

THE HIGH COURT**[2007 No. 8410 P]****BETWEEN****PHILLIP LEO****PLAINTIFF****AND****HEALTH SERVICE EXECUTIVE****DEFENDANT****JUDGMENT of Mr Justice Ryan delivered on the 25th July, 2013****Issues**

The plaintiff is a 52 year old former manual worker who suffered an extradural haemorrhage on the 2nd February, 2006, which left permanent physical disabilities in its wake. This catastrophe occurred following a period of medical procedures and hospital treatment that included treatment and advice that the plaintiff received in Merlin Park Hospital, Galway and its Out Patients Department. On the 28th November, 2005 he was recuperating in County Galway after a cervical discectomy operation that was carried out in Beaumont Hospital when he developed serious symptoms and was admitted to Merlin Park Hospital. Mr Leo was diagnosed as having pulmonary emboli and other related conditions. When the results of tests became known, the consultant in charge of the plaintiff prescribed a well-known anti-coagulant drug, Warfarin. He was discharged from hospital on the 7th December, 2005 with directions to continue on this drug long term.

The plaintiff claims that he was not given any or any proper advice or warning or information about Warfarin. He had for many years suffered from gout and when attacks came on he took a non-steroidal anti-inflammatory drug named Difene (pharmaceutical name Diclofenac) on an occasional as required basis for which he got repeat prescriptions. Difene should not be taken in combination with Warfarin. The two drugs operate on the blood in different ways to suppress the coagulant features and they increase the risk of haemorrhage.

The case is that the combination of these two drugs was the probable cause of the cervical haemorrhage that the plaintiff suffered on the 2nd February, 2006 and the resulting disability. Although he does not actually recall taking Difene in the period immediately prior to the 2nd February, he maintains that the probability is that he did so based on the pattern of attacks of gout that he has suffered down through the years since he was first afflicted by the condition.

The plaintiff's case is that when they prescribed Warfarin the hospital doctors should have warned him not to take Difene. They failed to do so both during his admission when he was first prescribed Warfarin and also at an out-patient attendance at the hospital on 16th January, 2006. By reason of those omissions, Mr Leo continued to use Difene while taking his regular dosage of Warfarin.

It is not in dispute that the two drugs should not be taken in combination. Warfarin suppresses the clotting factors in the blood and Difene, which is a non-steroidal anti-inflammatory drug, inhibits the effect of the blood platelets. When a person is put on Warfarin, he or she should be warned not to take NSAID's.

The hospital doctors deny Mr Leo's allegations. The consultant rheumatologist, Dr Amina Gsel, testified that she gave the plaintiff explicit warnings about taking other medications including Difene both when he was an in-patient and subsequently at an Out Patient Clinic on the 16th January, 2006. Her registrar, Dr Khadi Afridi, confirms her account of the latter occasion. Dr Afridi's record of Mr Leo's attendance on the 16th is relevant, as is his follow-up letter to the general practitioner. The two treating doctors and their experts are sceptical of the plaintiff's claim that he suffered as frequently or as regularly or as acutely from gout as he alleged. Moreover, the defence case is that there is no basis for a finding that Mr Leo actually took Difene at a material time prior to his suffering the haemorrhage on the 2nd February, 2006.

The issues in the case accordingly are first whether the plaintiff, Mr Leo, was given sufficient information or warning about Warfarin by the hospital and/or the consultant, Dr Amina Gsel, during his stay in Merlin Park Hospital between the 28th November and the 7th December, 2005 or at the Out-Patients Department when he attended on the 16th January, 2006. Secondly, did the plaintiff take Difene at a time that was close enough to the 2nd February, 2006 to be causally implicated in the haemorrhage?

Background Facts

Mr Leo was employed by Diageo in Dublin. He had suffered from gout since his 20s. The Diageo doctor, Dr Ling, prescribed Difene and Mr Leo got repeat prescriptions for this drug over the years. He said that he got an attack on average some two or three times per month and each attack lasted, again on average, some three to four days. He would take a 75mg tablet of Difene in the morning and evening.

The next relevant event in the plaintiff's medical history occurred in late 2005. He complained of weakness in his arms and legs and was referred to Tallaght Hospital where he was admitted on 25th October. He was diagnosed as having a cervical C5/6 disc compression and was transferred to Beaumont Hospital on 2nd November, 2005. The plaintiff underwent C5/6 and C6/7 anterior discectomy and fusion at operation on 8th November, 2005, and he was discharged home on 13th November, 2005.

At this time he was working in Dublin but his partner and daughter were living in County Galway. Mr Leo was recuperating at his partner's home when he complained of coughing and chest pain and a swollen leg on 28th November, 2005. He attended Dr John Kilraine, General Practitioner, who referred him to the A&E at Galway University Hospital for tests. From there he was transferred by ambulance to Merlin Park Hospital where he was detained from 28th November, 2005 until 7th December, 2005. He was investigated for suspected pulmonary embolism, which was confirmed by CT angiogram that revealed multiple emboli and deep vein thrombosis in his left leg. In light of these tests, in consultation with the consultant rheumatologist, Dr Amina Gsel, he was put on Warfarin oral anti-coagulant therapy on or about the 2nd December, 2005. He was discharged home on 7th December, 2005, to be followed up by

his Galway GP, Dr Kilraine. The nature of the advice about the drug that Mr Leo received while he was an in-patient and the occasion of such consultation are in dispute and of central importance and are discussed separately.

Mr Leo's first attendance at Dr Kilraine's surgery following his discharge from hospital on Warfarin treatment was on 9th December, 2005, but he did not see Dr Kilraine and instead saw Dr O'Flaherty, his locum, who did not give evidence and so we do not know what was said at this consultation. Dr Kilraine described Dr O'Flaherty as an experienced locum.

It is agreed between the parties that when Mr Leo was put on Warfarin he was given an instruction booklet. He said this was done by a student nurse who simply told him to read it, which he did. The edition that he was given did not contain a specific warning about NSAID's but it did refer to other drugs being taken in combination with Warfarin.

A nursing note on the day of discharge records "analgesics and antibiotics discontinued. May have Panadol (paracetamol) if required. On Warfarin".

A patient who is taking Warfarin needs to be monitored regularly by his general practitioner to ensure that the dosage is appropriate, which is done by testing the patient's INR, an international ratio, and ensuring that it is maintained at or close to a specified number. Mr Leo attended Dr Kilraine on some five occasions between his discharge from hospital and his attendance at the Out-Patients Department at Merlin Park on 16th January, 2006. He also attended Dr Ling in addition to seeing the locum, Dr O'Flaherty.

Mr Leo's attended at the Out-Patients Department of Merlin Park Hospital on 16th January, 2006, an occasion that has to be considered separately in relation to the evidence of the plaintiff and the doctors. On that day, following the attendance, the registrar, Dr Khadi Afridi, dictated a letter to Dr Kilraine in which he summarised the course of the patient's care in the hospital:-

"Diagnosis:

Asthma

Eczema

Gout

C5/C6 discectomy

Bi-lateral extensive PE November 05

Antiphospholipid syndrome.

Dear Dr Kilraine,

This gentleman was admitted under the care of rheumatology services on 28th November '05 after he had a discectomy almost 2½ weeks previously. He was complaining of a cough with productive sputum for five days, with a sharp radiating pain on the right rib. Looking into his history and clinical presentation, he was treated as respiratory tract infection and had scans to rule out pulmonary embolus. He had a lung perfusion scan, the report was of probable pulmonary embolus. We proceeded for CT pulmonary angiogram, which showed massive bilateral pulmonary embolus with multiple other emboli. He was commenced on low molecular weight Heparin and discharged on Warfarin.

Today, 16/1/06, he was reviewed again in clinic. He is doing well since discharge and is keeping an eye on his INR, recent INR was checked and was within therapeutic limit. He has no chest pain, shortness of breath, cough or haemoptysis. His pending investigations from discharge are as follows: anticardiolipin antibody, IGG, IGM and Beta2-glycoprotein I were all within normal limits. However, his lupus anti-coagulant was positive and his factor V and prothrombin mutation was not detected. His anti-thrombin III and protein C are still in progress.

He was seen by the consultant and the blood results were explained to him. He was told that even being negative for anticardiolipin antibody but again positive for Lupus anticoagulant, he still has a diagnosis of antiphospholipid syndrome. In view of his massive pulmonary embolus, he should be on Warfarin lifelong. The hazards of Warfarin were explained by the consultant and she suggested to keep his INR above 3. Some of the bloods were repeated again today and he is due for review in the Lupus clinic in three months time."

In the early hours of the 2nd February, 2006 Mr Leo was seen in the Emergency Department of St James's Hospital, Dublin from which he was transferred later in the morning to Beaumont Hospital. There he was an emergency admission under the care of the consultant neurosurgeon, Mr Rawluk. He had presented with sudden quadriparesis, with weakness in all limbs and decreased muscle power. An MRI scan revealed a cervical haematoma. He had an emergency operation to evacuate the extradural haematoma and perform a C3-6 laminectomy. The plaintiff gradually recovered from the operation but required long term rehabilitation in the National Rehabilitation Hospital, Dun Laoghaire.

Mr Leo is left with very significant disability. He uses a stick to walk which he can only do for short distances. He is incapable of returning to work. His intellect is not impaired, but his activities of daily living are greatly reduced and restricted and his quality of life has been greatly diminished. He is in a word seriously disabled.

The Expert Evidence

The medical experts were in agreement that the medical team in Merlin Park Hospital should have discussed with Mr Leo the inherent risks of Warfarin and warned him not to take Difene or other non-steroidal anti-inflammatory drugs at the same time. If such advice was not given, that would have constituted sub-standard care. There was disagreement as to whether there were indications or evidence from which it could be inferred that the plaintiff had actually taken Difene at a relevant time prior to his collapse on the 2nd February but that is of course a question of fact. The plaintiff's experts noted the references in the notes to the hazards of Warfarin but pointed out the absence of specific note of his being told not to take Difene or to any prescription of an effective alternative drug.

It seemed that there might also have been dispute as to the time duration of the effect of Difene; Professor Machin for the defendant was of opinion that its half-life was much shorter than the plaintiff's experts, Dr Giangrande, Dr Patel and Dr Merry. However, the zone of dispute narrowed considerably in cross-examination of Professor Machin by Mr O'Brolchain SC and in the result I do not think there

is a major issue to be decided as between the experts on this point. Some disagreement remained but its consequence is limited. Prof Machin accepted that the strength of dose of Difene was greater than he had supposed; he also thought that there could have been delayed effect because of the location of the haemorrhage that Mr Leo experienced.

All this does of course depend on a finding that the plaintiff did indeed consume the drug at some time when the effect of the combination with Warfarin would still have been operating on the 2nd February, a point on which the defendant's experts were sceptical.

Dr Costigan, consultant neurologist, testified in accordance with his expert report that the medical record suggested that Mr Leo's intake of Difene was minor in the two months that he was taking Warfarin. He also opined that there was no evidence that taking Difene additional to Warfarin caused an increased risk of bleeding. I found Dr Costigan to be an impressive witness as I did the other experts but this point was I think more central to the specialisations of his colleagues than to his area. Considering all the expert evidence, I take it that combining Difene with Warfarin does increase the risk of haemorrhage.

The plaintiff's witnesses were critical of a diagnosis made in Merlin Park of antiphospholipid syndrome, which can only be reached following a repeat test but the consultant and registrar said that their view was preliminary and provisional until confirmed subsequently. Any such criticism is irrelevant to the issues because the indicated level of the maintenance regime of Warfarin was within the accepted therapeutic range.

It is possible but unusual for a person who is taking Warfarin to experience bleeding. The defendant's experts referred to the fact that the haematoma occurred at the site of the neck surgery the plaintiff had in October, 2005.

The Critical Questions of Fact

The plaintiff's evidence

Mr Leo confirmed that he had a conversation with the consultant rheumatologist, who was Dr Amina Gsel, in Merlin Park Hospital but he disagreed as to the circumstances. Mr Leo recalled a conversation that he says took place at the time of his discharge on the 7th December, 2005, in the corridor of the hospital when he and his partner asked to see the consultant. Dr Gsel's recollection was that a conversation between her and Mr Leo about Warfarin and its hazards took place when he was in bed in the ward at or about the time when he was diagnosed with pulmonary embolism. That was the 2nd December, 2005 or maybe the day after the diagnosis which would be the 3rd December. It is not actually specified in the records as to when the diagnosis was made, but the 2nd December seems a reasonable inference. Dr Gsel says that she actually remembers the occasion and she was able to describe the position of Mr Leo's bed in the ward, a point that he did not disagree with.

Mr Leo's description of this conversation varied somewhat in the course of his evidence. His basic evidence was that nobody warned him about Warfarin and taking other drugs with it. He did acknowledge that the consultant told him not to eat green vegetables. He said he did not get any Warfarin warning at any time. The nurses did not do so. Specifically, the consultant Dr Gsel did not do so. In direct examination he described how he was in bed when "as the note suggests" a student nurse gave him a book about Warfarin and said casually that he could take paracetamol for pain.

He recalled the conversation when he and his partner were walking out of the hospital on his discharge on the 7th December, 2005 when they were casually talking to the lady consultant and she was referring to antiphospholipid syndrome and that he would have to be on Warfarin for life and to go to his doctor and get the INR's checked. There was no mention of Difene at all.

Mr Hanratty SC, for the defendant, asked the plaintiff whether it was his evidence that up to the time he was discharged on the 7th December, 2005, - "nobody told you that there were certain things or certain drugs that you cannot take and indeed certain foods that you cannot take while you were on Warfarin". Mr Leo replied: "Nobody told me that, no. There was no warning whatsoever". Neither was he given any warning about taking alcohol while on Warfarin. He was given the yellow book on Warfarin, but he was discharged without any instructions from anybody about the book and what he needed to do with it. Nobody told him that there were certain medications that it would be unwise to take while he was on Warfarin. Nobody told him that there were certain foods and alcohol. Dr Gsel did not do so.

"And that the hazards she told you was that you cannot take Difene, you cannot take any other kind of anti-inflammatories or analgesics, antibiotics, alcohol, foods stuffs, particularly green leaves, particularly spinach. You don't remember any of this? No."

Mr Hanratty referred to the conflict about the circumstances of the encounter between Dr Gsel the consultant and Mr Leo during his admission to Merlin Park. Dr Gsel's recollection was of a specific location in the ward where the conversation took place and that it happened around the time of the diagnosis and when he was put on Warfarin. Mr Leo said it happened on his way out of the hospital. "I recall we were leaving the hospital and we asked to see her. We were talking in the corridor and I recall she was telling me about the Warfarin would have to be checked and about green leaves can effect the blood". There was no mention about Difene or of any particular drug or drugs in general in connection with Warfarin. She told him about green leaves but not about drugs, according to Mr Leo.

Concerning the 16th February, 2006, attendance at the Out Patients' Department, Mr Leo said that there was no warning given about Warfarin. When he disclosed Difene there was no suggestion that it was a hazard; everything was a pleasant conversation.

As to whether he was taking Difene in the period leading up to the crisis of the 2nd February, 2006, he said that he was taking it before then but he could not put a date on it. He was anxious to get back to work and used to go on walks around where he lived and he was conscious of the gout and knows he was taking Difene.

In cross-examination Mr Leo accepted that during his admissions to Tallaght Hospital and Beaumont Hospital and Merlin Park Hospital, which covered an extensive period, he did not suffer from gout on any occasion. The same applied to his admission to Beaumont hospital again after he had his collapse on the 2nd February, 2006.

He had three general practitioners - Dr Kilraine in Co. Galway; Dr Ling the Diagio doctor in Dublin and Dr Lindsay in Walkinstown. Counsel for the defendant, Mr Hanratty S.C. went through these records in order to show that there are very few references to gout in them, from which he was inferring that Mr Leo suffered a lot less often from gout than he recalled. Mr Hanratty also drew attention to the increasing severity of Mr Leo's symptoms arising from his severe neck condition where he had a disc prolapse and that must have been causing him a great deal of disability, pain and discomfort. Counsel's point was that it was quite likely that Mr Leo was taking Difene, when he was taking it, for serious and painful conditions other than gout. It does seem to me to be puzzling why Mr

Leo would not take Difene for those conditions and would restrict it for exclusive use for episodes of gout.

Mr Hanratty invited Mr Leo to comment on the fact that the St. James's Hospital record of his emergency admission on the 2nd February, 2006, noted that he was on the drugs Warfarin and Symbicort but do not refer to Difene. Mr Leo said that he was going in and out of consciousness, but he was able to remember Warfarin and Symbicort and yet his evidence was that he had taken Difene in the recent past before his admission and he had a ready regular supply of it for episodic use, and it was the drug that he had had for longer than Warfarin.

Mr Hanratty put to Mr Leo that the context of the nurse's reference to paracetamol was pain relief and implicitly related to a restriction to that drug which was consistent with the case he was making for the defendant.

Mr Leo said that he could not remember having a discussion with his GP about the implications of being on Warfarin when he attended at Dr Kilraine's surgery on the 9th December, 2005, two days after his discharge from hospital. In fact, he did not see Dr Kilraine but rather his locum on that occasion and we do not know what the locum told him about Warfarin.

Mr Leo was with Dr Kilraine again on a number of occasions in early 2006, namely the 3rd January, 4th January, 24th January and in none of those entries is there any reference to gout. Dr Kilraine's record of the 24th January is that Mr Leo was on Symbicort Turbohaler with a dosage and ventilan and Warfarin, but he did not record that he was on Difene and Mr Leo did not know why that was and could not answer his suggestion that it was because he did not mention to the doctor that he was taking Difene.

Counsel turned to the events of the 16th January, 2006 at the OPD of Merlin Park Hospital. Mr Leo denied that he had been seen by the consultant Dr Amina Gsel on this occasion. Mr Hanratty put to him that Dr Afridi had written down in his note of the attendance that the consultant saw Mr Leo, but he simply denied that. "No, I didn't see her that day. I didn't, I never saw her. I don't know what he is talking about here but we never saw that consultant". The entry saying that the hazards of Warfarin were explained was wrong: "No, this is the crazy, it's mad".

Mr Hanratty S.C. suggested to Mr Leo that Dr Gsel would say in her evidence that she told Mr Leo that he should not be taking Difene and should not take it any further, that he should not take any kind of medication PRN, she told him the reason why he should not be taking Difene while on Warfarin, she said that there were certain foodstuffs he should avoid including green leaves and that she specifically mentioned spinach and also said that he should not take alcohol while on Warfarin. His answer was that that did not happen because "she wasn't there".

Mr Leo simply denies that this note by Dr Afridi could be true when it says that he was seen by the consultant and he even went so far as to say that Dr Afridi was lying. Mr Hanratty discussed with the plaintiff what possible reason the registrar might have for saying that when there was no question of any litigation or any interest that he or anybody else might have in suggesting that there was a meeting with the consultant when it did not happen. Mr Leo accepted that the import of his evidence was that this statement was a fabrication.

Mr Leo was unable to say what the longest period was and what was the shortest period between episodes of gout and when he had to take Difene. The only thing he could say was that on average he would be on it two to three times in a month, but that is an average and it does not describe the actual experience. Mr Leo was unable to provide the court with any information other than this average which is a conclusion or an analysis of other information. He did not give any basis to the court on which to evaluate the likelihood whether he was on Difene at a relevant time before the 2nd February, 2006.

Evidence of Dr Amina Gsel

Dr Gsel has been a consultant rheumatologist at University College Hospital, Galway since 2004. That hospital and Merlin Park operate together and she was the consultant on duty at the time of Mr Leo's admission to Merlin Park via Galway University Hospital. She remembered Mr Leo's case. He was referred by his General Practitioner Dr John Kilraine, who had worked under Dr Gsel and whom she viewed very favourably for his medical knowledge. He suspected a pulmonary embolism and that was a major concern. Mr Leo was subjected to a number of tests in Merlin Park Hospital to confirm or refute this potential diagnosis and ultimately it was confirmed that he did indeed have a serious condition of extensive pulmonary emboli in both pulmonary arteries and with shower emboli on the lungs. She was contacted by the radiologist who confirmed the diagnosis of what the doctor had suspected and she conveyed the message to the hospital team to start the patient on Warfarin. She said that she had a discussion with Mr Leo about Warfarin and the implications of being put on it on the day of the diagnosis and when he was started on Warfarin or the next day.

Dr Gsel said that the conversation took place in the ward beside Mr Leo's bed which was either beside the window or one in from there. She recalled telling him that he was starting on Warfarin and would be taking it for a certain length of time and he needed to be quite careful with medication, with food and with alcohol and if there were any side effects or unusual effects or any changes in his condition he was to contact his GP immediately. She spoke about food, mentioning green leaves and specifically spinach, which was a somewhat humorous mention. She said that Warfarin was a very complicated drug which is very sensitive and has lots of drug interaction – "it is a huge list, but actually we normally explain the side effects regarding the most common medication like aspirin, non-steroidal anti-inflammatories and the main named products of that kind". She mentioned alcohol and food, mainly green leaves as things to be avoided. She specifically mentioned Difene and she did that "because from the note, when you go back to the note, actually when he came in, he was taking Difene and that was quite serious, actually, with Warfarin and I don't think that any reasonable medical professional will miss that".

Dr Gsel said that she has been practising medicine for a good number of years at consultant level and is not a dietician who would mention green leaves and not the more serious things like drugs, but on the contrary was a medical professional and she would obviously mention medication rather than food, which is what is normally done.

Dr Gsel did not recall a conversation with Mr Leo in the corridor on the day of his discharge. Her recollection was that it took place in the ward when she was at his bedside.

Out Patients' Department 16th January, 2006.

Dr Gsel said that Dr Afridi spoke to her and she came to Mr Leo. On this occasion she explained to Mr Leo that he should not be on Difene or Nurofen and yet he was taking it PRN. She explained again the hazards of taking Difene especially on an "as needed" basis and the side effects. That is why Dr Afridi wrote on his note that the hazards of Warfarin had been explained to the patient and he ticked that. Dr Gsel also said that she mentioned to Mr Leo that he should not be on Difene because his asthma might flare up again. Her view was that the patient should not be on Difene at all and it was worse to be on it on a PRN basis. Difene interacts with Warfarin and affects the platelet aggregation and it also affects the INR. If a person is taking Difene as he or she needs it, he might take different quantities on successive days with the result of disturbing the INR and causing hazards and she said that everything

was explained to Mr Leo.

The plaintiff's experts had criticised the diagnosis of antiphospholipid syndrome on the basis that this is something that can only be done after at least two examinations some three months or so apart. Dr Gsel's answer was that the diagnosis was provisional subject of course to being reviewed and refuted by a subsequent test, which in fact is what happened.

In cross-examination by Mr O'Brolachain SC, Dr Gsel recounted once again her conversation at the plaintiff's bedside. She said that the scan proved that he had a pulmonary embolism; it was quite serious, quite extensive and he would be on Warfarin; Warfarin can interfere with a lot of medication – the most common thing is medication, drugs, alcohol; the medication is antibiotics, aspirin, Nurofen and Difene. It was mentioned not to take aspirin, Difene and Nurofen or Brufen.

Counsel suggested to Dr Gsel that if she had known about the Difene or adverted to it in her conversation with the patient, then she would have suggested an alternative medication to be taken for gout instead of Difene. The doctor said Mr Leo was told that he could take paracetamol for pain. Counsel maintained that paracetamol would not be effective or indeed have any use in an attack of gout, to which the doctor replied that he, the patient, did not have any features to indicate that he had gout. By that she meant that he had no clinical features. The patient was taking Difene for pain, not actually for gout according to Dr Gsel. The essential point that she was making was that Mr Leo did not present or complain with a condition of gout. She said that she did not recommend colchicine, a medication suggested by the plaintiff's doctors as an alternative, because she believed and believes that it interferes with Warfarin and can cause hazards and increases the INR. Then Mr O Brolchain went to Dr Afridi's note about the OPD on the 16th January, 2006. She said she told Mr Leo not to take any irregular medication; any medication given has to be regular with Warfarin which means that the PRN element of Difene was particularly unacceptable.

Evidence of Dr Khadi Afridi

Dr Afridi was a Registrar in general internal medicine and rheumatology in a number of hospitals in Ireland before coming to Galway where he was employed as a Registrar for three years at Merlin Park Hospital and then as a research assistant for a year. He went to England in May 2010 and he is currently working as a locum consultant in rheumatology at Adenbrooks Cambridge University Hospital.

Dr Afridi described the plaintiff's course of treatment as recorded in the clinical notes in the hospital. He then turned specifically to the 16th January, 2006, at the Outpatients Department. The note that Dr Afridi made is long and detailed and it is unnecessary to set it out in full. It records that Mr Leo had a C5/C6 disectomy, that he had bilateral pulmonary emboli in December 2005, that he suffered from asthma/eczema and that he had gout – (since 20's). The note says that he was on Warfarin and was stable; also symbicort turbohaler and Difene PRN. Dr Afridi drew attention to the fact that he put PRN in brackets and underlined it because of the significance of that drug in conjunction with Warfarin.

The doctor said that he explored some present complaints that Mr Leo had about a rash and what might be the cause of it. He checked to see whether there were outstanding test results and followed up on blood tests by making a number of phone calls. When he had all the information he went and spoke to the consultant Dr Gsel who then herself came into the room and spoke to Mr Leo.

In his note he recorded that Mr Leo was seen by Dr Amina, that is Dr Gsel's first name. The blood results were seen and explained; there was a diagnosis of antiphospholipid syndrome. "Hazards of Warfarin explained". He said that Difene was specifically discussed by Dr Amina and that the patient was not to take it, but was to use paracetamol if he needed to.

Dr Afridi insisted that events happened as he described them in his note. He could easily have said and would have done so if that had been the case that he had discussed with the consultant instead of writing "seen by the consultant".

Dr Afridi was sceptical about the evidence that he had read in the transcript as given by Mr Leo that he had suffered as many attacks of gout as Mr Leo claimed. The doctor's point was that if a person had suffered an average of two or three attacks every month lasting some three to four days that he would have had physical evidence which was not present. He also said that at the consultation he was dealing with an active issue that was not gout and he was simply recording what the patient told him.

Dr Afridi said that Dr Gsel came in and discussed the blood results. Antiphospholipid syndrome was a rare diagnosis and she had asked for these blood tests on the 4th or 5th December, 2005. Dr Afridi had found out the results of the tests and told Dr Gsel and she made the diagnosis of antiphospholipid syndrome. Obviously, that was so to speak a provisional diagnosis which would on re-testing be confirmed or disproved.

Mr McDonnell S.C. for the plaintiff suggested as Mr O'Brolachain had to Dr Gsel that if the linkage between gout and Difene had been made, then an alternative medicine should have been prescribed or indicated for the plaintiff. Dr Afridi said that Mr Leo did not have an active gout problem, he did not complain of gout as an in-patient and he did not complain of any joint pains between his discharge and being seen by the clinic. This was a historical diagnosis of gout which was a matter between the plaintiff and his GP.

Discussion

The plaintiff acknowledges that he was given the Warfarin book by the student nurse during his stay in hospital when he was in bed in the ward; he read the book but he did not appreciate the significance of the statement in it about drugs containing aspirin and there was no mention in it of Difene or even its generic name Diclofenac.

Mr Leo did have a conversation with the consultant Dr Gsel but not in the ward; the meeting happened in the corridor at a time when he was leaving the hospital and at the request of Mr Leo and his partner Helen. Dr Gsel did refer to green vegetables or greens, but she did not mention any drugs and Mr Leo could not remember whether there was any mention of alcohol but he knew about alcohol anyway because his father was on Warfarin.

Mr Leo did recall being told that he could take paracetamol for pain while he was in hospital, but he did not take that as meaning he was confined to paracetamol.

He did not meet Dr Gsel on the 16th at the Outpatients Department; Dr Afridi's note about the meeting is untrue and is in fact a fabrication; the same for Dr Afridi's letter dated the 16th January, 2006 to Dr Kilrairie.

The net result of all this is that there is a series of fundamental issues in dispute between the parties. In his note of the 16th January, 2006, Dr Afridi records the relevant information that Mr Leo was then or had been taking Difene PRN. He highlighted it. If he had not made a note of it, it could be suggested that he was not aware that Mr Leo was taking Difene. But in light of the note, there can be no doubt that Dr Afridi was indeed aware and if one accepts his evidence as to the fact that he highlighted this part of the note by underlining and putting it in brackets, it is clear that he knew it was significant. As a Registrar, he was a senior doctor in the

hospital and this was information that even a junior doctor should have been aware of. It is not easy to understand why he would have written it down and highlighted it if he did not appreciate the importance and obviously it makes no sense to write it down and not mention it to Dr Gsel the consultant. It must be Mr Leo's contention that Dr Afridi wrote this down, but did not understand the significance or did not remember to do anything about. The reference to the hazards of Warfarin is not specifically related to Difene. But Dr Afridi and Dr Gsel both swear that she specifically mentioned Difene in talking to Mr Leo. Dr Afridi twice mentions that Dr Gsel spoke to Mr Leo, but he denies that there was any such meeting. It follows if Mr Leo is correct that Dr Afridi and Dr Gsel are not only mistaken, but they are telling lies and that they have done so on oath in court.

It is also necessary for Mr Leo to make the case that Dr Afridi and Dr Gsel were aware or ought to have been aware of the fact that Difene was relevant in that it was available for use by Mr Leo and used by him PRN and yet they did not say anything about it. Moreover, Dr Gsel did warn the plaintiff about eating green vegetables, including spinach according to her, and accepted by Mr Leo but if he is correct she mentioned these vegetables without saying anything about drugs that might interfere with Warfarin.

The difficulties facing Mr Leo in this account are formidable. There is an inherent improbability in a consultant speaking to a patient and mentioning one of the minor restrictions that are associated with taking Warfarin – green vegetables – but not specifying a major point that would arise in that very context, that is, other drugs that would be incompatible or contra-indicated with Warfarin. Similarly it is difficult to understand why paracetamol would be mentioned if not in a context of pain relief and if not in circumstances where other drugs were being excluded.

It is impossible to understand any rational basis for the conduct that Mr Leo ascribes to the Registrar, Dr Afridi. On the plaintiff's case, this doctor's note of the consultation at the Outpatients' Department must represent a flagrant breach of medical ethics and constitute serious wrongdoing towards his patient insofar as the suggestion is that the doctor has invented a meeting with the consultant that simply did not take place. He did not have any identifiable interest in doing so. But it is even more difficult to see why Dr Afridi would actually have recorded that Mr Leo was using Difene and underlined it or that he would have made such a thorough note of his examination. In other words, why would he record the Difene if there was no warning about it or no mention of it or no meeting with the consultant in respect of that?

I do not believe that the doctors made up a story about the consultant's meeting with the plaintiff and what she said to him. I accept their evidence as being truthful and coherent. Dr Amina Gsel and Dr Khadi Afridi, the consultant and registrar respectively, are highly qualified in their fields and they struck me as being caring and professional physicians. I do not believe that they were telling lies in court or that Dr Afridi fabricated his note of the 16th January 2006. The detailed record of the consultation is evidence of a careful and thorough approach by the doctor.

Independent of any other question, on any reasonable assessment of the evidence, there is no sufficient basis for rejecting the clear evidence of Dr Gsel and Dr Afridi as to the sequence of events on 16th? The plaintiff's case is a mixture of assertions and allegations by Mr Leo that are flatly contradicted by the evidence of Dr Afridi and Dr Gsel; there are inconsistencies and absences and gaps in Mr Leo's recollection that are not easy to understand; there are illogicalities in what he says – incoherent elements that simply do not fit together; there are features in his evidence that actually tend to corroborate a case of the defendant – e.g. the reference to greens and to paracetamol. The written records, especially the note and letter written by Dr Afridi on the 16th January, 2006, are entirely inconsistent with Mr Leo's recollection and account.

None of this makes sense, and when one considers these disputes on the balance of probability, it seems to me irresistible that the doctors' evidence has got to be preferred over that of the plaintiff.

I turn to the question whether the plaintiff had taken Difene in the recent past when he suffered the haemorrhage that precipitated his admission to St James's Hospital in the early morning of the 2nd February, 2006. Mr Leo does not remember whether he suffered an attack of gout and took Difene for it in the days preceding the 2nd February, 2006. The plaintiff's case is that the pattern of onset of attacks of gout and consequent imbibing of Difene indicates or establishes that he must have had attacks in the period between his discharge from Merlin Park Hospital and, indeed, following the out patients attendance on 16th January, 2006, and the attack on 2nd February, 2006. If he was having attacks on average two to three times per month and lasting for three to four days, then it does follow that if that pattern was established in the relevant period it may well be a matter of deduction that he was on Difene at the material time. But is that the case? In other words, is there a basis for thinking or accepting that Mr Leo had an attack close enough to the 2nd February to infer that he took Difene? On this point, there is some disagreement between the plaintiff's experts and the defendants, particularly Professor Machin, who gave evidence. The Professor's view was that there was nothing to indicate that Mr Leo took Difene at any relevant time.

Mr Hanratty S.C. for the defendants points out that there is no evidence in any of the hospital records for Tallaght or Beaumont or Merlin Park of any attack of gout having happened to Mr Leo. That accounts for a substantial period of time from the end of October until the beginning or early part of December. Neither is there relevant reference in any of the GP records to attacks of gout. It is of course true that Mr Leo could have had attacks and not mentioned them because they were simply part of his routine life and not a cause of specific mention to his doctor. On the other hand, I think that the point about the hospital admission is significant because Mr Leo agreed that he did not have any such attack while in hospital.

Is there a rational basis for inferring that Mr Leo was indeed on Difene or had been taking the drug at a relevant time prior to the 2nd February, 2006? Is there sufficient evidence to warrant inferring that he did in fact take it on the basis of the average that he expressed. One has to bear in mind obviously that attacks of gout must have been intermittent and occasional and not regular in their occurrence. Without any evidence as to attacks of gout between the end of October – he was admitted to Tallaght Hospital on 25th October, 2005 – and the 2nd February, 2006, how is one to conclude that Mr Leo did actually have a gout attack and did take Difene for it within a range of about four days prior to 2nd February? I am left wondering whether even assuming everything else in his favour it is possible to come to that conclusion.

The fact that the plaintiff was unable to provide any information about the onset and duration of his attacks of gout and simply claimed that they occurred on average does not assist his proof. An average is an analysis of separate pieces of information and it is indeed strange that Mr Leo could give no assistance on the range of his experience of the episodes. Taking into account his incapacity to say whether he had actually taken the drug at a relevant time before his attack, I think Professor Machin's scepticism about the influence of Difene on the plaintiff's haemorrhage is justified. It cannot be ignored also that the bleed happened at the site of the previous surgery, as that expert pointed out.

On this question also, the plaintiff's evidence falls short on the balance of probabilities.

The plaintiff's claim fails accordingly.

