

SHERIFFDOM OF GLASGOW AND STRATHKELVIN AT GLASGOW

***INQUIRY HELD UNDER
FATAL ACCIDENTS AND
SUDDEN DEATHS
INQUIRY (SCOTLAND)
ACT 1976
SECTION 1(1)(b)***

DETERMINATION

by

SHERIFF JAMES KENNETH MITCHELL,
Esquire, Advocate, Sheriff of the Sheriffdom
of Glasgow and Strathkelvin following an
Inquiry held at Glasgow on the Twenty
Seventh, Twenty Eighth, Twenty Ninth,
Thirtieth and Thirty First days of October and
Twenty Fourth, Twenty Fifth, Twenty Sixth
and Twenty Seventh days of November, all
Two Thousand and Eight into the death of
ALEXANDER CUSKER, aged 75 years, who
normally resided at 47 Brownside Road,
Cambuslang.

GLASGOW, 16 December 2008.

The Sheriff, having considered all the evidence adduced, the competing submissions and the relevant statutory provisions, DETERMINES:-

(1) in terms of section 6(1)(a) of the Fatal Accidents and Sudden Deaths Inquiry (Scotland) Act 1976 that

(i) ALEXANDER CUSKER, born 4 February 1930, who resided at 47 Brownside Road, Cambuslang died shortly before 1810 hours on 21 AUGUST 2005 in Ward 64 of the Southern General Hospital, Glasgow; and (ii) the accident which resulted in his death took place around noon on 22 JUNE 2005 within the Aseptic Dispensing Unit of the Pharmacy Department at Gartnavel General Hospital, Glasgow;

(2) in terms of section 6(1)(b) of the Act that

(i) the cause of Mr Cusker's death was bronchopneumonia as a result of a clinical chest infection due to loss of brain function due to the damage caused by a wrongly dispensed and

administered dosage of the cytotoxic chemotherapeutic drug chlormethine and underlying cerebral vascular disease; and

(ii) the causes of the accident which resulted in Mr Cusker's death were (i) human errors on the part of two members of staff then working in the Aseptic Dispensing Unit; and (ii) defects in the then standard operating procedure followed in this Unit in respect of the dispensing and release of the prescribed cytotoxic chemotherapeutic drug Carmustine;

(iii) in terms of section 6(1)(d) of the Act that the defects in the system of work then in use in the Aseptic Dispensing Unit of the Pharmacy Department of Gartnavel General Hospital which contributed to the accident resulting in Mr Cusker's death were:-

(1) the standard operating procedure then in use in respect of prescriptions for cytotoxic chemotherapeutic drugs not included on the chemocare computer system did not require the use of a worksheet, previously prepared by the senior technician and approved by the Responsible Pharmacist in the Aseptic Unit, which was based solely upon information contained in the standard reference books used in pharmacies throughout Scotland and held in the Unit, and included a written protocol on how to prepare the individual product and the standard formulation of the individual components to be laid out;

(2) the standard operating procedure then in use in respect of cytotoxic chemotherapeutic drugs not included on the chemocare computer system did not prohibit completion of the calculation section of the worksheet solely on the basis of information contained on the information prepared by the manufacturer and inserted into the package containing such cytotoxic chemotherapeutic drugs;

(3) the standard operating procedure then in use did not prevent the second check in the dispensing process, namely, the tray check (the check to confirm that the drug prescribed by the medical clinician had been correctly selected by the pharmacy technician) being carried out by the same registered pharmacist who would carry out the final check in the dispensing process (the check to confirm that the product which had been dispensed (1) was that which had been prescribed by the medical clinician; (2) had been correctly made up in accordance with the worksheet; and (3) was free from particulate contamination) and authorise release of the product for administration to the patient shortly thereafter, there being no possibility of any further inspection or check to reveal the erroneous selection of a cytotoxic chemotherapeutic drug not prescribed by the medical clinician.

NOTE:-

Introduction

[1] This fatal accident inquiry into the death of Mr Alexander Cusker, aged 75 years, who resided at 47 Brownside Road, Cambuslang was heard in Glasgow Sheriff Court over the course of nine days, concluding on 27 November 2008. Ms Judith Hutchison, procurator fiscal depute, conducted the inquiry on behalf of the procurator fiscal. Mr Smith, solicitor, Glasgow, appeared for Mrs Helen Cusker, widow and Mr Joseph Cusker and Mrs Helen Sloss, the children of the deceased resident in Scotland. Mr Scott, Advocate, appeared for Greater Glasgow Health Board and Mr Lamont, Advocate, appeared for Ms Adele Johnstone.

[2] At the outset, the procurator fiscal intimated that evidence from Mr Cusker's family would be by way of affidavit. Mr Smith read the affidavits of Joseph Cusker, his partner Margaret McClemon and Mrs Helen Sloss to the inquiry. The procurator fiscal led evidence from seven witnesses, namely, Dr Tobias Hatter, Mrs Gail Caldwell, Dr Norman Lucie, Ms Karen Beattie, Mr John McQueen, Ms Adele Johnstone and Ms Heather Dalrymple. The parties entered into a joint minute and agreed that Crown production No 6, a medical report dated 10 August 2006, prepared by Dr Robert Grant, Consultant Neurologist, Edinburgh constituted Dr Grant's evidence; that the autopsy report dated 10 October 2008, contained within the third inventory of productions for Mr Cusker's family, was prepared by Dr Istvan Bodi, Consultant Neuropathologist, Kings College Hospital, London and constituted Dr Bodi's evidence to the inquiry; that the curriculum vitae contained within the third inventory of productions for Mr Cusker's family is that of Dr Bodi; and that labels 1 - 6 contained within the third inventory of productions for Mr Cusker's family refer to pathological slides taken from the deceased, which were used by Dr Bodi in the preparation of his report. At the conclusion of the evidence led for the procurator fiscal, no other evidence was led.

[3] In the closing submissions, there was agreement that each of the witnesses who had given evidence should be regarded as credible and reliable, subject only to certain differences in recollection between Ms Karen Beattie and Ms Adele Johnstone as to precisely what occurred on 22 June 2005. For the reasons later given, I had no difficulty in accepting the

unanimous position of the procurator fiscal and those parties appearing at the inquiry. In the result, it was not in dispute that the administration of the wrong cytotoxic chemotherapeutic drug in overdose to Mr Cusker had resulted in his untimely death.

[4] In Mr I H B Carmichael's *Sudden Deaths & Fatal Accident Inquiries*, third edition, at para 5.69, the learned author states:- "Accidents can occur anywhere and in almost any context...If a patient died...as the result of an error which occurred in a...therapeutic procedure, that death results from an 'accident'." I respectfully accept the learned author's approach to and interpretation of the term "accident" as it is used in the 1976 Act. In its common usage, an "accident" is "an unfortunate incident that happens unexpectedly and unintentionally, typically resulting in damage or injury": see the New Oxford Dictionary of English.

[5] The accidents which resulted in Mr Cusker's death occurred some two months earlier, around lunchtime on 22 June 2005 in the Aseptic Dispensing Unit of the Pharmacy Department at Gartnavel General Hospital. Mr Cusker was in Ward 4C of the hospital as a day patient to receive day 1 of cycle 2 of his chemotherapy treatment. Two cytotoxic chemotherapeutic drugs had been medically prescribed for Mr Cusker. This prescription had to be dispensed in the Aseptic Dispensing Unit. One of the two drugs prescribed was correctly dispensed but the prescription of the other was not: the wrong drug was erroneously selected by a qualified pharmacy technician and this error was not detected by the competent and experienced pharmacist, who was not in doubt that the drug selected by the technician was the correct one. Although these two accidents occurred in that way with the result that the wrong drug was subsequently released for administration to Mr Cusker, the standard operating procedure then in use was followed by everyone involved in the dispensing of the wrong drug.

[6] There are aseptic dispensing facilities in hospital pharmacies throughout Scotland. The standards against which aseptic facilities are audited are drawn up with reference to current national guidelines and are agreed through the Scottish Aseptic Services Specialist Interest Group (ASSIG) and the Scottish Quality Assurance Specialist Interest Group

(QASIG). The ASSIG audit scheme is a system of external audit of aseptic facilities applied throughout Scotland. The aims of this audit schedule are to assess compliance with agreed standards for Aseptic Dispensing Services; to identify and initiate action to rectify deficiencies of the Aseptic Dispensing Services; and to report results of audits to Health Board Pharmacy Managers and Chief Executives.

[7] On 9 February 2004, the standard operating procedure then in use within the Aseptic Dispensing Unit of the Pharmacy Department at Gartnavel General Hospital had been independently and externally audited by an external auditor against the Aseptic Dispensing Services Audit Schedule then in force. That audit revealed no deficiencies in the worksheets used for the dispensing of chemotherapeutic drug prescriptions. There was no criticism of the standard operating procedure. Nevertheless, the undisputed evidence led at this inquiry has highlighted defects in that standard operating procedure, which did not prevent the release from the Unit of not only the wrong cytotoxic chemotherapeutic drug for Mr Cusker but also did not prevent him receiving about five times the appropriate dosage of that wrong drug.

[8] It was established on the undisputed evidence led that once the authorised pharmacist checked and authorised the release of the cytotoxic chemotherapeutic drug dispensed for a particular patient, the point of no return was reached: there was no possibility of any further inspection or check to reveal the erroneous selection in the Aseptic Dispensing Unit of a drug other than the one which had been prescribed by the medical clinician. Moreover, it was established that what a medical clinician prescribed for a particular day care patient, such as Mr Cusker, depended on the results of tests taken when that patient arrived. Accordingly, such prescriptions could not be pre-prepared: they required to be dispensed in the Aseptic Dispensing Unit on the day once the medical clinician's prescription had been received and in time for administration to the patient shortly thereafter in the day care ward.

[9] The undisputed evidence established that on the next day, 23 June 2005, it was discovered that the wrong cytotoxic chemotherapeutic drug had been given to Mr Cusker. As appears later, this came to light because Mr John McQueen, who prepared and dispensed the product in the isolator, discussed the correct method of preparation of the product with his

wife, also a pharmacy technician, overnight. Mrs Fiona McQueen (non-witness) thought "it did not sound right" and immediately took up the matter with Ms Johnstone the next morning.

[10] These accidents and standard operating procedure defects resulted in Mr Cusker becoming unwell within a few days. Thereafter, despite the very best efforts of the medical, nursing and hospital staff, both at Gartnavel General Hospital and the Southern General Hospital, Mr Cusker's health progressively declined with distressing and unpleasant consequences, which were very upsetting and embarrassing for him to suffer, and for his family to witness, until his eventual death on 21 August 2005.

[11] On the undisputed evidence, Mr Cusker had to be admitted to the hospital on 25 June 2005. He developed sickness, loss of appetite, headaches and abdominal discomfort. He developed severe bone marrow suppression and then a fever. His family considered that he had become somewhat depressed because of a lack of stimulation in the hospital and because he wanted back to his own home. The hospital staff considered that Mr Cusker had become confused and vague. He was discharged home on 19 July 2005, at which point his family considered that he was weak and frail. He continued to attend for out-patient treatment but his condition deteriorated badly. He became less mobile, incontinent and confused. On 3 August 2005 he was admitted, as an emergency, to Gartnavel General Hospital with confusion, urinary and faecal incontinence and tremor and unsteadiness. He was disoriented in time with confusion. He underwent a CT scan, which was reported as showing communicating hydrocephalus and a small right frontal calcified area. Mr Cusker continued to deteriorate with worsening left sided problems and right sided jerks consistent with cortical myoclonic seizures. He deteriorated further and an MRI of the brain was performed on 10 August 2005. This confirmed hydrocephalus. In the next few days there was generalised neurological decline consistent with a worsening widespread brain disorder with confusion and bilateral upper motor neuron findings. The clinical picture was of a progressive encephalopathy/encephalitis on a background of severe myelosuppression with phancytopenia (deficiency of all 3 cellular components of the blood: red cells, white cells and platelets). On 16 August 2005, because of concern that the hydrocephalus was relevant, Mr Cusker was transferred to the Institute of Neurological Sciences at the Southern General Hospital,

Glasgow. He was taken to theatre where neurosurgeons commenced performing a ventriculo-peritoneal shunt. The insertion of an external ventricular catheter via a right occipital burr hole was started but had to be suspended because of cardiac complications. On 17 August 2005 a CT scan was performed, which showed hydrocephalus, air in the frontal and temporal horns and blood in the right occipital ventricle and at the entry point of the external ventricular drain. Mr Cusker subsequently developed a clinical chest infection and he died around 6.00 pm on 21 August 2005.

[12] In evidence, Dr Lucie stated that had there been no overdose of the wrong chemotherapeutic drug and had Mr Cusker continued on his prescribed course of chemotherapy, he did not believe that Mr Cusker would have died on 21 August 2005. Dr Lucie was of opinion that Mr Cusker might have lived for up to a further 2 years.

[13] It was clearly established on the undisputed evidence that Mr Cusker's death did not result from any error or fault on the part of any member of the medical or nursing staff at Gartnavel General Hospital. This was, so far as is known, the first occasion upon which the wrong cytotoxic chemotherapeutic drug has been dispensed by the Aseptic Dispensing Unit to a patient receiving chemotherapy treatment at Gartnavel General Hospital. In evidence Dr Lucie stated that his reaction on hearing what had happened was one of "absolute amazement". He could not recall any prior mistake in the dispensing of cytotoxic chemotherapeutic drugs to patients.

[14] It should be emphasised that no criticism was made by anyone appearing at this inquiry of any of the treatment which Mr Cusker received from medical or nursing staff at either Gartnavel General Hospital or at the Southern General Hospital. The occurrence of these accidents in the Aseptic Dispensing Unit of the Pharmacy Department at Gartnavel General Hospital was treated very seriously by the hospital authorities. As a result a review of procedures was commenced and changes in standard operating procedure were devised and implemented shortly after 22 June 2005. The Aseptic Dispensing Unit where these accidents occurred has now closed. The closure of this Unit was not in any way a consequence of the

dispensing of the wrong cytotoxic chemotherapeutic drug to Mr Cusker but as a result of the opening of the West of Scotland Cancer Centre at Gartnavel General Hospital.

[15] The procurator fiscal has, in the public interest, thoroughly investigated the circumstances of these accidents and Mr Cusker's death. It is not difficult to understand why the holding of this inquiry was entirely appropriate and why the inquiry lasted 9 days. It would have lasted longer without the benefit of the considerable assistance of those who appeared both at the preliminary hearings and at the inquiry. The careful preparation, focused presentation of the issues and comprehensive closing speeches by Ms Judith Hutchison, procurator fiscal depute, Mr Smith, Mr Scott and Mr Lamont has greatly assisted me and I express my profound gratitude to each of them.

Mr Alexander Cusker

[16] At the time of his death Mr Cusker was 75 years old. He left a widow, Mrs Helen Cusker and three adult children. Mrs Cusker is now unwell and was unable to attend or participate in this inquiry by reason of ill-health. Mr Cusker was a much loved husband and father. He was a very happy family man, who was very intelligent and well read. Although he had had some health difficulties over the years, he remained active and interested and involved in life. Mr Cusker was a very outgoing man. He had particular interests in history, politics and music. He was a very keen gardener. He was very good with DIY. He worked throughout his life in the construction industry and latterly for the local authority. Mr Cusker's family have been much distressed by his untimely death and by what he had to endure in the last two months of his life. Mrs Helen Sloss described her father as "a very good father and husband. He was humorous, intelligent and polite....He was a very lovely and supportive father". Mr Joseph Cusker regarded his father as his "best friend". He wished an answer as to why his father, as an apparently successfully treated chemotherapy patient, degenerated and died within two months of receiving an overdose of the wrong cytotoxic chemotherapeutic drug. Mr Joseph Cusker has made it clear that he does not lay the blame for his father's death at any one individual: his view was that his father's death was as a result of a systemic management failure in the hospital system, which could and should have been avoided.

[17] Mr Cusker had suffered from high blood pressure for some time. This was controlled by medication. In 1976 he was found to have chronic renal dysfunction. In essence, he was healthy with only non-life threatening medical complaints until the year 2000 when he suffered a stroke with associated left sided weakness. It left him almost blind in one eye but apart from that he made a good recovery. A CT brain scan showed widespread vascular changes and an asymptomatic left sided lacunar infarct. In May 2003 a prostate biopsy confirmed benign prostatic hypertrophy. In September 2004, a biopsy of a lesion on his ear demonstrated a basal cell carcinoma.

Diagnosis of mantle cell non-Hodgkin's lymphoma in the USA

[18] In early January 2005, Mr and Mrs Cusker went on their regular trip to visit their daughter Teresa and her family in Scottsdale, Arizona, USA. Mr Cusker was able to organise all aspects of this trip. Normally, Mr and Mrs Cusker stayed in Arizona for about 3 months.

[19] Shortly after his arrival in the USA, in mid-January 2005, Mr Cusker noticed a sudden and somewhat painful swelling in his left facial area. He attended a doctor there and, after evaluation, surgical intervention was recommended. On 9 February 2005, at the Scottsdale Shea, Mr Cusker underwent removal of his left parotid gland. The pathology report revealed mantle cell non-Hodgkin's lymphoma involving a total of six lymph nodes.

Mantle cell non-Hodgkin's lymphoma

[20] Mantle cell non-Hodgkin's lymphoma is not a common type of cancer: statistically about 5/10% of all lymphomas. This B cell type lymphoma has been recognised since the mid-1990s as a clear separate entity. Dr Lucie, a most experienced consultant haematologist who has specialised in the treatment of haematological cancers for many years, advised that there are about 3 or 4 cases each year in the west of Scotland. Dr Lucie advised that this was a difficult disease to cure: it was regarded as not being currently curable, certainly in an older patient such as Mr Cusker. Dr Lucie advised that 2-4 years was the average life expectancy from the time of diagnosis.

The treatment offered to Mr Cusker in Scotland on his return in April 2005

[21] On 22 April 2005 shortly after his return to Scotland, Mr Cusker was seen at the Western Infirmary, Glasgow. At that time, he was 75 years old. Dr Lucie explained the situation to Mr Cusker, who understood the need for good palliative chemotherapy treatment. In evidence, Dr Lucie explained that without treatment Mr Cusker would have survived for 12-18 months. This advice broadly confirmed what Mr Cusker had been told by the doctors who treated him in Arizona.

The course of palliative chemotherapy proposed

[22] Dr Lucie recommended treatment with chemotherapy. In his affidavit, Mr Joseph Cusker stated: - "The response from Dr Lucie and his team was swift and efficient". His father accepted the diagnosis and treatment offered. He planned to carry on with his life as usual, keeping an optimistic outlook. It was proposed that Mr Cusker receive six courses or cycles of ABCM cytotoxic chemotherapy regime. A is the drug Doxorubicin; B is Carmustine; C is Cyclophosphamide and M is Melphalan. In evidence, Dr Lucie explained that it was more difficult for patients aged in their seventies to tolerate chemotherapy because its toxicity suppresses bone marrow function (myelosuppression) with increased risk of bleeding and increased susceptibility to infection. Not all such patients can tolerate six cycles. At this inquiry, it was accepted that this cytotoxic chemotherapy regime was the appropriate course of treatment for Mr Cusker.

The first chemotherapy treatment given to Mr Cusker

[23] On 5 May 2005 Mr Cusker was admitted to Gartnavel General Hospital. Whilst his treatment was to be given to him as a day patient, standard procedure was to admit patients to hospital for the first cycle and to keep them in hospital for a few days to monitor progress and check that there had been no adverse reaction to the cytotoxic chemotherapeutic drugs. On 5 May 2005 Mr Cusker was treated with Doxorubicin (adriamycin) and Carmustine (BCMU) and 19 days later he received Cyclophosphamide and Melphalan. This constituted one course of ABCM chemotherapy. This was successfully delivered.

[24] On 14 June 2005 Mr Cusker was due a second course of chemotherapy but this had to be delayed for a week because of chemotherapy induced myelosuppression. There was a proposed plan to reduce the dose of Cyclophosphamide and Melphalan in future to reduce the risk of further bone marrow suppression (myelosuppression) and in view of Mr Cusker's renal dysfunction.

22 June 2005

[25] On 22 June 2005 Mr Cusker attended at Ward 4C of Gartnavel General Hospital as a day patient to receive the second cycle of ABCM chemotherapy. He was to be given day 1 of cycle 2 of his course of chemotherapy. This was to have been Doxorubicin and Carmustine. In her evidence, Adele Johnstone explained that Mr Cusker's prescription for Carmustine could not have been pre-prepared as the dosage he was to receive depended upon the results of tests carried out that day. The medical clinician treating Mr Cusker wrote out a paper prescription for 52.8 mg Carmustine and 53 mg Doxorubicin. There was no dispute that this was a medical prescription of the chemotherapeutic drugs in the correct dosage for Mr Cusker to receive that day. Ms Karen Beattie, an MTO2 Pharmacy Technician who dispensed the prescription, recalled it being hand delivered by a pharmacist, Jonathan Allan, who worked in Ward 4C.

The Aseptic Dispensing Unit of the Pharmacy Department at Gartnavel General Hospital

[26] The evidence of Mrs Gail Caldwell, then Pharmacy Manager at Gartnavel General Hospital, was heard over the course of 3 days. She explained that at the time the stock control management system in place was known as Ascribe. Upon receipt of the drugs they were stored in alphabetical order on shelves in the appropriate storage unit. There were three sub-stores including one in the Aseptic Dispensing Unit.

The naming of chemotherapeutic drugs

[27] This inquiry was greatly assisted by the evidence of Ms Heather Dalrymple, Principal Pharmacist, Edinburgh Cancer Centre, Western General Hospital, Edinburgh. She had prepared a written report, which comprised Crown production No 13. Both she and Mrs Caldwell were agreed that the naming of all medicines including those used in

chemotherapeutic treatment is a responsibility of the World Health Organisation. This is facilitated through the International Non-Proprietary Names (INN) Programme. As well as INN names, manufacturers of medicines also have what is called a proprietary or "trade" name for their product. This can also be referred to as the "brand" name of a drug. As the number of drug substances being registered during the last decades has constantly increased, there is a strong need to ensure the identification of each pharmaceutical compound by a unique, universally available and accepted name. Nowadays, the INN Committee assumes the lead role worldwide in assigning generic names to drug substances. Instances where a national generic name for a new pharmaceutical substance is different from the INN are rare exceptions. Prior to 2003 the continued use of BANs (British Approved Names) which differed from INNs had led to a great deal of confusion on the part of healthcare professionals and patients. Following a widespread consultation the Medicines Commission, the Government's principal advisory body of medicines, implemented a changeover to the use of INNs in the UK. The name changes were published in the British Pharmacopoeia 2003, which became effective on 1 December 2003. From that date the industry had 12 months to make the necessary changes to licence and product labelling to reflect the name changes.

Carmustine

[28] The cytotoxic chemotherapeutic drug prescribed for Mr Cusker was Carmustine. Its INN was Carmustine; its proprietary name was BCNU and its former BAN (British Approved Name) was Carmustine. It is a cytotoxic chemotherapeutic drug used in the treatment of mantle cell lymphoma. As this is a relatively rare type of cancer, Carmustine is rarely prescribed or dispensed.

Chlormethine

[29] The cytotoxic chemotherapeutic drug wrongly selected and dispensed to Mr Cusker was Chlormethine. Its INN was Chlormethine; its proprietary name was Caryolysine and its former BAN was Mustine. Mrs Caldwell explained, and it was confirmed by Ms Dalrymple, that the Medicines & Health Care Products Regulatory Agency (MHRA) licence all medicines in the United Kingdom. Particular products cannot be marketed with a product licence from the MHRA. However, unlicensed drugs could be used in the treatment of patients if a medical

consultant clinician so prescribed. In 2005 Chlormethine (Mustine) was not licensed in the United Kingdom. It had formerly been licensed but the manufacturer had not renewed its licence and it had become an unlicensed drug. It must be emphasised that this does not mean or imply that there was something wrong with the drug. It was a decision for the manufacturer to decide whether to seek renewal of the licence from the MHRA. It was still perfectly proper for a medical consultant clinician to prescribe Chlormethine for a particular patient. In March 2004 Chlormethine had been purchased for another patient, when it had been necessary to obtain this unlicensed cytotoxic chemotherapeutic drug from France. Crown label No 1 was the cardboard box in which the Chlormethine administered to Mr Cusker was obtained. The brand name on the drug is "Caryolysine". The words on the packet are all in French without any English translation. The name "Mustine" does not appear anywhere on the packaging.

Carmustine/Chlormethine

[30] Dr Lucie gave unchallenged evidence that there was a strong chemical similarity between Chlormethine (Mustine) and Carmustine. Each produces a similar result but produces different side effects. Dr Lucie explained that both drugs were alkylating agents; they each kill cells. Whilst Dr Lucie explained that the use of Chlormethine with Doxorubicin was not contraindicated, Chlormethine (Mustine) and Doxorubicin are not part of a known cocktail of drugs used in chemotherapy treatment. In answer to Mr Scott, Dr Lucie explained that Chlormethine (Mustine) is used in the treatment of Hodgkin's disease.

The effect of the overdose of Chlormethine on Mr Cusker

[31] Dr Lucie had the opportunity of considering the report (Crown production No 6) by Dr Robert Grant, Consultant Neurologist, Edinburgh. He agreed with Dr Grant's opinion that there was a contributory causative link between the administration of the wrong cytotoxic chemotherapy drug Chlormethine (Mustine) in the dose given and Mr Cusker's subsequent death. Dr Lucie had also considered the report prepared by Dr Istvan Bodi (third inventory of productions for relatives). Dr Lucie expressed the opinion that Mr Cusker would have recovered from the overdose of Chlormethine (Mustine) but for the fact that he suffered from pre-existing cerebral vascular disease. He pointed out that in the research papers referred to,

particularly that published by Sullivan K M, Storb R, Shulman H M et al, "Immediate and Delayed Neurotoxicity after Mechlorethamine Preparation for Bone Marrow Transplantation" Ann Intern Med 1982 August; 79(2): 182-9, it was shown that most patients recover providing they survive the initial event. Dr Lucie stated that Mr Cusker's bone marrow had recovered from the effects of the Chlormethine (Mustine) overdose by early August 2005.

Storage of unlicensed medicines

[32] In September 2004 Greater Glasgow Health Board introduced a policy for the use of unlicensed medicines. Mrs Caldwell stated that "there was nothing laid in stone". In her report and evidence Ms Dalrymple made it clear that she had not seen these guidelines, which were not produced at the inquiry. At all events, Mrs Caldwell's point was that the Chlormethine had been purchased prior to the coming into force of these guidelines. Ms Dalrymple drew attention to a document produced by the NHS Pharmaceutical Quality Assurance Committee and published in June 2004 entitled "Guidance for the Purchase and Supply of Unlicensed Medicinal Products". In her report Ms Dalrymple stated:- "Because of the necessity to ensure that unlicensed medicines are identifiable as being non-standard stock it would now be considered standard practice for them to be segregated and for individual records to be kept for each unlicensed medicine purchased and supplied."

[33] At all events, the Chlormethine was stored along with licensed drugs in the Aseptic Dispensing Unit Sub-Store. It was listed alphabetically on a shelf. It should be noted that Chlormethine (Mustine) is a liquid contained in an ampoule, which should not be stored in a refrigerator. On the other hand, the Carmustine which the Aseptic Dispensing Unit had in store came in the form of a powder in a phial and required to be stored in a refrigerator.

Standard operating procedure in the Aseptic Dispensing Unit

[34] The standard operating procedure in use in the Aseptic Dispensing Unit of the Pharmacy Department at Gartnavel Hospital in June 2005 was spoken to by Mrs Gail Caldwell, Adele Johnstone, Karen Beattie, John McQueen and Ms Heather Dalrymple. In June 2005 it was known that this Unit would close upon the opening of the West of Scotland Cancer Centre. The Unit was in the course of rolling out and moving towards full

implementation of the chemocare computer system, an electronic prescribing system which carried out all necessary calculations. Mrs Caldwell explained that in 2005 the vast majority of chemotherapy prescriptions were dispensed using the chemocare system. However, as Mr Cusker was being prescribed Carmustine and his cytotoxic chemotherapeutic regime was not a common one, it had not yet been included on the chemocare system. Mrs Caldwell stated that once Mr Cusker's prescription was received in the Aseptic Dispensing Unit, it would be entered into the batch book and given a unique reference number. A pharmacy technician would calculate the volume of the drug required and complete the worksheet for it. At this stage the worksheet would be checked (transcription and volume check) by either a pharmacist or a PACT (a Pharmacy Aseptic Checking Technician). Mrs Caldwell explained that once a worksheet had been checked the necessary equipment, and the prescribed drug, would be obtained by the pharmacy technician and the tray assembled. Once this had been done the next check (tray check) would be done by either a pharmacy technician or a pharmacist. The tray contents were then sprayed into the clean room where another technician would prepare the product prescribed in sterile conditions in the isolator. Mrs Caldwell explained that each drug had its own method of preparation. Once the drug had been prepared there had to be a final check by the authorised pharmacist, who released the prepared medication for administration to the patient. There was a legal requirement that only an authorised pharmacist who is trained to do the final release could do so.

[35] According to Mrs Caldwell, the pharmacy technician Karen Beattie would require to have prepared the worksheet. According to Mrs Caldwell, the pharmacy technician would have gone to the Master Formula referred to in the standard operating procedure, which contained all information necessary to prepare a worksheet and to enable the volume of the drug to be worked out. Mrs Caldwell explained that if the drug prescribed was not in the Master Formula then it was necessary for the technician to refer to the responsible pharmacist. Mrs Caldwell pointed out that Carmustine was only used about six or seven times a year. Mrs Caldwell stated her opinion that had Karen Beattie referred to the Master Formula on this occasion, her error in the selection of the wrong chemotherapeutic drug from the shelf might have been revealed. Mrs Caldwell pointed out that Ms Beattie wrongly selected Chlormethine, which was a liquid in an ampoule and was not stored in the refrigerator.

Mrs Caldwell stated that had Ms Beattie consulted the Master Formula, she should have seen that it referred to Carmustine as a powder; and as what she had before her was a liquid, she should have realised that she had selected the wrong drug.

[36] Mrs Caldwell was clear that it was only once the technician had assembled the tray that the person carrying out the tray check had the opportunity to observe that the wrong medicine had been selected. The purpose of the tray check was to check that the prescribed cytotoxic chemotherapeutic drug had been selected by the technician. That was why there was a tray check. Mrs Caldwell explained that it was good practice to avoid the same person doing all the checks. On 22 June 2005 Adele Johnstone was the only pharmacist in the Aseptic Dispensing Unit at the time when Mr Cusker's prescription was being dispensed and there was no alternative to her having to carry out all the checks because there was no one else available. Mrs Caldwell conceded that it would have been better to have had "a fresh set of eyes". She explained that at the final check and release stage the authorised pharmacist required to look at the final product, the process and the worksheet to make sure that all the checks had been correctly done and that the prescribed drug had been prepared in the prescribed dose. She explained that at that check the empty phials or ampoules were there to be seen and the error in the selection of the wrong drug should have been capable of being picked up by the responsible pharmacist.

What occurred in the Aseptic Dispensing Unit around lunchtime on 22 June 2005?

[37] Karen Beattie was working in the course of her employment as a MTO2 pharmacy technician in the Aseptic Unit. She recalled the pharmacist Jonathan Allan bringing down a prescription for Mr Cusker. It was required as soon as possible. Ms Beattie was tasked with making it up. Only she and Adele Johnstone were in the preparation room. Ms Beattie remembered generating the labels on the prescription. She selected the drugs and accepted that she had selected Caryolysine. She explained that she looked at the shelf in the sub-store under "C". She was looking for Carmustine. Ms Beattie was wholly unable to explain why she selected a packet which stated Caryolysine and Chlormethine on the front as being the drug Carmustine. She stated "I can't remember why I thought that the product I selected was Carmustine". She was shown Crown label 1 and accepted that the package said neither

"Carmustine" nor "Mustine". She was clear that she did not look at any textbook or at the Master Formula. She said that she consulted Adele Johnstone about the method of preparation. In answer to Mr Smith, Ms Beattie accepted that she had obviously got it wrong. She stated "I got what I thought was the right one". She was clear that whilst she did not consider the staffing level that day to be adequate, that she did not think that the wrong selection of drug had anything to do with staffing levels. Her position was that she went to the shelf "C" and did not find Carmustine. She took the drug she thought was the one with the other name for Carmustine.

[38] Adele Johnstone gave evidence at this inquiry. She is a well qualified and experienced pharmacist. She holds the degree of BSc (Hons) in Pharmacy and an MSc in Clinical Pharmacy. She qualified in 1993 and, after gaining appropriate professional experience, applied for and was successful in being appointed to the post of Responsible Pharmacist in this Aseptic Dispensing Unit. On 22 June 2005 a combination of unexpected circumstances had a bearing on the operation of the Aseptic Dispensing Unit. However, to her credit, Ms Johnstone accepted full responsibility for the serious error which had occurred. She explained that she thought that the pharmacy could not get Carmustine because of a supply problem and that the drug selected by Ms Beattie had been purchased from overseas. She explained that she thought it was Carmustine under a different name. She could not explain why but she was clear that she had been certain that Karen Beattie had selected the right drug because there had been a difficulty obtaining Carmustine. In answer to Mr Lamont, Ms Johnstone stated "I thought we had had supply problems with Carmustine and we had bought in this Chlormethine from abroad". She continued that she "must have confused Carmustine and Mustine". She explained she did not feel confused at the time. She further explained that even the next day when she became aware of a potential problem after Mrs McQueen had approached her, she was still confident that the correct drug had been dispensed. When she checked and found that she had made an error she was devastated. Ms Johnstone explained that she had done all three checks in this instance and would not have done so if there had been someone else to assist.

Closing Submissions

[39] Ms Hutchison, procurator fiscal depute, presented a very full submission. Essentially, she sought the findings which I have made in terms of section 6(1)(a) and (b) of the 1976 Act. She pointed out that it was agreed by Mrs Caldwell, Karen Beattie, Adele Johnstone and Heather Dalrymple and Dr Lucie that the root cause of the events which resulted in Mr Cusker's death was the selection of the wrong chemotherapeutic medicine by Karen Beattie. Mr Cusker had received the wrong drug and, as a result, a considerable overdose. Under reference to section 6(1)(c) and (d) of the 1976 Act, the procurator fiscal pointed out that on 22 June 2005 standard operating procedures were in place in the Aseptic Dispensing Unit. She pointed out that since then some practices and procedures had been updated and changed. However, the procedures then in place allowed for the selection of a wrong drug, the wrong drug to be prepared and then sent to the ward for administration to Mr Cusker. At the time unlicensed medicines were still stored along with licensed medicines. Karen Beattie had selected an unlicensed medicine Chlormethine thinking it was a prescribed drug, a licensed product, Carmustine. The procurator fiscal submitted that this was inexplicable and pointed out that it was part of Ms Beattie's job to correctly get the medicines prescribed from the shelf in the store. However that may be, on this occasion all the required systemic checks failed and this had resulted in Mr Cusker's untimely death. Adele Johnstone believed that Chlormethine was Carmustine. The procurator fiscal stated that it was clear that she had made a serious mistake but an explicable one. The procurator fiscal made no criticism of Mr McQueen, the technician. He was one of three pharmacy technicians. His job that day was to make up the product in the isolator. At the time he did not doubt that the correct drug had been selected but had questions over the correct method by which to prepare the product. The procurator fiscal submitted that a reasonable precaution whereby Mr Cusker's death might have been avoided would have been to have had unlicensed medicinal products, together with detailed records of the origin of the product and for whom it had been prescribed, stored separately from the licensed products. She pointed to the evidence of Mrs Caldwell to the effect that the guidelines by the Health Board in September 2004 did not apply to this particular prescription of Chlormethine. The procurator fiscal departed from her submission that it would have been a reasonable precaution to ensure that all product inserts were in English on the basis that there was no evidence as to whether this could have been

achieved. She submitted that reasonable precautions would have been to have more than one member of staff carrying out the required checks and that the member of staff carrying out the tray check did not carry out any of the other checks. She also submitted that it would have been a reasonable precaution to have a written protocol of how to prepare individual products in the Aseptic Unit in the form of pre-printed worksheet. Essentially, she urged adoption of the system in Edinburgh Cancer Centre spoken to by Ms Dalrymple.

[40] In terms of section 6(1)(d) of the 1976 Act, the procurator fiscal submitted that there was a defect in the system for checking prescriptions in that it allowed for an error to be made from the outset. She submitted that it should become mandatory to have two pharmacists involved in these checks with the tray check being done by a pharmacist and final check by another pharmacist, namely, the Responsible Pharmacist or the deputy Responsible Pharmacist. She quite accepted that this submission may result in financial resource implications for the health board but submitted there remained a material risk that should another wrong drug be selected there could be the "gravest of outcomes".

[41] Mr Smith took no issue with the findings sought by the procurator fiscal in terms of section 6(1)(a) or (b) of the 1976 Act. Essentially, Mr Smith sought the same findings in terms of section 6(1)(c) and (d) of the Act. He agreed that the evidence had identified a defect in the system in that the tray check and the final check could be done by the same person. The death of Mr Cusker had been as a result of the administration of the wrong cytotoxic chemotherapeutic drug to him on 22 June 2005. He was 75 years of age and an exceptionally well liked, happy, family man. He had had numerous health issues throughout his life but was a reasonably healthy man who did not allow very much in terms of his health to get in the way of what he wanted to do. He had received prompt and effective treatment in Arizona. After the telephone call from Dr Lucie advising that Mr Cusker had been given the wrong chemotherapeutic drug on 22 June 2005 the family witnessed a rapid deterioration in his health. His family regarded his death as due to the administration of the wrong chemotherapeutic drug. He had had a reasonable expectation of a further 1 to 2 years of life and perhaps more. Mr Smith submitted that it was shown on the evidence that there should have been a full-time deputy Responsible Pharmacist. Whilst certain unexpected

circumstances had occurred on the day in question, which were undisputed, Ms Beattie had not felt any impact as a result of reduced staffing levels. The chemocare system applied to many drugs but did not apply to Carmustine. Although it was not contrary to the system under the standard operating procedure, Adele Johnstone had carried out all three checks and this was a defect in the system then in operation. Ideally, all three checks should be carried out by a different person. In his submission, no-one should be able to carry out more than one check. He submitted that the tray checks should be carried out by a Pharmacy Aseptic Checking Technician or by a Pharmacist and that the final check should be carried out by the Responsible Pharmacist or the Deputy Responsible Pharmacist. The worksheet system in use at Edinburgh Cancer Care should provide a platform for the way forward. Mr Smith also urged that there be separate trays for separate drugs, as in Edinburgh.

[42] Mr Scott submitted that all witnesses did their best to assist this inquiry and that no issues of credibility arose. He did not seek any particular findings and took no issue with what was sought in respect of section 6(1)(a). He questioned whether there had been an "accident" but, having considered Mr Carmichael's work, accepted that he could not properly contend that there had been no accident here. In terms of section 6(1)(b) Mr Scott referred to the evidence of Dr Hatter who carried out the post-mortem. The difficulty for Dr Hatter was that he could only see what was there to be seen on post-mortem examination. Dr Lucie had direct experience of a Mustine overdose in the past as a result of another's clinical error. There a man in his sixties had received four times the correct dose but survived. With the overdose which Mr Cusker had received there had been a major risk of irreversible brain damage but Mr Cusker had started to recover and his bone marrow suppression was improving. Dr Lucie's opinion was that Mr Cusker would have recovered from the Mustine overdose but for the background of cardiovascular problems. Mr Scott entirely accepted that it may be held that the overdose of Mustine was a significant contributory factor in the death. Mr Scott submitted that in terms of section 6(1)(c) the new guidelines in respect of unlicensed medicine storage had not been made retrospective. However, he submitted that this was the *causa sine qua non* of the mishaps which occurred rather than their *causa causans*. He submitted that the fact that Chlormethine was unlicensed was neither here nor there because Ms Beattie was sent for what it said on the prescription and that was "Carmustine". He

pointed out that the evidence had not disclosed and we still did not know why Ms Beattie selected the wrong chemotherapeutic drug: she did not know herself. He submitted that any finding under sub-paragraph (c) involved reasonable foresight and he submitted that on the evidence led it was not appropriate to make any findings, particularly since what had happened here had not happened before at this Aseptic Dispensing Unit.

[43] In respect of section 6(1)(d) Mr Scott accepted that there were defects in the system of work then in place. He pointed out that there had been no departure on the part of the staff from the standard operating procedure which had been the subject of an external audit by ASSIG. It was not mandatory for different persons to carry out the individual checks nor did the standard operating procedure require the transcription and volume check and the tray check to be carried out at different times. Mr Smith pointed out that Edinburgh Cancer Centre has a different system from that then in place at Gartnavel General Hospital. He submitted that the ASSIG checks allowed for differences in systems as between hospitals. He submitted that on the evidence the chemocare system then being introduced in the Aseptic Dispensing Unit was pretty similar to the system in place in Edinburgh Cancer Centre. Unfortunately, Carmustine was not one of the drugs on the chemocare system at that time. He pointed out that the ASSIG audit on 9 February 2004 had found only minor deficiencies regarding documentations not related to chemotherapeutic worksheets, about which there had been no adverse comment. Mr Scott submitted that this echoed with Dr Lucie's expression of amazement that this Aseptic Dispensing Unit had made this error. Mr Scott emphasised that Dr Lucie could not recall any mistakes having been made in the past. The subsequent audit conducted on 5 October 2005 had made very positive comments about this Aseptic Dispensing Unit and the staff who worked there. This was a committed and well run unit with procedures that were adhered to at all times. He referred to the evidence of Mrs Caldwell to the effect that 25,000 prescriptions had been dispensed per year since 2000 and there had only been three errors including this one. The other two errors had been detected by the system before administration of any drug to the patient. He pointed out that changes had been considered and made shortly after this incident. The checks required that there be a "fresh pair of eyes". Mr Scott recognised that the standard operating procedure then in place did not prevent this accident even though the checks were carried out by the Responsible Pharmacist

who was a well qualified, experienced, confident and conscientious pharmacist. She made a mistake: a human error. She was satisfied that the drug was the correct one. She was not in doubt about that and had she been she could have and would have checked the position. Mr Scott sought a finding in terms of section 6(1)(e) of the 1976 Act to the effect that the errors here occurred in a facility which now no longer existed. Finally, he stated that he had specific instructions to repeat the expression of deepest sympathy to Mr Cusker's family together with sincere apologies on behalf of Greater Glasgow Health Board for the errors which had occurred here and for the consequences to both Mr Cusker and his family.

[44] Mr Lamont, on behalf of Adele Johnstone, presented his own personal condolences to the Cusker family and adopted the submissions advanced by Mr Scott. In particular, he agreed with Mr Scott's submission as regards unlicensed drugs being the *causa sine qua non* of the mishaps. He agreed that there was a defect in the system as more than one pair of eyes was required to carry out the checks. He pointed out that Ms Johnstone would have preferred there to have been more than one person involved in the checking. In the circumstances in which she found herself on that day she had to get on with the job. Her attempts to get assistance were unsuccessful. She proceeded in accordance with the ASSIG guidance. The root cause here had been the selection of the wrong drug by Karen Beattie but the system had failed and the system required to be robust enough to take account of the serious consequences of such an error. Mr McQueen's concerns were related rather to the dispensing process and he felt able to speak out about them. When he discussed them with his wife overnight the wrongful selection of the drug and its dispensing came to light. Mr Lamont also pointed to the evidence of Dr Lucie and to his amazement that the Aseptic Dispensing Unit had dispensed the wrong chemotherapeutic drug. Mr Lamont pointed out that Adele Johnstone was a well qualified and experienced Responsible Pharmacist. She was competent and conscientious. She did not believe that she had made a mistake but when it was drawn to her attention and realised that she had made a mistake she was plainly devastated. She acted entirely properly at all times after it was discovered that the wrong chemotherapeutic drug had been dispensed to Mr Cusker and she co-operated fully with all enquiries. She wished to offer the Cusker family her sincere apologies for her part in the system failure. Mr Lamont made it clear that he had advised that this expression of regret

should be expressed at this stage of proceedings and I entirely agreed that this was the appropriate stage in proceedings for such an expression.

Decision

[45] I have been greatly assisted by the competing submissions and the careful review of the evidence in this case. Whilst no challenge of either credibility or reliability was made, the evidence was fully tested throughout this inquiry. I was in no doubt that each of the witnesses was credible and that each was doing her or his best to assist this inquiry by giving as reliable as possible evidence. Although Dr Hatter was not able to do more than report his findings at post-mortem, I am entirely satisfied on the basis of the evidence of Dr Lucie and the written evidence of Dr Grant and Dr Bodi that the overdose of Chlormethine administered to Mr Cusker on 22 June 2005 resulted in his untimely death.

[46] In my judgment, it is established that a combination of unexpected circumstances occurred in the Aseptic Dispensing Unit of the Pharmacy Department at Gartnavel General Hospital on 22 June 2005. In addition to planned leave, two pharmacy technicians reported sick and did not attend for work. At the time, advertisements had not resulted in the post of deputy Responsible Pharmacist being filled. The Aseptic Dispensing Unit outsourced some of the more commonly used cytotoxic chemotherapeutic drugs, which were bought in made up. On 22 June 2005 there had been a failure by the supplier to deliver the ordered quantity of Doxorubicin. This had increased the workload for the available staff in the Aseptic Dispensing Unit because the shortfall in supply had to be made up by being dispensed by them. The chemocare computer system had not been fully introduced into the Aseptic Dispensing Unit. Unfortunately, at that stage, Carmustine was not included on the chemocare computer system and that required the preparation of an individual worksheet.

[47] It is clear from the evidence of Ms Beattie that she did not prepare the individual worksheet for Mr Cusker's prescription from information held in the Aseptic Unit of the Pharmacy Department: nor did she refer to the British National Formulary or the other standard reference works held in the Unit. Instead, she prepared this worksheet from the instructions contained within the packet of the drug which she selected. Then she went to find

the prescribed drug. She did not find Carmustine but instead selected Caryolysine (Chlormethine). This was an unlicensed drug and was stored on a shelf in the department. I agree with the submissions advanced by both Mr Scott and Mr Lamont in this regard: on the evidence led from Karen Beattie, the fact that the drug was unlicensed and on a shelf along with licensed products were only the *causa sine qua non* of what was about to happen. I also accept Mr Scott's submission that the fact that Chlormethine was unlicensed did not contribute to what happened. Ms Beattie did not look in the refrigerator where the Carmustine was stored. She looked only on the shelf and when she could not find Carmustine (which was not there) she selected the drug which she did, for reasons which she now cannot explain. She was unable to remember why she thought that Caryolysine (Chlormethine) was Carmustine. But she did not claim that it had anything to do with it being unlicensed. In fairness, she fully accepted her responsibility for the selection of the wrong cytotoxic chemotherapeutic drug. I agree with the procurator fiscal that it was Ms Beattie's responsibility to select the correct drug. In answer to Mr Smith, Ms Beattie accepted that she "obviously got it wrong. I got what I thought was the right one." She very fairly accepted that she did not think that her error was anything to do with the shortage of staff on the day or the increased workload. In my judgment, the selection of the wrong cytotoxic chemotherapeutic drug by Ms Beattie on this occasion was a serious but human error.

[48] Whilst Ms Beattie did not consult the British National Formulary or Martindales, she said that she consulted Ms Johnstone about the method of preparation and the package insert being in French. Ms Johnstone was clear in her evidence that Ms Beattie got the drug before she (Ms Johnstone) did the transcription and volume check. Ms Johnstone explained that there was no reason not to do the transcription and volume check and the tray check at the same time. She made it clear that she had independently checked the calculations which had been done by Ms Beattie. I did not regard the differences in recollection as between Ms Johnstone and Ms Beattie as being in any way sinister but rather due to recollection being adversely affected by the elapse of time since 22 June 2005. In my judgment, taking account of the content of the evidence, the manner in which it was given and the demeanour of the two witnesses, Ms Johnstone gave the more reliable and coherent account of events. I accept that Ms Beattie had filled in the worksheet calculations, which she had correctly copied from the

prescription, and had made up the tray which Ms Johnstone then checked in the assembly room in the Aseptic Dispensing Unit. Ms Johnstone also had regard to the package instructions but was able to carry out a calculation and got the same figures as had Ms Beattie.

[49] After the tray check had been completed, the tray and its contents were sprayed into the sterile environment of the isolator and Mr McQueen made up and dispensed the prescription on the basis of the worksheet. He had a query regarding the appropriate way to prepare the product according to best practice. I agree with the procurator fiscal that Mr McQueen is not to be blamed to any extent for what happened. He had no reason to doubt, and did not doubt, that the drugs prescribed were in the tray.

[50] Once he had dispensed the prescription, the final check had to be carried out by the Responsible Pharmacist. This was required by the standard operating procedure in order to comply with the requirement that to be exempt from the provisions of section 7 and 8 of the Medicines Act 1968, as amended, a registered pharmacist must supervise the dispensing of a prescribed medicinal product: section 10. When Ms Johnstone did this final check, she did not discover that the prescription for Carmustine had been dispensed with the wrong drug Chlormethine. In my judgment, Ms Johnstone made the same human error twice. She did not know why she was certain that Ms Beattie had selected the correct drug, but, in my judgment, it is established that she was not in any doubt that Ms Beattie had brought the appropriate drug for Mr Cusker's prescription for Carmustine. In my judgment, that being her conclusion at the tray check, it was unlikely that she would realise the error at the next check. There was no-one else available to have done the earlier checks and so she did them, as was permitted under the standard operating procedure then in force. Accordingly, Ms Johnstone was deprived of the opportunity and benefit of having "a fresh pair of eyes": an independent check of her check.

[51] In my judgment, it was clearly established on the evidence that this Aseptic Dispensing Unit was a well run unit with competent and dedicated staff. This Unit has since closed and been replaced by the new West of Scotland Cancer Centre. I accept the submission made by Mr Scott in relation to the ASSIG audits. When this independent

external audit was carried out on 9 February 2004, no deficiency was found in the chemotherapeutic worksheets in use. On 5 October 2005 in the next ASSIG audit, the Unit was commended as a well run unit with conscientious and enthusiastic staff. It was noted a new Aseptic Dispensing Unit was planned for next year.

[52] I was particularly impressed by the evidence of Heather Dalrymple, Dr Lucie and Adele Johnstone. I am most grateful to Ms Dalrymple for her full and careful report and the way she explained it so clearly in evidence. I also accepted the evidence of Mrs Gail Caldwell to the effect that since the wrong cytotoxic chemotherapeutic drug was prescribed to Mr Cusker on 22 June 2005, there has been a full introduction of the chemocare computer system. Other checks and system changes were introduced. The importance of the full introduction of the chemocare system is that, as Ms Johnstone made clear, it eliminates the transcription and volume check because this information is generated by the computer much in the way as the system operates in Edinburgh Cancer Centre, as described by Ms Dalrymple.

[53] It was established from the evidence of Ms Dalrymple that the three recommendations made by Mrs Caldwell, as contained in Crown production 7, were not sufficient to prevent a recurrence of what occurred here. Whilst it may be useful to have English translations of the package inserts on all imported medicines, the critical point, which became clear at this inquiry, is that all worksheets in respect of prescriptions require to be completed from information available in the Aseptic Dispensing Unit from reference works such as the British National Formulary and Martindales and not from information comprising the manufacturer's package inserts. In the system in place in Edinburgh Cancer Centre all cytotoxic chemotherapeutic drugs have pre-prepared worksheets: these are prepared by the Chief Technician and signed off by the Responsible Pharmacist. In my judgment, it is established that the system in place in respect of the prescribed drug Carmustine on 22 June 2005 was defective. Had the chemocare computer system included Carmustine this might well have avoided the selection of Chlormethine instead of Carmustine. The second recommendation that the transcription/volume check be carried out by a different person from the person who carries out the tray check would not have made a difference in Ms Dalrymple's view. I respectfully accept Ms Dalrymple's opinion on these matters. Ms Dalrymple's point was that

the tray check was the first opportunity to see what drug had been selected by the pharmacy technician. If a worksheet of the type suggested by Ms Dalrymple, as used in the Edinburgh Cancer Centre, and similar to that now available on the chemocare system, had been in place it would have revealed that Chlormethine came in a phial whereas Carmustine came in ampoule. It should have been evident from the computer generated worksheet calculation that the drug selected, namely Chlormethine, simply could not be the prescribed drug. Ms Dalrymple stressed that the worksheet is a very important document. I accept that it was very important that the worksheet was not completed from the instructions, in whatever language, contained within the drug package; the point being that, as here, it masked the selection of the wrong drug.

[54] It was established from the evidence of Ms Dalrymple, Ms Johnstone and Mrs Caldwell that a major defect in the standard operating procedure was that the tray check and the final check could be carried out by the same person. Unfortunately, the review of procedures and recommendations led by Mrs Caldwell after her investigations into what had happened in the Aseptic Dispensing Unit on 22 June 2005 (Crown Production No 7) did not eliminate that defect. In closing submissions, there was no dispute that it was necessary for these two checks to be carried out by a different person. In my judgment, the defect was that the same authorised registered pharmacist could carry out both the tray check and the final check. However, I have concluded that it is not appropriate for me to recommend that consideration be given to the standard operating procedure requiring that the tray check be carried out by a registered pharmacist. This is because the system then in use in this busy Aseptic Dispensing Unit had not previously failed with the result that the wrong cytotoxic chemotherapeutic drug had been administered to a patient and the system currently in use at Edinburgh Cancer Centre does not require a pharmacist to carry out the tray check. I am satisfied on the undisputed evidence led at this inquiry that the proper carrying out of the tray check to ascertain that the cytotoxic chemotherapeutic drug selected by the pharmacy technician is the drug prescribed is within the competence of a qualified pharmacy technician of MTO2 grade.

[55] It was established on the evidence led that once the final check was carried out and the Responsible Pharmacist authorised release of the dispensed cytotoxic chemotherapeutic drug for administration to the patient, there was no opportunity of further intermediate inspection by anyone whether pharmacist, doctor or nursing staff, which might have revealed a dispensing error. In my judgment, it was reasonably foreseeable that if the wrong type of cytotoxic chemotherapeutic drug were to be dispensed, whether or not in overdose, the consequences for the patient to whom it was administered would be adverse. As against that, prior to 22 June 2005 there had been no such occurrence in this busy Aseptic Dispensing Unit and the system of external ASSIG audit of the Unit had taken place on 9 February 2004 without any adverse comment on the standard operating procedure then in use. It was subsequently satisfactorily audited again on 5 October 2005. It is established, as is obvious, that had there been more staff available Ms Johnstone would not have had to do all the required checks with the result that there would have been another person involved in the checking process. On this occasion the shortage of staff occurred by reason of unexpected illness and because there was no deputy Responsible Pharmacist in post at the time, which post the Health Board had unsuccessfully tried to fill. I accept the submissions advanced by Mr Scott and Mr Lamont to the effect that difficult issues arise for consideration as to whether a particular suggested precaution was reasonable, particularly as there was no evidence as to financial resources or constraints which applied. In my judgment, for the reasons mentioned below, the evidence discloses the only real possibility of avoiding the release of the wrong cytotoxic chemotherapeutic drug for administration to Mr Cusker would have arisen if someone else other than Ms Johnstone had carried out the earlier checks. For these reasons, in my judgment, it is not appropriate to make any finding in terms of section 6(1) (c) of the Act.

[56] In terms of section 6(1)(d) of the 1976 Act, I have specified the defects which, in my judgment, are established to have existed in the system of work then in use and which contributed to the human errors or accidents which resulted in Mr Cusker's death. These have already been fully discussed in the foregoing paragraphs. I would wish to emphasise that the undisputed evidence led at this inquiry established that the tray check and the final check are both critical checks in the dispensing process in the Aseptic Dispensing Unit. In my

judgment, the undisputed evidence established that it is vital that the person who is charged with the responsibility of carrying out a particular critical check is able to do so as a new and completely independent inspector of the process to date, which becomes quite impossible if that person has had any prior involvement in the process. In universal experience, most people tend to expect to get what has been ordered or prescribed. But sometimes things go wrong and so it is necessary to have checks. However, if the person carrying out the check has been previously involved in the process, it is likely that that person will think that what has been done has been correctly done. In other words, that person will not think that he or she has made an error. This is why it is vital that for critical checks in the dispensing process, the inspector cannot be permitted to inspect him or herself. In my judgment, the system then in use, which permitted the same person to carry out more than one critical check, failed to recognise the essential purpose of inspection and was a defective system, which failed to be effective to support those who were involved in the dispensing process and those patients whose prescribed cytotoxic chemotherapeutic drugs were dispensed under that system. I fully appreciate that what I have found to be defects in the standard operating procedure in use on 22 June 2005 were not criticised in the previous or subsequent ASSIG audits. It is for ASSIG, if so advised, to take account of the determination at this fatal accident inquiry. I do not consider that the evidence led at this inquiry established a need to have a separate tray for each drug. Whilst that may be best practice, and is the standard practice at Edinburgh Cancer Centre, on the evidence led the fact that there were two cytotoxic chemotherapeutic drugs in the tray made up by Ms Beattie did not contribute in any way to what happened. Finally, I have not considered it appropriate to make the finding sought by Mr Scott in terms of section 6(1)(e) of the 1976 Act but I have confirmed that this Aseptic Dispensing Unit closed upon the opening of the West of Scotland Cancer Centre.

[57] At the outset of the inquiry I expressed my condolences to Mr Cusker's family. I should like to repeat these condolences and to join with the procurator fiscal, Mr Scott and Mr Lamont in their expressions of condolence and sympathy to Mr Cusker's family. I have referred earlier to the apology which Mr Lamont tendered on behalf of Ms Johnstone for her part in the system failure. Mr Joseph Cusker attended throughout the inquiry. His view was that there had been systemic failures which resulted in his father's death. I sincerely hope that

this inquiry has served to give him and his family a clear picture as to how it came to be that a dearly loved husband and father received an overdose of the wrong cytotoxic chemotherapeutic drug.

[58] Once she became aware of it, Ms Johnstone was clearly devastated by her error. The undisputed evidence was that she has since remained very upset by the consequences which resulted for Mr Cusker and also for his family. She became distressed on several occasions during the course of evidence. She impressed me as a well qualified, conscientious and competent pharmacist. That was the view expressed by Mrs Caldwell. Over twenty years ago, in a determination dated 20 January 1987, following upon a fatal accident inquiry, I observed:- "It is universal experience that when something goes wrong, we all look back and say "If only". However that is not the proper test to apply. It seems to me to be regrettably true that it tends to be the caring, conscientious and competent who apply the test of hindsight most stringently to their own area of responsibility and, as a result, often unnecessarily torture themselves." I consider that that observation bears repetition as it does apply to Ms Johnstone. I sincerely hope that the conclusion of this inquiry and being aware Mr Cusker's family do not blame her will now provide some comfort to and closure for Ms Johnstone.