side effects and how it works and all those things? How – will you have to go and depend on the radiotherapist, is it?
Mr Khoo	Yes, radiation therapist.

Witness I would recommend but I would always refer the patient to the radiotherapist for another consultation, independent of what I've said. And then if the patient agrees, and the radiotherapist also agrees that it is a good indication, then we would proceed. I will never make a decision on my own because I do not perform the procedure on my own.

Court In any case, you will give the full details to the patient and the parents?

Witness Yes, of course. [NE 3468-3469]

19.23. So Dr Ho was unfit to advise the Gunapathy as to radiosurgery. Dr Devathasan ought not to have sent her to Dr Ho Kee Hang. Dr Ho Kee Hang spent in all 10 minutes including the time taken to study the MRIs and his papers. His notes dealing with a high risk procedure were appallingly scanty. He discussed the "pros and cons" but this could only have related to whether to wait and see or proceed to conceive. Dr Ho Kee Hang ought not to have advised her to go back to Dr James Khoo.

19.24 In the result, I conclude on the basis of the evidence of Gunapathy and her husband and the notes of Dr James Khoo, Dr Khor and Dr Ho that she had consented to radiosurgery without adequate and accurate information and advice. She was recommended radiosurgery when there was no prophylactic or therapeutic reason for such a procedure. In the result there was no informed consent based on appropriate and adequate advice. It was obtained by misinformation and ill-advice. At all events the defendants' assertion, that they performed the radiosurgery because of the plaintiff's insistence despite their advice, was unproven.

## **Chapter 20 Dr James Khoo's knowledge and training**

20.1. As to Dr James Khoo's knowledge, training and experience about XKnife radiosurgery, the essence of his evidence was as follows:

I attended the Gamma Knife course half-way then I stopped because of other commitments. I decided I won't do it." [NE 1754]

When Linac Radiosurgery Unit was set up in Gleneagles Hospital, Dr Balaji Sadasivan, another consultant colleague was the person who was responsible for setting up in Gleneagles Hospital sometime in 1996. I learnt my linac radiosurgical role through him. He took me through about four cases or so, and basically it was learning on the job. There was no formal training, there was no formal training requirements for linac radiosurgery in Singapore, not like Gamma Knife. Dr Balaji had training in America. He basically taught me what to do. It was in 1996. I cannot remember the exact month. It was Dr Prem Pillay who introduced radiosurgery into Singapore – that was Gamma Knife. At about the same time Linac Radiosurgery was set up in Gleneagles. [NE 1774-1775]

In linac radiosurgery, the neurosurgeon takes a much smaller role than in Gamma Knife radiosurgery. He has to understand a lot more about the doses produced by the cobalt sources, the collimation and so on. In linac radiosurgery, and this is practised by most of the neurosurgeons I know in Singapore and Australia too, the radiotherapist has a very important primary role in regulating the physics and the radiation treatment of the lesion. My role as a neurosurgeon is to find that the cases are suitable for this; map out the target, map out the important parts of the brain and make sure that the plan doesn't involve radiating good parts of

the brain which I want to avoid. And basically the dose is left to the radiotherapist, and this is the practice done by most surgeons here in Singapore, in Australia and many parts in America. It's always been a radiotherapist to the linac. I don't profess to know all about it, because they understand the machine much more than I do, and I don't have any training in radiotherapy. [NE 1778-1779]

20.2.The Court asked Dr James Khoo : What knowledge had you acquired before you referred her (Gunapathy) to radiotherapy, in 1995?" Dr James Khoo answered :

Well, I basically left the options to Dr Deva but I felt radiotherapy was one of the many options of treatment for this type of tumour. The actual referral was from Dr Devathanan. I suggested further treatment. [NE 1780]

20.3.As he did not give a direct answer, the question was repeated : What is the knowledge you acquired in order to recommend radiotherapy? Dr James Khoo's response was this :

Well, I felt that the tumour is one of the type of tumours, although slow growing or low grade, has a reasonable chance of relapse. And I therefore felt that radiation or chemotherapy could have an effect in reducing this risk for the patient. [NE 1780-1781]

He never revealed exactly what knowledge he had of radiosurgery. He dodged it.

20.4.Dr James Khoo was asked whether the advice of *XKnife* radiosurgery was given by himself solely or in consultation with Dr Khor. He responded as follows :

After I felt that she should have this form of treatment, I consulted Dr Khor as to whether this lesion is a suitable one, because Dr Khor would have to agree before he helps me --- before we do the radiosurgery together. So it was in consultation with Dr Khor and of course in consultation with Dr Deva who's attending doctors too. [NE 1754]

20.5.In relation to the **Radionics XKnife** manual he said he had read it. He had a copy that Dr Khor passed to him in November or end of the year in 1996. As to the requirement for training he said :

This is not a legal requirement by the hospital or by the government of Singapore to us. We obviously are expected to learn how to use the machine in terms of our role in it. But this caution is just a standard sort of I think manual for the machine. And then as long as the member of the team, I think basically the person in charge of the XKnife, the Linac, has all these requirements and training, he could, I think, be expected to make sure that his physicists, his clinicians, his consultants would be also keep up with this sort of --- this type of requirement. I don't think this is a requirement that is expected of us in Mount Elizabeth in Singapore. [NE 2085-2086]

And so according to Dr James Khoo XKnife radiosurgery was free-for-all at Mt E Hospital

20.6.As to the various recommendations and procedures stipulated in the **Radionics XKnife Protocol** he answered :

I was neither told nor required to follow this protocol by Radionics. I don't think any other surgeons was asked and to follow this protocol of this requirement. [NE 2083]

20.7. Dr James Khoo was asked whether the neurosurgeon is ultimately responsible for the dosage which may be proposed by radiotherapist, oncologist, and the physicist. Dr James Khoo's position was that the neurosurgeon should know the dosage that is to be given to his patient but is not responsible for the dosage selection. He said :

I think the dose is always basically for LINAC radiosurgery, determined by the radiotherapist because he understands radiation dose much better than I do. At least in my practice this is the case. He would tell --- I mean the radiotherapist usually would tell us what dose he's going to use and why and basically the neurosurgeon, unless he knows a lot more and he knows a lot about --- basically he would assent to this type of prescription. [NE 1786]

20.8. In other words whether the dosage matched the disease and whether there is a suitable disease to be treated at all by radiosurgery, according to him, was not the concern or responsibility of the neurosurgeon.

20.9. What about training in XKnife radiosurgery as stipulated in the **Radionics XKnife Protocol**? Dr James Khoo's position was as follows :

I did not have any formal training.

I am not aware of that legal requirement in Singapore.

So he did not go to Australia for training. If his argument holds true then even Dr Khor was not required to have any training. He was reminded that it was not a legal requirement but it was a manufacturer's requirement. His answer to this was :

Well they never actually imposed it on us and I am not aware that it is a requirement by the manufacturers to use it. The hospital certainly didn't ask us, all the surgeons in the Mt Elizabeth to have this training in Australia or anywhere else. We were not told or asked to undergo this training to use the facility. [NE 2082]

20.10. Before Gunapathy was given *XKnife* radiotherapy treatment, Dr James Khoo had participated in radiosurgery several times. There were 10 cases during the period of 20 September 1995 to 22 April 1996. All these were performed at Gleneagles Hospital. There was no case from May to October 1996. After the lull of six months there were three cases in November 1996 and one in December 1996. Next was Gunapathy's case on 31 January 1997. The 10 cases at Gleneagles Hospital involved astrocytoma – the most common form of glial tumour. Hence it is also known as "astrocytic glioma". There were two brain metastases. Of the four *XKnife* cases at Mt E Hospital, one was a glioma. It was not clear if there was previous irradiation in that case. One was acoustic neuroma, which is a benign tumour usually found in the auditory canal (inner ear). Gunapathy was the defendants' first case of radiosurgery for neurocytoma after surgical dissection and fractionated radiotherapy. As to the radiosurgery done at Gleneagles Hospital, it must be noted that the captain of the ship here was Dr Tsao Shiu Ying an expert witness called by the plaintiff. He was intelligent, well-trained and well-experienced. He struck me as a person who knew his job well and nothing could go wrong under his stewardship.



20.11.As to the practice of radiosurgery in Singapore, the evidence of Dr Tsao Shiu Ying, a radiation oncologist of the Department of Therapeutic Oncology of Gleneagles Cancer Centre contradicted the evidence of Dr James Khoo. According to Dr Tsao, the neurosurgeon is the Captain of the ship. I reproduce below extracts from his evidence :

The role of radiation oncologist would be to collaborate with the team head, which is the neurosurgeon, and also to co-ordinate with the medical physicist and also the technologist, to carry out this treatment called radiosurgery. And our job specifically is to make sure that the plan is being adopted and, if necessary, modify, and then also show the plan to the neurosurgeon for him to adopt and, if necessary, to modify, and then together, we have to go and discuss about the dose that we are going to give and then finally, the plan would be carried out by the team of technologists.

Q So that what you are saying is that the neurosurgeon is the head of the team?

A Yes, that is the practice in Singapore.

Q And who puts up the plan, the treatment plan?

A The medical physicist puts up the treatment plan.

Court What's the practice in Hong Kong?

A It is exactly the same as in Hong Kong.

Court UK?

A In UK, I am not sure, because at that time there were no radiosurgery. When I was there in UK, I did not participate in radiosurgery. So, but I am sure in Hong Kong and in Singapore, the practice is, neurosurgeon is the team head. [NE 850-851]

20.12.Dr Prem Pillay, who was the pioneer of radiosurgery in Singapore said very much the same thing. He set up the Singapore Gamma Knife Centre while he was employed by the Singapore General Hospital. His evidence established that when he performs radiosurgery he, the neurosurgeon, is the captain of the ship.

20.13.So the doctors disagreed on this issue as they did on the other issues. Alexander Pope asked in 1732 : Who shall decide when doctors disagree? Today there is a clear answer to the question : The Judge.

## **Chapter 21 : Malignant Tumour or Malignant Treatment?**

### Incompetence issue

21.1.The first issue for determination in relation to the charge of negligence against the doctors is the plaintiff's allegation of incompetence. As has been noted earlier, the law requires a specialist to acquire a reasonable level of skill, knowledge and experience. In relation to this case, this means reasonable skill, knowledge, training and experience in brain oncology and ionizing radiation. This

special requirement is emphasised in the **Radionics XKnife Protocol**. The *Sydney Protocol*, namely the teachings of Dr Robert Smee, cannot be understood or applied properly without compliance with that requirement. It is part of the reasonable duty of care that the neurosurgeon and radiation oncologist owe to a person to whom they offer an aggregative single fraction mega-dose of ionizing radiation to a lesion which has been previously irradiated.

21.2. The **Radionics XKnife Protocol** confirms that *XKnife* procedure involves the teamwork of three specialists – a neurosurgeon, a radiation oncologist, and a medical physicist. Each and every one of them must acquire an acceptable level of knowledge and experience. That, in turn, requires learning and training. The **Radionics XKnife Protocol** stipulates that "experience of years of clinical radiosurgery are essential for proper use of the technique." It further stresses that "in every case, good clinical judgement for the particular patient being treated is paramount". The manual emphasizes that "no two patients are identical and good clinical judgement is essential to the appropriate use of this exciting new technology".

21.3. So, as the first step before embarking on radiosurgery, the specialist must read the primer on it. In this case, the **Radionics XKnife Protocol** and the *Sydney Protocol* are the primers. Dr Khor said the **Radionics XKnife Protocol** was effectively a guide issued by Radionics to the users of *XKnife* equipment. It was, said Dr Khor, one of the definitive studies in medical literature on the subject.

21.4. The monograph gives a "step-by-step" description and explanation of the clinical and technical aspects of *XKnife* stereotactic radiosurgery. It contains the guidelines for patient selection, patient counselling, and securing informed consent of patients. More importantly, it states that the RTOG 90-05 study of patients with "*previously irradiated recurrent brain metastases and gliomas*" represents the best available guide to dose selection". It provides the essential knowledge on *XKnife* radiosurgery. The *XKnife Protocol* applies only to brain metastases. Anyone wishing to extend it to other tumours must read the RTOG 90-05 study. The radiation oncologist has a general knowledge of oncology. He does not know neuro-oncology. He does not know the particular sensitiveness of critical parts of the brain. He must rely on the neurosurgeon for guidance on these matters. More importantly the patient in this case was offered radiosurgery by Dr James Khoo. And so Dr James Khoo owed a moral and a legal duty to acquire adequate knowledge and experience in brain tumours, radiation therapy and radiosurgery.

#### Skill and experience in administering the treatment

21.5. I now come to the skill and experience in relation to the actual administration of the *XKnife* radiosurgery. Before the arrival of the *XKnife* equipment in Mt E Hospital in 1996, Dr Khor had observed radiosurgery being done in the United Kingdom and the United States – he had a week in England and a week in America. There, he watched, asked questions and talked with the doctors and the team. When *XKnife* equipment arrived he asked of the sellers : "Is there a course?" He was told that there was one in Boston and one in Sydney. Even then he had to wait for an opening as none was available immediately. He told them : "I will not start any treatments until I go for the course."

21.6. Then he attended the *XKnife* course in Sydney. He listened to lectures by the *XKnife* training centre and staff. That was all Dr Khor could say about his training and experience before he started treating patients in Singapore. Gunapathy was his seventh patient for radiosurgery. She was his first patient who had been previously irradiated with fractionated radiation therapy. That too where there was no recurrent glioma.

21.7. I have already set out Dr James Khoo's attitude towards acquisition of knowledge and experience. He was not bothered with acquiring knowledge contained in the **Radionics XKnife**

monograph because from his perspective it did not apply to Singapore. It applied to the United States. He did not trouble himself to attend the *XKnife* course and training because neither Singapore law nor Mt E Hospital required him to do so. There was the *XKnife* course and there were the materials (Radionics *XKnife* monograph which incorporated the RTOG 90-05 study) which contained all the essential knowledge, protocols relating to the selection of patients, and dosage and securing informed consent and the proper performance of *Xknife* radiosurgery. All these were available before the *XKnife* radiosurgery equipment was ready for use in Singapore. There was, therefore, no lack of necessary information in Singapore. The lack was in the mind of Dr James Khoo because he chose to ignore them. His claim was that he could ignore them because Mt E Hospital did not stipulate that he must have the requisite knowledge. That it was not a legal requirement is a spurious proposition. Dr James Khoo ignored the law of negligence which is part of the law of Singapore. Ignorance of the law of negligence, and ignorance of its requirements is not a defence to a claim by a patient who has suffered by reason of his ignorance. In particular a person who purports to be an expert.

*Unprecedented, unpractised and unproven treatment*

21.8. At this point I am reminded of the words of Sachs LJ in ***Hucks v Cole*** [1993] 4 MLR 393. It was a decision in 1968 but reported only in 1994. It was approved of and relied on by the House of Lords in the ***Bolitho*** case. Sachs LJ said at 397 :

When the evidence shows that a lacuna in professional practice exists by which risks of grave danger are knowingly taken, then, however small the risks, the courts must anxiously examine that lacuna – particularly if the risks can be easily and inexpensively avoided. *If the court finds, on an analysis of the reasons given for not taking those precautions that, in the light of current professional knowledge, there is no proper basis for the lacuna, and that it is definitely not reasonable that those risks should have been taken, its function is to state that fact and where necessary to state that it constitutes negligence.* In such a case the practice will no doubt thereafter be altered to the benefit of patients.

On such occasions the fact that other practitioners would have done the same thing as the defendant practitioner is a very weighty matter to be put in the scales on his behalf; but it is not, conclusive. *The court must be vigilant to see whether the reasons given for putting a patient at risk are valid in the light of any well-known advance in medical knowledge, or whether they stem from a residual adherence to out-of-date ideas – a tendency which in the present case may well have affected the views of at any rate one of the defendant's witnesses, who, at a considerable age, seemed not to have any particular respect for laboratory results.*

21.9. The accepted practice and knowledge in 1997 was that to justify radiosurgery (with its mega-dose radiation) there must be a recurrent glioma or other high-grade aggressive brain tumour. A low-grade glioma was not an indication for radiosurgery. In 1997, or even now, the administration of a high-single-dose radiation to a previously irradiated site of an *intraventricular neurocytoma* after it was surgically dissected was unprecedented, unpractised and not proven to be beneficial. There were instances of radiosurgery being done to neurocytomas but in those instances there was no surgical dissection followed by conventional radiotherapy. Radiosurgery was the sole treatment. In the present case radiosurgery was the third treatment administered to Gunapathy. It was done after dissection of the neurocytoma in November 1995 and radiotherapy in 1995/1996.

21.10. On 22 December 2000, Dr James Khoo in his affidavit evidence made this bold assertion :

"Recent studies show that radiosurgery is an excellent option for residual central neurocytoma". At the trial he admitted that there were no such studies. That statement appeared to have been induced by certain materials accessed by Dr Yeo Tseng Tsai. Those materials were not even remotely relevant to the issue before me. In the defence of the company defendant it was asserted that he considered radiosurgery as the best option on account of "the insistence and clear instructions from the plaintiff to have complete clearance of all *potential gliomas/tumours* that could be aggravated by powerful fertility hormonal therapy as soon as possible". "All potential gliomas" and "powerful fertility hormonal therapy", it became clear at the end of the trial, were all parts of the confabulations of Dr James Khoo. He had to confabulate because he failed to make and keep appropriate clinical notes. Dr Robert Smee said that the damage to the internal capsule, which links the cerebral cortex and other parts of the body, was done by what he called "the ripple effect". That is to say the beams after hitting the target radiated outside the isocentre of 22.5 mm diameter. Given that the dimensions of the lesion as measured by the mouse were 12 x 11 x 6 mm the dose delivered by a 22.5 cone would inevitably burn much of the previously irradiated normal tissue around it.

21.11.The recommendation and use of radiosurgery, according to *the Sydney Protocol* and the **Radionics XKnife Protocol**, read with the RTOG 90-05 study was for a previously eradicated recurrent malignant gliomas or other recurrent brain tumours, that manifested a malignant propensity after the patient had undergone radiotherapy. In this case, there was no such remnant viable tumour that manifested a malignant propensity after the resection or after the radiotherapy. Why was radiosurgery suggested, recommended or performed ?

21.12.The original tumour was not characterised or classified as a low-grade (malignant) primary tumour. It was determined to be a neurocytoma and no mitosis was found. It had a negligible propensity, if any, for cell division. It had none of the markers of a malignant tumour. The histological WHO classification does not describe a typical neurocytoma. It says that the behaviour of neurocytoma is variable. In this case the tumour was histologically determined to be benign. Dr Robert Smee said so. There was no histological finding to the contrary. That there was a viable aggressive remnant tumour to warrant any treatment, let alone radiosurgery treatment, was not established. This is a question fact to be determined by the Court with the guidance of expert witnesses. The **Bolam** case of reasonable standard of medical practice has nothing to do with this fact finding exercise. All the credible and acceptable expert evidence established that there was no aggressive growth. And there was no recurrent tumour. The radiosurgery, therefore, was done without any medical justification. It was analogous to striking a phantom fly with a sledge hammer. No reasonable and responsible doctor would do it. In the result the radiosurgery done to Gunapathy was a breach of the duty of care owed by the defendant doctors to her.

#### Dosage issue

21.13.As to the dosage, Dr Khor said that he relied on the RTOG 90-05 study. So it was essential that the each member of the *XKnife* radiosurgery team read the relevant parts of that study.

21.14.Dr Khor attended the Radionics course in Sydney and returned with his lecture notes. He was not given any printed materials by the course organisers, he said. Even the **Radionics XKnife** monograph was not referred to in the lectures. Dr Khor said he obtained the monograph because he insisted on something in writing.

21.15.Dr Khor said that he did not read the RTOG 90-05 paper "at that time" – that was in 1996 and 1997. He did, however, read the **Radionics XKnife** monograph. He appeared not to remember any information other than the dosage selection. He was surprised when I drew his attention to several other important parts of the monograph. He said he was not taught those points.

21.16. In my judgment, Dr Khor did not acquire the standard of knowledge required of a reasonably competent radiation oncologist advising, offering and performing the critical procedure of radiosurgery. He was amateurish.

21.17. Dr James Khoo was even less competent. He did not even trouble himself to access and acquire the basic knowledge about radiosurgery. He did not study and apply the single available written material on *XKnife* radiosurgery. In a blithe and bizarre fashion he said in the company defendant's defence that :

the exact nature and dose of radiation was determined solely by the 3<sup>rd</sup> defendant and the 2<sup>nd</sup> defendant owed no duty of care to the plaintiff in the determination of the same. The 2<sup>nd</sup> defendant only knew of the exact nature and dosage of the radiation given to the plaintiff from the reports sent to the 1<sup>st</sup> defendant on or about 3 February 1997 after the radiosurgery.

The word "sole" means that Dr James Khoo had nothing to do with dosage selection. This assertion is all the more appalling because the nature and measure of dosage were dependant on the nature and stage of the tumour, if there was one. It therefore follows that Dr James Khoo did not even possess a basic knowledge of radiosurgery. He was therefore unfit to recommend, advise, offer and perform the radical procedure of radiosurgery.

21.18. Dr Ho Kee Hang was in no better position when he advised Gunapathy to go to Dr James Khoo if she wanted radiosurgery. Apart from attending the lecture in Sydney organised by **Radionics** he had little to do with radiosurgery. He did not practise it. It did not appear that he knew the dosage-disease relationship in radiosurgery. He did not have the adequate knowledge necessary to advise whether stereotactic radiosurgery was an appropriate or acceptable prophylactic or therapy for "residual neurocytoma". He should have declined to advise the plaintiff on the matter and recommended a neurosurgeon and radiation oncologist who were experienced and knowledgeable in radiosurgery.

#### The cone (collimator) size

21.19. Further, the dosage administered and the collimator used were excessive and intolerable. There was a mega-dose of 20 Gy after 54 Gy of previous radiation of a possible remnant of an indolent tumour. That was missing in this case. To justify a collimator of 22.5 mm the size of the malignancy must have a diameter of 19 or 20 mm. Dr Robert Smee justified the cone size on the basis that the lesion was assumed to be 19 mm in diameter. In this case the maximum diameter of the lesion was not more than 15 mm. Accordingly the cone of 22.5 mm size was too excessive for a 15 mm (diameter) tumour. This inevitably would have caused much damage to the normal tissue which had already been subjected to a radiotherapy of 54 Gy. It was undisputed that it was the second single high-dose radiosurgery that caused the tragedy. It was a negligent act for which both doctors were responsible.

#### Advice and consent

21.20. As decided earlier, the plaintiff was not advised adequately or properly. She was talked into consenting to mega-dose radiosurgery when there was in fact no prophylactic or therapeutic reason for it. That again was negligence for which both doctor defendants must share the blame.

#### Side-issue on biopsy

21.21. There was much disputation as to whether a stereotactic biopsy should have been done to determine whether there was a remnant tumour, namely a viable tumour in January 1997 which justified radiosurgery. On the basis of all the evidence and medical knowledge available in January 1997, I hold that it was unnecessary to do such a biopsy or other investigation. The issue was a red herring. The reasons are as follows.

21.22. The purpose of a biopsy is to make a histological determination of the nature and categorisation of the tissue mass in question. In November 1995 a histological determination that there was an indolent neurocytoma had been made. The accuracy of that determination was accepted by all. No one questioned it in 1995 or 1996. Even Dr Robert Smee, the *XKnife* Radiosurgery guru, accepted at the trial that the biopsy of the tissue from the neurocytoma showed that it was benign; it was negative. Dr Carol Kwan did not describe it as low-grade malignancy. Dr Khor said that he spoke to her and she said that it was of low-grade malignancy. I do not accept his word for it. If that conversation had taken place, she should have been called as a witness by Dr Khor and subjected to cross-examination, in which she would have had to explain why she did not say so in her report. Why should she have verbally described the tumour as a low-grade malignancy when she did not say so in her report? Everyone, except Dr Khor, accepted Dr Carol Kwan's written histological findings and interpreted them to mean that this neurocytoma was histologically benign and indolent. A microscopic examination of the November 1995 slides done by Dr Jennifer Teo in 2000 with a sophisticated device demonstrated a proliferation index less than 1%. Its rate of mitosis was next to nothing. After the resection in November 1995, the plaintiff was subjected to an aggregated irradiation of 54 Gy. That would have eradicated the possibility of a re-growth of an indolent tumour. A stereotactic biopsy would have been an overkill.

21.23. The microscopic examinations of the neurocytoma done in 1995 and 2000 established that the mitosis was negligible. The proliferation index was very low. The November 1995 MRI scan did not demonstrate any infiltration. With negligible mitosis and absence of infiltration of the surrounding tissue possibility of recurrence was unthinkable. What was before all was an indolent intraventricular neurocytoma and not a recurrent glioma which had infiltrated the surrounding tissue.

21.24. In view of the above, one year after the resection the benign neuronal tumour could not have transformed into a glioma. All these factors only add logic and intellectual force to Dr Esther Tan's finding that there was no viable tumour in March or December 1996. Dr Esther Tan made her findings on the basis that there had been a glioma. She was not aware in 1996 that it was only a neurocytoma.. She was not aware that there was a post-surgical radiation therapy. Most certainly there was not an iota of evidence to establish a recurrent tumour. All the premises on which a recurrent neurocytoma was postulated turned out to be a false and unfounded. There was no *microscopic* total excision. There was no reliable radiological evidence to establish that there was a total excision without leaving a residue because no MRI scan was done for that purpose.

21.25. On the basis of the above, I make these conclusions : The biology of Gunapathy on 31 January 1997 was good in that she had no pathology in her brain ventricle. The biology of the doctors was bad in that they talked her into agreeing to radiosurgery when they were not sure whether she needed radiosurgery treatment. The physics of the doctors was also bad in that they fired a mega-dose of radiation to a previously irradiated volume of her brain which included the critical parts of the brain. They did it with too large a cone. In the result, it was not the tumour that was malignant; it was the treatment that was malignant.

## **Chapter 22 : Assessment of Witnesses**

22.1. In considering the merits and demerits of the medical issues of the case I have concentrated on

the objective value of the expert witnesses. In other words, I considered their evidence at face value without going into the question of the credibility of the witnesses and the weight of their evidence. Indeed, when it comes to expert opinion evidence, credibility should not even be in issue in the first place. Hence the "no hiding, no siding" rule. It is also reflected in the requirement that experts must assist the Court and not the party who calls him and, when necessary pays, for his trip and accommodation. Unfortunately the expert witnesses called by the defendants in this case did not live up to the legal standards required of them. In this respect, their lawyers were partly to blame because they were not aware of all the rules relating to expert evidence of facts and opinions. As I have said, Dr Francis Hui's expert opinion was contained in a three-sentence paragraph. Dr Yeo Tseng Tsai's report was only slightly better. Dr Robert Smee signed and tendered his report from the witness stand.

22.2. I am mindful that both Dr Esther Tan and Dr Tsao Shiu Ying did not submit a report. In the case of Dr Esther Tan she had already made her reports long ago in February and December 1996. She was called as a witness because I needed her guidance, particularly because I did not have a court assessor. Dr Tsao Shiu Ying did not want to give a report to the lawyers at all because he wanted to be seen as an impartial witness.

22.3. The suggestion that the evidence of some of the defence witnesses should be subjected to scrutiny was made when Mr Michael Khoo SC cross-examined Dr James Khoo. In answer to questions put to him Dr James Khoo admitted to a close relationship between him and Dr Ho Kee Hang. They were locum tenens for each other. When questioned about the discussions of this case that he had with Dr Ho Kee Hang, Dr James Khoo feigned a detachment. However Dr Ho Kee Hang's evidence established very clearly that they both discussed it. Dr Ho Kee Hang was a partisan witness. The partisan nature of his evidence was borne out by three other facts.

22.4. The first was that Dr Ho Kee Hang, Dr James Khoo and Dr Yeo Tseng Tsai were shareholders in a company called Consultant Neurospecialist Pte Ltd. There were several other shareholders in the company. None of the three doctors voluntarily revealed the fact that they had a common medical business interest. It was uncovered by the plaintiff's side. The fact that they had a common business interest did not make Dr Ho Kee Hang an incompetent witness, but he, Dr James Khoo and Dr Yeo Tseng Tsai ought to have revealed it to the Court. Counsel for Dr James Khoo commented on the fact that neither Dr Ho Kee Hang nor Dr James Khoo had been questioned on it. It was said that they were not given an opportunity to explain their relationship. This, in my view, was tantamount to standing the rules of expert evidence on their head. Dr Ho Kee Hang, Dr Yeo Tseng Tsai and Dr James Khoo ought to have revealed the fact because it had a bearing on their impartiality. Mr Michael Khoo SC said that the information had become available to the plaintiff only two days before the close of the case. He tendered the company searches when he made his closing speech.

22.5. Secondly, Dr Ho Kee Hang was asked for particulars of some of his patients with neurocytoma. He said that he would not reveal them because of medical professional confidentiality. But he was not similarly concerned about the duty of confidentiality to Gunapathy who had consulted him. He did not even contact her lawyers. He unilaterally offered to help his friend and business partner, Dr James Khoo. He gave the particulars to the lawyers appointed by the Medical Defence Union. Dr Ho Kee Hang said he was also in the Medical Defence Union.

22.6. Thirdly, Dr Ho Kee Hang said he was not an expert witness. This was a disingenuous statement because most of the evidence he gave was expert evidence about transcallosal neurosurgery, remnant tumour and scar tissue. He had spent 10 minutes listening to and advising the plaintiff. But he spent a whole week-end to shape his evidence in favour of Dr James Khoo. Before he gave evidence I directed that he should not remain in Court and listen to other witnesses because it was

said that he was not an expert witness. I also remarked before his affidavit evidence was filed that he was shaping his evidence to help Dr James Khoo. It turned out that he had indeed done so because he obtained the notes of evidence of other witnesses before his affidavit was finalised. It was apparent to me that he knew what was going on in Court and shaped and prepared his evidence to help Dr James Khoo. The final version of his evidence was delayed until others had given evidence on the issue of "scar or residual tumour".

Dr Robert Smee

22.7. Dr Robert Smee was another witness who was not frank to the Court as an expert witness. He had a vested interest in *XKnife* radiosurgery. Radionics Inc used him as its teacher and trainer. He had delivered the lectures attended by Dr Khor and Dr Ho Kee Hang. Yet he did not disclose these facts to the Court. But for the honesty and frankness of Dr Khor, the Court would not have known the contents of the **Sydney Protocol** and the **XKnife Protocol**. Dr Robert Smee ought to have revealed all the information in his possession and his special relationship with Radionics. His failure to do so and the evidence he gave compels me to conclude that he was an advocate for the defence and not an impartial expert witness assisting the Court to determine the truth.

Dr Yeo Tseng Tsai

22.8. Dr Yeo Tseng Tsai had made arrangements for Dr Karlsson to give evidence. This was the first time Dr Karlsson gave evidence in a Court of law. Dr Karlsson said he agreed to give evidence because he felt a moral obligation to do so because of his role in setting up the Singapore Gamma Knife Centre. Dr Yeo Tseng Tsai did not reveal that he had a joint business interest with Dr James Khoo. Dr Yeo Tseng Tsai's report was made in National Neuroscience Institute and in it he said : "In my position as Medical Director of Singapore Gamma Knife Centre, I have been asked to comment on the above case based on the written case notes as well as the MRI and CT images shown to me".

22.9. Dr Yeo Tseng Tsai made a short report before the trial began. In his report he made this statement : "The radiological appearance on the MRI scan on 26.12.96 of the enhancing nodule very likely represents tumour recurrence". He added that, "based on the MRI brain scan (scan and not scans) the enhancing nodule was indeed tumour recurrence and not radionecrosis". He used the singular "scan" and not plural "scans". He did not give any reasons in his so-called report.

22.10. He was the last expert witness to give evidence. When he gave evidence he radically revised and reshaped his evidence. In his evidence in Court he contradicted his earlier statement and said he gave evidence in his personal capacity. He brought the plastic model of the brain and gave me a long demonstration lecture on "transcallosal neurosurgery". The purpose of it was to convince me that there was a "remnant tumour" and not a "recurrent tumour" as he had stated in his report. In his evidence he said :

We know surgeons always make mistakes. As they say, the MRI scan never lies.  
Surgeons lie but MRI scans never lie.

22.11. In his evidence he said that before he agreed to be a witness, Dr James Khoo gave an oral history, a factual presentation, of the facts of the case. He said : "I have to trust Dr Khoo's word as being true." But as the trial progressed Dr James Khoo had shifted his position and resiled from several important assertions he had made earlier. So the premises upon which Dr Yeo Tseng Tsai had based his conclusions, namely on Dr James Khoo's oral discussion with him, turned out to be false. In the result, Dr Yeo Tseng Tsai's evidence, like Dr James Khoo, lost its weight and value. At the beginning of his evidence he cited this statement from **The American Association of Neurological Surgeons**:



The neurosurgeon should champion what he/she believes to be the truth, not the cause of one party or the other.

22.12. When all was said and done, it was apparent to me that Dr Yeo Tseng Tsai was championing the cause of Dr James Khoo. He was a partisan witness.

#### Dr Esther Tan

22.13. Dr Esther Tan did the February and December 1996 MRIs because they were asked for by Dr James Khoo's clinic. She had no self interest to protect and no reason whatsoever to take sides in reporting on the MRIs. She had no special relationship with anyone concerned. She did the MRI scans and her reports with one sole thing in her mind : the interest of the patient. She appreciated the problem that confronted her – "Was this a tumour?" She was a radiologist with long and wide diagnostic experience. She had hands-on training and experience. Although at the time she gave evidence in this trial, she was concentrating on "breast work", in 1996 she was doing "brain work". MRI radiology in practical terms really means diagnostic radiology of the brain since the MRI is chiefly used for the brain. So she was not a general radiologist. She was a specialist. From the evidence she gave I could see that she was an extremely competent brain radiologist.

22.14. Dr Francis Hui's expertise was limited to interventional work and diagnosis connected with it. Dr Esther Tan's expertise was a holistic knowledge and experience on brain diagnosis. When she gave evidence she pointed out several fallacies in the evidence of others, in particular, the evidence of Dr Robert Smeeth and Dr Francis Hui. She convincingly explained that it was wrong to make conclusions about the nature of the lesion based on the brightness of the imaging (enhancement). Most if not all of the defendants' experts placed great reliance on greater enhancement of the December 1996 MRI. They also placed reliance on the nodular shape of the lesion. Dr Esther Tan explained that they were non-specific factors. Stability was the sole determinant in a case where the excision might not be complete. She was the first to appreciate there might not have been complete microscopic resection. Dr Ho Kee Hang followed her phraseology. All the other experts called by the defendants acted on the basis that there was a complete excision and that the negative CT scan was reliable. In the end Dr James Khoo, Dr Ho Kee Hang and Dr Yeo Tseng Tsai turned around and argued that there might not have been a complete excision. When it came to brain, brain pathologies and MRI diagnosis, the other experts enhanced her expertise like a foil. In all my life in law I have never seen a more outstanding expert witness than Dr Esther Tan. Everything she said illuminated the area she focussed on. She was completely knowledgeable in her field, completely impartial, and completely at the assistance of the Court. I, therefore, accepted her evidence that the lesion remained stable. The stability issue was an issue of fact. Dr Esther Tan's evidence was undented by the cross-examination or the evidence of the other witnesses.

## **Chapter 23 : The Damage**

### The effect of radiosurgery

23.1. This chapter shall consider the issue of causation and the damage suffered by Gunapathy. While Dr Karlsson was under cross-examination, Mr Michael Khoo SC, had this exchange with him :

Q What went wrong which caused (the plaintiff) to suffer this present condition?

A Then you pre-assume that something went wrong, and even if everything is done absolutely correctly with absolutely correct indications and doses and treatments, something still goes wrong. So, the fact that the patient suffers

from complication is not by itself a evidence that something went wrong. That is a very, very important underlying. In this case, there are several factors that contributed to this condition. All of them being obvious, and whether one of them contributed more than the other, it is impossible for me to tell.

Q All right. So what were the factors which contributed to this condition?

A The factors were :

(a) that the patient received whole brain radiotherapy. It was actually not whole brain, it was fractionated radiotherapy;

(b) Received radiosurgery following radiotherapy;

(c) Was operated when the brain was suffering the most.

In what extent or if any, and how this contributed to her condition, it's impossible for me to tell. But these are the 3 risk factors as I see it. [NE 2748-2749]

23.2. In relation to treatment, Dr Karlsson was asked what dosage he would recommend for the nodule if it was a tumour. Dr Karlsson said : "Personally, I say I will give around 15, 13 to 15 Gy to that lesion"" Then followed this exchange.

Q And why have you limited it to that dosage?

A Because I have 14 years experience, and I have seen if not hundreds, at least fifties of patients with severe radionecrosis. This made me a little bit concerned about the effects of radiation. So I start always at the lower end where I radiate. This does not however mean that I am doing the right thing.

Q Have you seen any as severe as in the present case?

A I have seen three patients die because of radionecrosis.

23.3. Dr Robert Smee in his report confirmed that : "it is without doubt that the combination of the two doses of irradiation have resulted in this complication". The combination of the two doses gave a total of 74 Gy.

23.4. Dr Robert Smee while giving his evidence in Court explained the effect of the radiosurgery on the plaintiff. Extracts from his oral evidence are as follows :

I based my assessment of the size on my own evaluation of the (axioemaslysis) and not on something that was marked out. The 19 mm is a transverse diameter, which is the maximum diameter .. to encompass this lesion, not an anterior, posterior, medial lateral transverse diameter. And I was able to verify that those coverage was adequate and appropriate for that lesion, much of the high dose area was in fact in the lateral ventricle. If one looks at the dose that was actually received by the internal capsule, then that dose is down to about 10 Gy. So although the specified dose was 2000 cGy at the 85% isodose curve encompassing a lesion, by the one gets to the internal capsule there had been

significant fall-off or drop-off of dose, and so the dose received by the internal capsule was of the order of a thousand centigray.

The internal capsule is that structure where the--- what are termed the motor fibres, passed from the outer surface of the brain down towards the brain stem. And that's the most crucial or critical point in terms of maintaining arm and leg function.

It is somewhat of an "L-shaped" structure, like that, that measures about 5mm in width and in length about 4 or 5 cm.

One has to look at the dose that's received by what's termed critical normal structures. What dose did the tissues receive that resulted in this patient's deficit.

So the tissues that resulted in a deficit were not the tissues that received the 2000 cGy.

In this situation the target, it's not a random event. The analogy I use for patients ---.

Is throwing stones into a pond.

One gets the "plop", where the stone goes into the water and that's the structure you're treating, and then one gets a series of concentric ripple rings.

Those ripple rings are really where the, what we call, the isodose falls off.

If he throws in a small stone, it has very narrow ripples, and they dissipate over a short distance. If he throws in a large stone, you'll get a big plop, widely spaced ripples and they'll take further to dissipate. So the concept that I am looking at is the internal capsule which is the area that was damaged, it's caused much of this patient's deficit, was in the ripples, not where the stone fell in. [NE 724-728]

23.5.It would be well to remember that Dr Robert Smee's explanation of the damage done to Gunapathy's brain based on the ripple effect was premised on a 19 mm diameter nodule when in fact it was not more than 15 mm in diameter. The use of a 22.5 mm cone resulted in the direct radiation of critical normal tissues. The nodule had negligible mitosis if any. If it would grow at all it would grow very slowly. It was known that lesions that are histologically benign (slow growing tumours) respond poorly to ionising radiation with the result that there is much damage to normal tissues. To inflict high dose radiation on such a tumour would result in intolerable damage to the normal tissues. The consequence of the combined effect of the mega-dose of radiation by a 22.5 mm collimator to a much smaller benign nodule was the cause of the immense damage to Gunapathy's normal brain cells.

23.6.MRI examinations done established that there was radionecrosis. This was at the end of 1997. Subsequently Dr Jennifer Teo made a pathological finding that there was radiation necrosis. That was Gunapathy's condition from 1998 before the surgical removal of the necrotic tissues by Dr Prem Pillay.

23.7.All the evidence which I have related above established beyond doubt that the damage to Gunapathy's brain in general, and in particular her internal capsule, was due to the high-dose

radiosurgery.

Removal of radionecrotic tissues

23.8. It emerged from the evidence of Dr Karlsson that he would not approve of Dr Prem Pillay's surgical removal of the necrotic tissue. His opinion was that the steroid treatment ought to have continued. Steroid treatment was beneficial for radionecrosis. He had seen many cases of recovery after steroid treatment.

23.9. As against this background about radionecrosis and steroid treatment, Dr Tsao Shiu Ying gave his opinion. According to him the usual period for steroid treatment was six weeks. Then it should be gradually reduced, not stopped suddenly. It was proper to continue steroid treatment for a longer period in order to manage cerebral oedema due to radionecrosis. Steroid treatment was a life saver. But continued steroid treatment had its downside. It could cause a condition leading to death due to uncontrollable infections. Uncontrollable meant "cannot be controlled by antibiotics". Defence counsel Mr Tan Beng Swee asked him :

Q Have you personally seen any cases of people dying from steroid overdose?

A I have seen 25 cases dying from this condition. [NE 1149]

23.10. Such was the objective scenario according to medical men. At the same time there was a subjective side to it. The real question for consideration here is whether Dr Prem Pillay was justified in removing the necrotic substance in her brain (the third operation on Gunapathy). In this regard, Gunapathy's husband related why Dr Prem Pillay removed the necrotic tissue. He was asked about the risk of the surgery by which Dr Prem Pillay proposed to remove the necrotic tissue. He answered as follows :

He told me about 30% chance maybe she won't wake up. Or she will become paralysed or, I mean, it's about the 30% risky operation.

He told me maybe she won't wake up or maybe she, I mean, she will be paralysed or something. I mean, it's up to us to choose, that's why I came with my family to talk about it. It was something very important for us to decide.

There is some risk, I mean, not death but paralysed or loss of speech or eyesight. I mean, can be anything, you see. It's quite a risky operation. Not to die but some side effects can be very risky.

Q And that risk of 30%, you decided that--- you all decided to proceed with the surgery?

A Yes, because she was in a very great pain for, I think, the last two months, in very great pain. And it was very clear to us, I was working overseas, I flew back especially for that to meet Dr Pillay and all my in-laws, we went there with my brother-in-law, about 6 of us. He told us "Very simple". If you wait anymore, maybe can be a big problem, you know. Maybe she can be in a coma or she can--it's very bad because her brain is so swollen", so, it's very bad. She was in very great pain. Everyday she was crying, she was very depressed. She was in big pain. So he told us "It's up to you now, I mean, I think in the next---a week time, you have to do something." So we went out, we discussed with everybody,

we came back, we said "OK, we go ahead." But we never just said "Yes" like that. We just left to talk about this with the family. And we decided with the brothers to go for it.

It was earlier '97, she was complaining of a lot of headache, very bad headache."

Q Early '97?

A Yes, and after became very often like everyday after that. But slowly came like once a week or once a fortnight. Became, after that, everyday.

Q It became worse?

A Yes.

Q Progressively, it became worse?

A Yes.

Q OK, when you were told of the risk of 30% by Dr Prem of the surgery, intended surgery, you'd agree that the risk was high?

A I mean, he explained to us on the X-ray and all, explained to us about what happened to her brain. And the brain was so swollen, it was so big, I mean, it was like so obvious, like the thing going to, you know, I don't know what to say, I mean.

Because he explained to us on the normal brain, like you can see all the scar, you know, the brain, they have all the different, we have, thing, and her brain was like this, you know, like very smooth, like this, like a balloon, you know. I mean, you have all those threads, whatever, I mean, her brain was like so---like flesh, very like---

Like a balloon, you know, I can tell you. It was very strange, I mean.

Q Did you all ask Dr Prem Pillay or did he advise you that you could---can he control, is there other---other from surgery, could you have done by medication?

A He told us, I mean, at this stage, now, I mean, if you just leave it as it is now, I mean, he said this can be quite---pretty bad, you know, so he told us I think the best is to go for operation to relieve the pain. It's not to cure, but just to relieve the pain, because it was so painful, at least to make her a bit better, you know, to, I mean---

Q Now, witness, your wife was complaining of headache, and before this final where a lot of family members were there, you had seen Dr Prem Pillay together with your wife before this?

A No, because I just arrived from overseas, and the next day I went to see with

all---my brother-in-law went to see Dr Pillay, because he wanted to see me, me personally, and explained to us what's going on, and asked us to give him an answer, I mean, about the things. So we went out, outside, and we just talked for hours, we came back and we said, OK, we---I mean, because he said better don't wait, I mean it's quite urgent. Had to do it very urgently.

[NE 169-170]

23.11.The inference of what has been related is that Gunapathy and her kin had no other option but to ask Dr Prem Pillay to remove the necrotic tissues and "deflate the balloon" inside her cranium. The radionecrosis and the oedema caused the same kind of extreme suffering a malignant overgrown tumour would have. This was not a case where Gunapathy could reasonably be expected to suffer the agony any longer. In any event much of the permanent damage had been done in that her internal capsule had been damaged. Dead neurons do not regenerate. They do the opposite. They destroy other viable neurons. The inflated brain had to be deflated. There was no other practical option. Continued steroid treatment was not a practical option. Dr Karlsson had seen patients die of radionecrosis caused by radiosurgery. Dr Tsao had seen patients die because of prolonged administration of corticosteroid. Gunapathy, as Mr Michael Khoo SC put it, was between the devil and the deep blue sea and in extreme agony. There was no other option but to remove the necrotic tissue – palliative though it was. There was therefore objective as well as subjective justification for Dr Prem Pillay's interventional surgery. After that she was in a much better condition. It did not worsen her condition at any rate.

### The disabilities

23.12.The result of the radiation damage done to her brain was immense and intolerable agony for Gunapathy. Now, when she walks she walks with a grotesque gait. So she avoids walking. She uses a wheelchair with the help of a maid. Her own hands cannot even push it. The few words she utters she utters as though she was born with a birth defect like cerebral palsy. She is not even half the lively person that everyone said she was before the radiosurgery. She is crippled by severe dysphasia and right-sided severe hemiparesis. This happened when she was on the ascent of a promising career as the chief executive officer of a service providing company connected with a construction industry. She needs to be permanently cared for because her deficits are permanent. Emotionally she is insecure in the extreme. The radiosurgery is the direct cause of all these consequences. According, the law must compensate her.

## **Chapter 24 : The Damages**

24.1.I now turn to the question of damages. Gunapathy was the managing director of Haneda Services Pte Ltd until the end of 1997. The company in effect was a quasi-partnership and she was the precedent partner. She was proficient in the Japanese language. The activities of Haneda Services and other companies in the group were connected with Japanese construction companies. The activities of the group to a great extent depended on her for she provided the force and fuel for the company to prosper. She had spent much time in Japan clinching business deals and establishing business ties.

24.2.In 1995, 1996, 1997 and 2000 the financial high-lights relevant to this case were as follows :

Year	Profit/Loss	Directors Remuneration Fees	Directors
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1995	\$19,312	\$222,218	\$160,000
1996	\$581,838	\$241,920	\$310,000
1997	(\$115,175)	\$207,360	\$330,000
1998	(\$301,168)	\$207,360	\$ 10,000

24.3.The profits or the losses were arrived at after charging the directors remuneration and fees. If they are charged back (added to the profits or losses) the position would have been as follows :

1995	\$ 401,530	profits
1996	\$1,133,758	profits
1997	\$ 422,185	profits
1998	(\$ 83,808)	(loss)

The above does not include the CPF payments.

24.4.It was the evidence of Gunapathy's brother that because of her disabilities the company lost much of its existing business, as well as additional business that was in the pipeline. The company will not recover its business because it has lost her services and talent. "Following the departure of my sister as managing director, the business of Haneda Services declined as the company had difficulties in procuring fresh ventures and maintaining links with our clients", was his evidence.

24.5.There was evidence to the effect that in 1998 she was paid \$86,400 and in 1999 she was paid \$57,600. Although this was called "salary", it was in fact not so because she ceased to work. That is understandable because in a family private company such a course of action is neither reasonable nor unusual. It is also not unusual in such a company to award special bonuses to the MD who brings in the business and profits. The payments obviously were meant to help her out during the difficult period she was going through.

24.6.The company's three shareholders were :

Gunapahhty	33,334 shares
Ramakrishnan (brother)	33,333 shares
Gopal (brother)	33,333 shares

24.7.The plaintiff's real income was directly linked to the revenue and profits of the company. Her real financial loss of earnings therefore was inevitably and inextricably related to the loss of the entire company.

24.8.Having stated the source of her income I shall now consider Gunapathy's claims.

#### Medical and other expenses

24.9.This was agreed at \$50,000.

#### Pain and suffering

24.10.Gunapathy claimed damages for pain and suffering and loss of amenities. The damages under this head are at large. It is assessed on the basis of what would be a fair compensation. In assessing damages under this head it is customary to be guided by previous awards in like cases. At the same time previous awards are not treated as statutory tariffs. In this regard, the Court in **Tan Joon Heng v Thiam Boon Kiap & Anor** [1989] BLD Yearbook 681 cited and discussed in **Peh Diana & Another v Tan Miang Lee** [1991] 3 MLJ 375 awarded \$100,000 for pain, suffering and loss of amenities. The

plaintiff in that case had right hemiplegia and head injury. That was in 1987. In the present case, Gunapathy has suffered greater agony and for a longer time. Accordingly, to award anything less than \$100,000 would be egregiously low. So I award \$100,000.

Loss of earnings

24.11. Gunapathy calculated her average monthly income at \$12,180 (\$146,171.36 annual). This was the average of her gross income from 1993 to 1997, after deducting income tax. This was generous to the defendants because in computing average income it is usual to calculate the average of the previous three years. That would have given a yearly average of \$183,000 or \$15,250 per month. The amounts received by her as "salary" after 1997 must be taken as a loan. Accordingly I award \$511,560 as pre-judgment loss of earnings (\$12,180 x 42 months – January 1998 to June 2001). Loss of future earnings should be based on a multiplier of 11 years at \$146,171.36. She is 41 years old now. This gives \$1,607,884.96.

24.12. Gunapathy asked for CPF contributions on future loss of earnings at \$13,824 per year. She is entitled to it and I therefore award \$152,064 under that head.

24.13. In addition I award \$100,650 for past and future domestic care as claimed at \$550 per month.

24.14. Finally I allow her \$33,000 for future medical care as claimed.

Sgd:

GP SELVAM  
JUDGE

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