INQUIRY UNDER THE FATAL ACCIDENTS AND SUDDEN DEATHS INQUIRY ACT INTO THE DEATH OF ISABELLA GILLIES

B26/05

UNDER THE FATAL ACCIDENTS AND SUDDEN DEATHS INQUIRY (SCOTLAND) ACT 1976

DETERMINATION

by

SHERIFF RODERICK JOHN MACLEOD, Adv.

in Inquiry into the circumstances of the death of

ISABELLA GREIG GILLIES

KIRKCALDY, 28th September, 2005

The Sheriff having resumed consideration of the cause, DETERMINES as follows;-

- In terms of section 6(1)(a) of the Fatal Accidents and Sudden Deaths Inquiry (Scotland) Act 1976 (hereinafter referred to as 'said Act' or 'the Act'), that Isabella Greig Gillies, who was born on 8th November 1933, and who lived at 168 Aitken Road, Glenrothes, Fife, died at approximately 2210 hours on 28th November 2003 at Victoria Hospital, Kirkcaldy.
- In terms of section 6(1)(b) of said Act, that the cause of death was a haemorrhage in the anterior abdominal wall with chronic obstructive airways disease as a secondary cause.
- In terms of section 6(1)(c) of said Act, that there were no reasonable precautions whereby her death might have been avoided.
- In terms of section 6(1)(d) of said Act, that there were no defects in any system of working which contributed to her death.
- In terms of section 6(1)(e) of said Act, that the following facts are relevant to the circumstances of her death;-

The over prescription of the drug Dalteparin and the subsequent administration of three dosages thereof in the wrong amount.

NOTE

- ***Parties and representation at the Inquiry***

  Four parties were represented at the Inquiry; the Procurator Fiscal, Fife Health Board, Dr. Rachel Peters and Dr. Rachel Pollock. Ms. Pasportnikov, Procurator Fiscal Depute, represented the Crown, Mr. MacLeod, solicitor, represented Fife Health Board and Mr. Paterson, solicitor, represented the two doctors. Despite

earlier indications to the contrary, at the end of the day the family of Mrs. Gillies decided not to appear or be represented as parties before the Inquiry but evidence was given by Mrs. Shona Dryburgh, daughter of the deceased.

- ***Witnesses and evidence***

  The procurator fiscal depute led evidence from the following witnesses;-

  The said Mrs. Shona Dryburgh;

  Dr. Mark Francis, Consultant Cardiologist, being the consultant in charge of the Coronary Care Unit and Ward 15, Victoria Hospital, Fife;

  Dr. Rachel Pollock, now a doctor at the Marie Curie Centre, Edinburgh, but at the time of the death a Senior House Officer at the Victoria;

  Dr. Peter Henriksen, Specialist Registrar in Cardiology, Western General Hospital, Edinburgh, who held a similar post at the Victoria at the time of the death;

  Dr. Robert Iain Cargill, Consultant Cardiologist at the Victoria and Lead Clinician for Medicine for Fife;

  Dr. Derek Bell, Consultant Physician and Associate Medical Director at the Royal Infirmary of Edinburgh, who had prepared a report on Mrs. Gillies's care on the instructions of the procurator fiscal (Crown production 5).

  I found all of the witnesses to be both credible and reliable. All of them were frank and helpful in the giving of their evidence but I would like to pay particular tribute to Mrs. Dryburgh for the very dignified and measured way in which she gave her evidence. As well as her oral evidence I had the benefit of a diary of events (Crown Production 7) which she had helpfully written about a week after her mother's death.

  In addition to the evidence of these witnesses, parties agreed by Joint Minute the terms of a report prepared by Dr. Maeve Rahilly, Consultant Pathologist, Fife Acute Hospitals NHS Trust, who had carried out the autopsy on Mrs. Gillies (Crown production 2 and its addendum Crown Production 3) and an affidavit by Mr. Alexander Peter Kopyto, Principal Clinical Pharmacist at Victoria Hospital.

- ***The issue which emerged***

The purpose of the inquiry, as with all such inquiries, was, of course, to investigate the matters on which a determination requires to be made in terms of the various parts of section 6 of the Act. In some inquiries, however, particular issues emerge around which the inquiry centres. The issue which emerged during this inquiry was whether, and if so to what extent, the prescription of an excessive dosage of an anticoagulant drug called Dalteparin caused or contributed to the death of Mrs. Gillies.

(iv)Narrative of events

[1]Mrs. Gillies was a 70 year old lady. Sometime in the forenoon of Saturday 22nd November 2003 she was taken by ambulance to the Victoria Hospital, Kirkcaldy as a result of breathlessness and chest pains which she had been experiencing overnight. After initial assessment she was admitted to Ward 12 there at or around 2 p.m.. It was thought that the breathlessness was an exacerbation of her asthmatic condition and that the chest pains were caused by angina. Ward 12 is an Acute Medical Admissions Unit.

[2]In addition to asthma and angina, Mrs. Gillies suffered from osteoporosis, rheumatoid arthritis, hypothyroidism and ocular hypertension. She was taking the following medicines for her various conditions; Adizem, Aspirin, Clopidogrel, Didronel, Lanzoprazole, Nicorandil, Pravastatin, Prednisolone and Thyroxine. In addition she used various inhalers.

[3]Due to her various ailments Mrs. Gillies was no stranger to the Victoria Hospital in November 2003. Most recently she had been an inpatient there between 12th and 19th June of that year when the complaint had also been chest pain and the principal diagnosis acute coronary syndrome. She had been seen as an outpatient, for follow-up purposes, in the interim. Her initial contact with the hospital in a cardiac/respiratory context, however, went back as far as 9th August 1996 when she was first referred to Dr. Francis's Outpatient Clinic. Angina was diagnosed and she was seen intermittently by or on behalf of Dr. Francis until 24th December 1999 when he discharged her, her condition having stabilised.

[4]On admission on 22nd November 2003 oxygen was administered, blood samples were taken and tested, and an echocardiogram was performed. In the later part of Saturday 22nd she was transferred from Ward 12 to Ward 15, a coronary care ward.

[5]Although the chest pain came and went, shortage of breath, particularly following the slightest exertion, was to be a more or less constant feature of Mrs. Gillies' time in the hospital. During that time it often caused her to be very unwell and in a very distressed state.

[6]Shortly after her admission to the hospital she had been prescribed what the medical witnesses called a 'prophylactic' dose of Dalteparin, a form of the anti-coagulant drug heparin which is administered by subcutaneous injection to the abdomen. That prophylactic dose was one of 2,500 units once daily. Her aspirin prescription, on the other hand, was stopped because aspirin can exacerbate breathlessness.

[7]Over the next two days Mrs. Gillies' respiratory symptoms, far from resolving, appeared to worsen and medical staff began to suspect a pulmonary embolism. Pulmonary embolism is a life-threatening condition and once suspected certain steps require to be taken immediately, even before conclusive diagnosis is possible. One such step taken in this case was to change the dosage of Dalteparin referred to above from a prophylactic dose to a 'treatment dose', the treatment now being contemplated being that for a pulmonary embolism. For that reason, at or around 1950 hours on 25th November Dr. Rachel Pollock, a Senior House Officer who normally worked in Ward 16, a respiratory ward, but was at this time on call to cover

the hospital's general medical wards, changed Mrs. Gillies dosage of Dalteparin to one of 18,000 units once daily.

[8]Treatment dosages of Dalteparin are calculated by reference to the patient's weight. Where the patient's weight is unknown and the patient cannot be weighed the weight has to be estimated. It seems that at all times from her admission on 22nd November until said change of dosage on the 25th November Mrs. Gillies was too ill to be weighed. No doubt because of that, her admission notes did not record her weight and Dr. Pollock could not recall whether when deciding to change the prescription she had had available to her Mrs. Gillies' general medical records. In any event she was acting in a situation of great urgency which may not have allowed her the leisure of perusing these records even if available. So she had to estimate the patient's weight. Her practice was to do so in consultation with the other medical staff available and there is no reason to think that she did otherwise on this occasion. She assessed it as being over 84 kgs which, in terms of the relevant guidelines, attracted the maximum dosage of 18,000 units of Dalteparin once daily. Dr. Pollock's apprehension of possible pulmonary embolism and her decision to switch to a treatment dose of Dalteparin as a result of it were entirely appropriate and proper. The urgency of the apprehended situation required immediate action and she took it.

[9]On the following day, 26th November 2005, it did prove possible to weigh Mrs. Gillies. She was found to weigh 66.80 kgs. The correct treatment dosage (for suspected pulmonary embolism) of Dalteparin for a patient of that weight is 12,500 once daily. At that point, therefore, a new prescription for Dalteparin in that dosage should have been issued. That was not done and Mrs. Gillies continued on a dosage of 18,000 units once daily.

[10]A CT pulmonary angiogram, the definitive way of testing for a pulmonary embolism, was carried out on 27th November. It showed that there was no pulmonary embolism. Dalteparin was then stopped. By that time Mrs. Gillies had received three doses of Dalteparin of the wrong amount, a total overdosage of 16,500 units spread over three days.

[11]Although Mrs. Gillies seemed to her family to be brighter when they visited her shortly after she had had her angiogram on the morning of the 27th, she did complain to them of great pain in her left side. In an episode which her family found alarming, she began to cough and turn red. She was holding her stomach. She told her daughter, Mrs. Dryburgh, that she thought she had ruptured something internally. Mrs. Dryburgh immediately reported this to the available medical staff. A doctor told her that she thought that Mrs. Gillies had pulled a muscle in her groin while coughing and indicated that there was not much that could be done about it.

[12]During the night of 27th November Mrs. Gillies complained of extreme pain in the area of the abdomen and groin. By the early afternoon of the following day she had gone into a sharp decline. Her blood pressure and haemoglobin level fell and her pulse was elevated. These are all signs of heavy blood loss. Such blood loss causes what is known as 'hypovolaemic shock' and Mrs. Gillies's condition deteriorated throughout the afternoon and evening of 28th November. The family were told that the prognosis was poor. A blood transfusion was arranged and partially administered

but her condition did not improve, she stopped responding to verbal stimuli, her breathing began to fail and she was pronounced dead at 2210 that evening.

[13]A post-mortem examination was carried out by Dr. Rahilly with the consent of the family. It established that the blood loss which led to death had taken the form of the haemorrhage referred to above.

On the basis of the medical records the likely time of the haemorrhage starting is overnight from the evening of 27th November to the morning of the 28th. More particularly the entry marked as 27/11 (1) on page 229(14) of the medical records probably (on Dr. Bell's evidence) marks the approximate time. That entry is not timed but begins by saying that nebulisers were refused at 10 p.m. so I take it to be a record of Mrs. Gillies' condition at that time. It goes on to say that the patient complained of *'extreme lower abdo/groin pain'*.

It was Mrs. Dryburgh's recollection, however, both in terms of her near-contemporaneous diary of events (Crown Production 7) and as spoken to in her evidence, that her mother had complained of severe abdominal pain at around lunchtime on Thursday 27th November, as recorded at [11] above, and that her mother had indeed at that time told her that she thought she had ruptured something internally. As has been said above, Mrs. Dryburgh reported these matters to the medical staff who happened to be in the vicinity at the time but these concerns do not appear to have found their way into the medical records. Thus the earliest entry in the records which can be linked to the haemorrhage possibly having taken place is that of the evening/night of 27th November quoted above. But whenever the haemorrhage took place the clinical signs which pointed unequivocally to such an event were not apparent before the afternoon of the 28th and by that time nothing which was or could have been done could have altered the outcome for Mrs. Gillies.

(v)Discussion of issues relevant to determination

(a)Section 6(1)(a) of the Act - where and when the death took place

The only matter on which to comment here is the time of death. The Procurator Fiscal Depute in her closing submissions suggested 2140 hours. I am not sure where that time comes from. Mr. Paterson and Mr. MacLeod favoured 2200 hours, being the time on the death certificate. The time disclosed by the medical records (I refer in particular to page 229(15) thereof) is in fact 2210 and that is the time I have given in my determination under this subsection. In any event, nothing turns on the exact time of death.

- *Section 6(1)(a)(b) - the cause or causes of death*

The primary cause of death had to do with a major abdominal haemorrhage. There are various ways of expressing the mechanism which resulted in death. Thus in the intimation of death to the Procurator Fiscal (Crown Production 1) it is given as *'Spontaneous rectus sheath haematoma'*; in Dr. Rahilly's autopsy report (Crown Production 2) it is stated as *'Haemorrhage anterior abdominal wall'*; and in Dr. Bell's report (Crown Production 5) it is expressed as *'hypovolaemic shock secondary to anterior abdominal wall haemorrhage'*.

The rectus sheath comprises a sheath of fibrous tissue enclosing the muscles in the front (anterior) abdominal wall on either side of the umbilicus. That is the area in which the haemorrhage took place. The haemorrhage was referred to by various witnesses as a *'spontaneous bleed'* by which is meant a bleed without an evident trigger. Prompted by what is said by Dr. Rahilly in her report about not being able to exclude the possibility that the bleeding may be related to the therapies and by the fact that the bleeding appears to have taken place in the same general area as the injections of Dalteparin would have been administered, I explored with Dr. Bell the possibility that the injections themselves may have been the trigger for the bleed. He thought this was unlikely, it being uncommon to get significant bleeding at injection sites. Since no one else suggested that the injections may have been the cause, I accept Dr. Bell's evidence on that matter. Accordingly there was no evident trigger for the haemorrhage.

But to say that there was no evident trigger for the haemorrhage is not to say that there was no cause. Manifestly something did cause the haemorrhage and the question for me has been whether it is possible on the evidence to identify that cause or these causes.

In answering that, the starting point is, I think, Mrs. Gillies general condition on admission to the Victoria Hospital in November 2003. She was, as we have seen, a 70 year old lady who had the misfortune to suffer from a multiplicity of medical conditions and who was on a wide variety of medication for these conditions. One result of her age, medical problems and her medication was that she was very susceptible to bleeding and that any bleeding which did take place would be worse than it would be in a person without these problems and susceptibilities. According to Dr. Francis she had *'just about every one'* of the relevant predisposing factors. Taking what he said in evidence, what Dr. Bell says in his report (Crown production number 5) and what Dr. Rahilly says in her autopsy report (Crown production 3) together, the following factors would seem to be relevant;-

- Her age - predisposition increasing with age;
- Her gender - this condition is more common in women;
- Her rheumatoid arthritis;
- Her arthrosclerosis - making it possible that small vessels in the abdominal wall were less elastic than they would otherwise have been so that they may not have contracted normally in the event of puncture;
- The fact that she had been on anti-coagulants, in particular Aspirin and the anti-platelet agent Clopidogrel. As we have seen aspirin had been cancelled as at 23rd November but by that time she had been started on Dalteparin.

That is probably not an exhaustive list, but it enough to show that Mrs. Gillies was very vulnerable to bleeding. The medical evidence was agreed that any bleeding which did take place would be rendered worse by the anticoagulants.

Against that background it is certainly possible to say that the over-dosage of Dalteparin would not have helped in terms of minimising either the risk or extent of any bleeding. Indeed it is possible to go further and to say that the over-dosage of

Dalteparin would have increased both the risk of bleeding happening in the first place and the amount of blood lost once bleeding had started.

What it is not possible to say, however, in my opinion, is that this over-dosage caused or contributed to Mrs. Gillies death. And the reason for that is the very multiplicity of factors at work here. So complex is the situation that it is not possible to quantify the effect of any one factor in what happened. Thus Dr. Francis was able to go as far as to say that what had happened could have happened even if Dalteparin had not been prescribed at all.

In all the circumstances, therefore, it is not possible to be more precise as to the cause of death. In particular and with reference to the issue identified above, it is not possible to say whether the over-dosage of Dalteparin was a cause, far less the cause, of Mrs. Gillies' death.

A secondary cause of death was chronic obstructive pulmonary disease.

(c)Section 6(1)(c) - reasonable precautions whereby death might have been avoided

In his closing submission Mr. Paterson founded on what is said in *Carmichael 'Sudden Death and Fatal Accident Inquiries' 2nd edition at paragraph 5.53* to the effect that what is envisaged by the use of the word *'might'* in this paragraph of section 6(1) is *"not a 'probability' but a real possibility that the death might have been avoided by the reasonable precaution."* I am content to adopt that approach but perhaps it needs to be developed, in terms of what is meant by *'real possibility.'*

I take that phrase to mean something more than a remote possibility but less, of course, than a likelihood (which would be the same as a probability) and, viewing matters in that way, I have considered whether, notwithstanding the conclusion I have come to under section 6(1)(b) above, it can be said that there is a real possibility that the death might have been avoided had certain reasonable precautions been taken to try to ensure that only the correct amount of Dalteparin was prescribed.

I have come to the conclusion that it would be unsafe to go that far on the evidence before me. Again the reason for that is that the witnesses were just not able to quantify the effect of the over-dosage of Dalteparin in the context of the many other relevant, or potentially relevant, factors which were present. That there was an increased risk of bleeding and of greater blood loss in the event of bleeding does not, of itself, enable me to go as far as to say that without that increased risk there was a real possibility that the death might have been avoided.

In that state of affairs I consider it preferable to deal with the question of reasonable precautions to prevent the over-prescription of Dalteparin under paragraph (e) of section 6(1) and I do so below. But before leaving my consideration of paragraph (c) I should record that it was not suggested that there were any other precautions, not having to do with the prevention of excess dosages of Dalteparin, which might have avoided this death. In this connection the Procurator Fiscal Depute in her closing submission raised a question as to whether the haemorrhage should have been identified earlier than it was but there was absolutely no evidence to that effect and,

on the evidence as opposed to her submission, therefore, no such question arises. Accordingly I have not made any findings under this head.

(d) Section 6(1)(d) - defects which contributed to the death

For the same reasons as given in my discussion of paragraphs (b) and (c) above, I do not think that it is possible to say that any defects in the system for prescription of Dalteparin contributed to the death and accordingly I have not made any findings under this head

- *Section 6(1)(e) - other facts relevant to the circumstances of the death*

Although I have not found that the over-prescription of Dalteparin contributed to the death nor that there were reasonable precautions for avoiding such over-prescription which might have avoided the death, the fact that Mrs. Gillies was given more Dalteparin than she should have been is clearly relevant to the circumstances of the death: it was part and parcel of the events leading up to it and had a bearing on the risk and extent of bleeding.

When I refer to 'over-prescription' I am referring in fact to two errors which were made here rather than one. The first error was in the estimation of the weight: it turned out to be wrong. The second error was that once the correct weight had been established the prescription was not changed.

So far as the first of these is concerned, it was an easy mistake to make. Estimating weight is probably always difficult but Dr. Francis explained that it was made more difficult in this case by Mrs. Gillies's somewhat puffed-up appearance, a result of her medication. In that situation it was understandable, he said, that weight could be overestimated.

I accept that and I have also already accepted that Dr. Pollock may not have had the leisure to peruse the earlier medical records for a more accurate weight, even if these were available to her.

The second mistake is less easy to understand. When a patient is on a drug dosage based on an estimate of her weight and it subsequently becomes clear that that estimate is wrong, rectification of the relevant prescription should follow automatically. Procedures should be in place to ensure that that happens. There were no such procedures in place in Ward 15 of the Victoria Hospital in November 2003.

Since then, however, steps have been taken by Fife Health Board to deal with the risk of such errors being repeated. Essentially the change in practice which has been introduced is that where a prescription is based on an estimate of the patient's weight it must be a once-only prescription. It must not be used for repeated administrations of the drug in question. Instead what has to happen is that, in the continued absence of an accurate weight, the weight has to be re-estimated before each and every subsequent administration.

Applying that procedure to Mrs. Gillies's case, the question of weight would have had to be addressed anew before any Dalteparin was administered on 26th November. As it happened, however, it proved possible to weigh her on that day. The correct weight would, therefore, have been available to the person making out the new prescription and the second and third excessive dosages would therefore have been avoided.

Had it not proved possible to weigh Mrs. Gillies at any stage there would have had to be repeated estimations of her weight and this, to my mind, raises a question as to the efficacy of the new procedure. The question can be put in this way: how likely is it that a re-estimate is going to be more accurate than the original? It may be the same person doing the re-estimate, in which case, one imagines, a different result is very unlikely. But even if the second and subsequent estimates are carried out by different people how likely is it that they are going to differ from the original? The original estimate is probably going to be their starting point and unless it seems obviously wrong it is more probable that they will go along with it. But even if they do not, is the 'new' estimate any more likely to be accurate than the 'old'? Is one person's estimate any more likely to be accurate than another's? Indeed the original might be right and the re-estimate wrong.

What all of this demonstrates, to my mind, is that an estimated weight is no substitute for a measured weight. There will obviously be situations in which it will be inappropriate to weigh a patient due to that patient's condition but in that situation consideration should be given to obtaining the weight from another source, such as earlier hospital records or by reference to the G.P.. In the context of the present case I have accepted that Dr. Pollock might not have had the leisure to peruse the records before the prescription and administration of the first dose of Dalteparin but there will always be a substantial interval between first and second dosages (in this case 24 hours) during which enquiry can be made. I question therefore whether the steps already taken by Fife Health Board go far enough towards ensuring that an accurate weight is used for prescription purposes where prescription is dependant upon weight and urge them to give further consideration to this aspect of matters.

For completeness I should record the steps being taken to enforce the new procedure. There are two of these. One is the display of notices, such as represented by Fife Health Board production 1, emphasising that such prescriptions are to be on a once-only basis, at appropriate points within the hospital. The second is that each successive intake of new doctors (the Victoria being part of a circuit of hospitals for the training of young doctors) is to be trained in the new procedure. These seem to me to be appropriate steps but, as I hope I have made clear, to my mind the emphasis should be on removing so far as possible the need to rely on estimated weights in the first place.

Postscript

I close by expressing my condolences to the family of Mrs. Gillies on their sad loss. She was obviously a cherished mother who is sadly missed. I hope it is of some comfort to them to know that as a result of the investigations made into the circumstances of her death procedures have already been changed so as to reduce the risk of the mistakes made in their mother's treatment being repeated in the

treatment of others. And I trust that as a result of this Inquiry that process will be taken a stage further with consideration being given as to whether further improvement in the relevant procedures, along the lines suggested above, is possible.