PRELIMINARY MEDICO-LEGAL REPORT

RE. TRACIE LAWLOR (DECEASED) (DOB 28.04.1983 DOD 10.11.2007)

I have prepared this report for the Court on the instructions of:-

Branigan Cosgrove Finnegan
BCF Solicitors
31 Pembroke Road
Dublin 4.

I practice as a Consultant Paediatrician with a special interest in paediatric infectious disease, immunology and respiratory medicine and Clinical Director of Cystic Fibrosis Services at St James's and Seacroft University Hospitals, Leeds Teaching Hospitals Trust, Leeds. I was a Committee Member of the Royal College of Paediatrics and Child Health, Standing Committee on Immunisation and Infectious Disease (1995-2001), and the Royal College of Paediatrics and Child Health Infectious Disease and Immunology Group (1995-2002). I also served as a member of the Joint Committee on Vaccination and Immunisation for five years. I was Deputy Chair of the Medical Advisory Committee of the United Kingdom Cystic Fibrosis Trust from 2004 to 2008 and am Deputy Chief Editor of the European Cystic Fibrosis Journal. From 1988 - 1998 I was one of three consultants responsible for the Regional Infectious Disease Unit at St James's and Seacroft University Hospitals, Leeds. During that time I was responsible for the care of patients of all ages presenting with infection or infectious diseases. As a Consultant I have had wide experience of patients affected by chronic fatigue syndrome. Many of these patients are referred to me because of my interest in infection, infectious diseases and immunology. I have received many referrals not only directly from general practitioners but also tertiary referrals from Consultant Paediatric colleagues. I have published in excess of 170 papers in peer review journals with reference to General Paediatrics, Paediatric Infectious Disease and Cystic Fibrosis.

I understand that my duty is to the Court and I have complied and will continue to comply with that duty.

I have been instructed to opine on the level of care afforded to Miss Lawlor.

I have had access to and therefore based my opinion upon –

1. Medical records Waterford Regional Hospital.

2. Death Certificate.

antibiotic but I cannot find it listed in the present British National Formulary. I believe orbenin might be a preparation of the antibiotic cloxacillin.)

1.6 On the 19th of September, 1985 Tracie was reported to be very well and on the 18th of December her chest was clear.

1.7 On the 23rd of October, 1986 Tracie was receiving the antibiotic augmentin for her respiratory exacerbation. On the 26th of November, 1986 septrin and orbenin were prescribed. Tracie was noted to be well on the 17th of December, 1986 with good appetite and an overall good weight gain. She had an occasional cough with green sputum which was sent for culture. Antibiotics were not prescribed.

1.8 On the 19th of March, 1987 it was noted that her growth was satisfactory.

1.9 On the 16th of July, 1987 it was noted that her sputum was green and that Tracie had a night time cough. She had crackles at the left lung apex. She was treated with two weeks antibiotics, septrin and orbenin.

1.10 On the 20th of August, 1987 Tracie was described as well with a clear chest. On the 19th of November, 1987 Tracie was receiving oral antibiotic treatment but her chest was clear. Clinical review in Out-Patients was at three monthly intervals.

1.11 On the 19th of May, 1988 Tracie was well. It was advised that a restricted fat diet was no longer necessary.

1.12 On the 14th of June, 1988 a growth of the bacteria *Pseudomonas aeruginosa* was noted from a sputum sample.

1.13 Tracie was admitted on the 15th of June, 1988 by Dr. Counahan for treatment for the new growth of pseudomonas. In a home based programme Tracie received treatment with two intravenous antibiotics and increased chest physiotherapy. Tracie had one week in hospital and one week out of hospital. She was described as very well on discharge. Other treatment continued with standard therapy for cystic fibrosis, i.e. pancreatic enzyme supplement and vitamin supplements. On admission, even in the presence of a new growth of pseudomonas, Tracie's respiratory rate was not raised (20), her chest was clear, she had good air entry, and her chest x ray was clear.

1.14 On the 19th of January, 1989 Tracie had a respiratory exacerbation although her chest was clear on auscultation. She was treated with intravenous antibiotics.

1.15 On the 20th of April, 1989 Tracie complained of a recurrent respiratory tract infection. Oral antibiotics were prescribed and Tracie's cough settled. She was described as very well on the 20th of July, 1989.

1.16 Tracie received a course of intravenous antibiotic therapy on the 16th of August, 1989. Her chest was clear. She was treated for three weeks. On the 6th of September it was noted that her chest x ray was clear. Tracie's weight was 20.35 kg (50th centile) and her height was 115 cm (25th centile).

1.17 The Senior House Officer documented on the 6th of September, 1989 that Tracie was being treated with two anti-pseudomonal antibiotics and had been so for three weeks. She was still producing green sputum but her chest x ray was clear. Intravenous antibiotic therapy was stopped and oral antibiotic therapy with septrin and orbenin commenced.

1.18 On the 21st of December, 1989 Tracie was described as well since her intravenous antibiotic treatment in September.

1.19 On the 10th of January, 1990 Dr. Counahan wrote that Tracie had decreased appetite and cough with a positive pseudomonas growth. She had been noted as intermittently positive for pseudomonas infection since the first isolate in June 1988. Her chest was clear. She was prescribed six weeks of the oral antibiotic ciprofloxacin.

1.20 On the 21st of June, 1990 Tracie was noted to be well. On the 24th of August at Out-Patient review it was noted that she had been receiving ciprofloxacin for six weeks and she was commenced on intravenous treatment with two anti-pseudomonal antibiotics.

1.21 On the 18th of October, 1990 it was noted that following ten days of intravenous treatment in September Tracie's sputum nonetheless remained green.

1.22 On the 20th of December, 1990 Tracie was chesty again despite just having completed a course of antibiotics. She was commenced on ciprofloxacin.

1.23 Tracie had a further respiratory exacerbation in March 1991 which was treated with oral antibiotic therapy.

1.24 Tracie commenced a course of intravenous antibiotic therapy when she was described as chesty and with pseudomonas infection on the 10th of May, 1991. On the 20th of June she was still coughing but her weight had increased and

she looked well. Her chest was clear and her chest x ray was clear. She was treated with oral ciprofloxacin.

1.25 On the 10th of July, 1991 Tracie was reviewed in hospital Out-Patients. She had a history of cough with green sputum and poor appetite. Her weight was on the 50th and height on the 25th centile. She had a few crackles all over her chest but good air entry and no other abnormalities on examination. Sputum was positive for pseudomonas infection and she was commenced on oral ciprofloxacin. On the 26th of November, 1991 her chest x ray and her chest were described as clear.

1.26 Tracie was again chesty on the 21st of January, 1992, producing green sputum and with decreased appetite. She was treated with oral ciprofloxacin.

1.27 It was noted on the 27th of April, 1992 that a sputum sample at the end of March had cultured positive for *Staphylococcus aureus* and pseudomonas. It was felt that there was no need to treat these bacteria unless there was an abnormal amount of sputum or clinical signs in Tracie's chest. On the 30th of August she was described as well with a clear chest.

1.28 On the 1st of December, 1992 a history of a week's cough was reported at Out-Patients with the production of thick greenish sputum. Tracie's appetite was down. She was clinically well and her chest x ray was clear. She was treated with ten days oral ciprofloxacin but on the 16th of December intravenous antibiotic therapy was commenced.

1.29 On the 5th of January, 1993 Dr. Counahan noted that Tracie still had a dry cough although her chest x ray was clear and clinical examination of her chest was normal. Tracie remained well when seen in April 1993. On the 24th of August it was noted she had a marked cough and green sputum with decreased appetite and she was treated with intravenous antibiotics. On the 7th of September, 1993 after completion of two weeks of intravenous antibiotic therapy, treatment was commenced with the antibiotics nebulised colomycin and oral ciprofloxacin on a monthly alternating basis. Chest x ray on the 7th of September, 1993 was normal.

1.30 Tracie was referred by Dr. Sheehan to Dr. Greally. On the 6th of July, 1994 Dr. Greally summarised Tracie's condition. She was reported to be doing quite well from a respiratory point of view with no recent lower respiratory tract infection. She had occasional cough with white sputum and occasional

wheeze with exercise. Her stools were normal. She had problems with nasal polyps. She was active physically. Oxygen saturation was 95% in air, height and weight on the 25th centile. She had some clubbing and a hyperinflated chest. Her chest was clear on clinical examination. Chest x ray showed bronchial wall thickening more in the left lower lobe than the right. Tracie was receiving dietetic and physiotherapy review. Investigations showed a normal blood count, blood clotting, urea and electrolytes, and only slightly abnormal liver function tests. She continued with pseudomonas infection.

1.31 On the 12th of July, 1994 Tracie was described as well and her chest as having been very good. Respiratory function was over 60% predicted.

1.32 On the 29th of July, 1994 it was noted that Tracie was receiving treatment with ursodeoxycholic acid for mild liver disease shown by the slight elevation in the liver function tests. Tracie was also receiving the mucolytic agent pulmozyme.

1.33 On the 18th of October, 1994 Dr. Counahan described Tracie not quite as well as usual with some linear shadows in the right lower zone on chest x ray and increased sputum production. Her General Practitioner had prescribed ciprofloxacin. Two weeks of intravenous antibiotic therapy was commenced. Following this Tracie was much improved with less sputum and clearer sputum. Chest x ray was normal. Following development of a "cold" oral antibiotic therapy was commenced in October 1994.

1.34 On the 17th of January, 1995 Tracie's forced vital capacity was 70% predicted and FEV_1 was 59% predicted. Treatment included nebulised pulmozyme and nebulised colomycin.

1.35 On the 2nd of May, 1995 at twelve years of age Tracie's weight was on the 25th and height just below the 25th centile. She was reported to be very well with respiratory function about 55% predicted, clear chest and no acute changes on the chest x ray.

1.36 On the 29th of August, 1995 some fall off in the rate of weight gain was noted. Tracie's chest was clear. Respiratory function was 40% predicted. On the 12th of October, 1995 intravenous antibiotic therapy was commenced and on the 27th of October Tracie had a glucose tolerance test and dietetic review.

1.37 On the 3rd of November, 1995 liver ultrasound showed hyperechoic areas. On the 5th of December weight and height were on the 25th and just below the 25th centiles respectively. Respiratory function was 61% predicted.

1.38 In 1996 it was noted in September that Tracie's weight had fallen to less than the 10th centile with height above the 10th centile. She was nonetheless eating well but had marked cough. Chest x ray showed only very minimal changes of cystic fibrosis. Respiratory function was 50% predicted. On the 30th of September coarse crackles were heard bilaterally and Tracie had a faecal mass in the right iliac fossa. Her chest x ray was clear. She received therapy with laxatives. On the 18th of October, 1996 it was noted that Tracie had completed two weeks of intravenous antibiotic therapy and had improved a lot. Her weight remained below the 10th centile and height below the 25th centile. She was clinically well with a clear chest. She was to continue treatment with nebulised colomycin.

1.39 On the 14th of February, 1997 in a "To whom it may concern" letter, Tracie's treatment was documented to include physiotherapy, nebulised bronchodilators and antibiotics, inhaled therapy, and pulmozyme.

1.40 On the 30th of May, 1997 Tracie was more productive of sputum and was receiving oral antibiotic therapy. Her weight remained on the 10th centile and height on the 25th. The chest x ray was reassuringly normal. She received ten days of intravenous antibiotic therapy.

1.41 On the 14th of November, 1997 chest x ray showed minor changes of cystic fibrosis with no focal consolidation. Tracie had a productive cough but was generally well. Sputum continued to show infection with staphylococcus and pseudomonas. Tracie's weight had increased to the 25th centile and her height was just below the 25th. She continued on standard therapy for cystic fibrosis. She was described as very well.

1.42 Liver ultrasound in December 1997 suggested the presence of cirrhosis and portal hypertension.

1.43 In March and May 1998 a heavy growth of staphylococcus and pseudomonas was isolated. The pseudomonas was fully sensitive to routine antipseudomonal antibiotics.

1.44 At fifteen years of age on the 19th of May, 1998 Tracie's weight was on the 50th centile and height just below the 50th centile. It was noted that she had

shown no real improvement in chest problems or sputum over the last six weeks and had continued to produce thick green sputum despite treatment with oral flucloxacillin, klaricid and ciprofloxacin (all antibiotics). She had a heavy growth of pseudomonas. Bilateral coarse crackles were heard on clinical examination. Chest x ray showed bilateral changes, possibly worse than previously. Intravenous antibiotic therapy was commenced.

1.45 Tracie was described as improved on the 29th of May with a clear chest. Her chest x ray was described as much improved. Respiratory function was 74% predicted.

1.46 On the 25th of September, 1998 Tracie had a dry cough and was treated with an oral antibiotic. Her chest was clear and chest x ray showed no acute change.

1.47 At Out-Patient review on the 7th of October, 1998 Tracie was complaining of a dry cough for seven days. She was receiving treatment with an oral antibiotic. Chest x ray showed no change.

1.48 Tracie was reviewed on the ward on the 16th of December, 1998. Weight and height were between the 25th and 50th centiles. She was complaining of cough despite ten days treatment with ciprofloxacin and two weeks treatment with klaricid. She had dark green sputum. On examination crackles were heard bilaterally. Her liver was enlarged 2 cm and spleen 3 cm. Chest x ray showed bilateral basal changes. She was commenced on two weeks intravenous antibiotic therapy.

1.49 On the 5th of February, 1999 Tracie was described as having been unwell for a week with basal changes on her x ray and sputum showing infection with staphylococcus and pseudomonas. She had a faecal mass in her right iliac fossa. It was noted that she had been coughing since Christmas of 1998. Tracie showed a good response to treatment with oral antibiotics and was described as much better on the 18th of February. Her chest was clear and her respiratory function 51% predicted.

1.50 On the 4th of May, 1999 weight and height were around the 50th centile. Tracie had a marked cough and was treated with intravenous antibiotic therapy. Following this treatment her chest cleared.

1.51 Tracie was referred on the 15th of May, 1999 for shared care with Dr. Gallagher. She was noted to have moderate pseudomonas and heavy

staphylococcus infection. Weight was on the 25th centile and height above the 50th with a satisfactory BMI of 21. She had crackles at the left base and chest x ray showed chronic changes mostly at the left base. Tracie was treated with two weeks of intravenous antibiotic therapy and on the 4th of June was noted to be coughing much less with a normal chest on examination.

1.52 On the 15th of June, 1999 it was noted that Tracie had recently had two weeks of intravenous therapy as a "top up" before her Junior Certificate Exam. She had shown good improvement with decreased cough and a marked reduction in sputum production. Weight of 56.2 kg and height of 161.8 cm were on the 25th and 50th centiles respectively. Her chest x ray had improved and respiratory function was 63% predicted.

1.53 In a letter of the 12th of July, 1999 it was noted that overall Tracie had deteriorated over the previous year and had been particularly unwell since Christmas 1998. She had had a six month chronic productive cough with wheeze and increasing shortness of breath. She had had two intravenous antibiotic treatment courses since Christmas. In December 2000 it was noted that respiratory function was 49% predicted.

1.54 In 2001 Tracie had intravenous antibiotic therapy in April and November. She had further intravenous antibiotic treatment in September and December 2002.

1.55 The clinical records are sparse from 1999. I suspect that I have not had access to all of Tracie's consultations as I have not had the St. Vincent's Hospital notes. I note further intravenous antibiotic treatment in August 2005. Detailed clinical records resume in 2007.

1.56 Tracie required a course of intravenous antibiotic therapy in February 2007. After three weeks treatment she showed a significant improvement but she was still producing more and darker sputum than normal. It was thought that she might have an anaerobic infection and she was prescribed the antibiotic metronidazole for two weeks. In the middle of February she had complained of increasing volumes of dark green sputum.

1.57 On the 26th of June, 2007 Dr. McKone documented that Tracie was well with respiratory function 58% predicted. He noted the observations were back to baseline.

1.58 Tracie was admitted from the 10th to the 24th of July, 2007 with a respiratory exacerbation. She was treated with intravenous antibiotics and gradually improved. At discharge her respiratory function had returned to its baseline.

1.59 Tracie was admitted on the 22nd of October, 2007 at I believe 20.00 hours although the time has not photocopied clearly. It was noted that she had cystic fibrosis and was under the management of the Cystic Fibrosis Team at St. Vincent's Hospital in Dublin. Tracie was receiving comprehensive treatment at the time with the following medication – nebulised colomycin (antibiotic), nebulised pulmozyme (mucolytic), oral flucloxacillin (antibiotic), inhaled bronchodilator and corticosteroid, steroid nasal spray, ursodeoxycholic acid (for CF liver disease), pancreatic enzyme supplements, calcium supplements, vitamin supplements, medication for osteoporosis.

1.60 Tracie complained of tiredness, a two day low grade temperature and more green sputum than usual possibly streaked with blood. She had had a course of ciprofloxacin two weeks previously for one week and had not improved.

1.61 On examination Tracie was not in respiratory distress but was febrile at 38.5 degrees with decreased air entry bilaterally and crackles in both lung bases. Her blood pressure was 113/70, and oxygen saturation 97% in room air. The report on her chest x ray (page 604) is difficult to interpret. It appears to initially state that there was widespread opacification and chronic changes in the right middle lobe, but then states there was no pleural effusion and no obvious opacity.

1.62 Blood was sampled for routine tests and a blood culture sample sent. The initial results showed a normal haemoglobin but a low white cell count at 3.7 and a low but still normal neutrophil count at 2.48. Platelet count was low at 57. I note that an earlier full blood count from the 23rd of July, 2007 had shown a haemoglobin of 12.0, white cell count at 3.3, neutrophil count 2.2 and platelet count 58. Liver ultrasound on the 24th of January, 2007 had shown a very nodular liver with splenic enlargement with varices. Repeat ultrasound on the 18th of September, 2007 had shown a liver picture consistent with cirrhosis and a very large spleen at 18 cm with varices at the hilum. The picture was consistent with cirrhosis and portal hypertension.

1.63 (It is likely that the reduced white cell and platelet counts were a result of splenic sequestration.)

1.64 On the 22nd of October Tracie had slightly abnormal blood clotting with an INR at 1.3. The liver enzyme AST was slightly raised at 44 and blood potassium was slightly low at 3.4.

1.65 Chest x ray showed apical infiltration in the left lower lobe and the right lower lobe.

1.66 Tracie's presentation was discussed with the Cystic Fibrosis Registrar at St. Vincent's Hospital and treatment with the antibiotics tobramycin 8 mg/kg once daily and ceftazidime 2 grams 3 times daily and flucloxacillin 1 gram four times daily was recommended. Daily full blood counts were requested and treatment with intravenous potassium advised.

1.67 At 00.20 hours on the 23rd of October the nursing records document admission following presentation to the Accident and Emergency Department with tiredness and a low grade temperature. Tracie was febrile at 38.5 degrees and producing green sputum. It was noted that she had had a Port-A-Cath (PAC) in situ for six years. Tracie was dyspnoeic on 2 litres of supplementary oxygen. Initial monitoring noted heart rate 102, oxygen saturation 96%, blood pressure 132/62.

1.68 On the 23rd of October Tracie was reviewed by the Respiratory Team and Dr. Foley. She had crackles in the right mid and lower zones. The management plan was to continue with physiotherapy, to obtain sputum culture and sensitivity results, to send a further blood culture. The initial sputum culture was reported as showing a heavy growth of *Staphylococcus aureus* and multi-resistant pseudomonas. The pseudomonas was later reported as only sensitive to the antibiotic colomycin. The Microbiologist advised adding ciprofloxacin intravenously twice daily.

1.69 No detailed clinical examination was recorded for the 23rd of October.

1.70 I inform my Instructing Solicitors that very few of the entries in the medical records have a time noted for them.

1.71 On the 24th of October on Dr. Foley's ward round (time not given) it was noted that Tracie was still complaining of a fever. She was shivering and short of breath. The recorded temperature was 36.5 degrees. Oxygen saturation 100% on 1.5 litres. Tracie had bilateral crackles in her chest. Blood pressure 86/58.

1.72 The management plan was that if there was a further rise in temperature the choice of antibiotic therapy should be discussed with the Microbiologist. Meantime the dose of flucloxacillin was increased from 1 gram to 2 grams four times daily. The Microbiologist informed that the pseudomonas sensitivities would not be available until the 25th.

1.73 The Physiotherapist noted spontaneous ventilation with 2 litres supplementary oxygen, air entry throughout and no added sounds. Tracie had a dry non productive cough. She was instructed in the use of the Acapella device for self administered physiotherapy.

1.74 The blood results on the 24th of October (no time given) noted a fall in haemoglobin to 9.3, in the white cell count to 1.8, and in the neutrophil count to 0.79. The platelet count had fallen to 40. The potassium had fallen to 2.6. A significantly low albumin of 15 was noted. The inflammatory markers, CRP and ESR, were significantly raised at 117 and 24.

1.75 The Senior House Officer was asked to review Tracie at 19.00 hours on the 24th of October. She had had a temperature of 40.0 degrees at 17.00 hours which had responded to paracetamol and fallen to 37.0. Heart rate was noted at 100, blood pressure 86/48, saturation 96% in room air. The Senior House Officer considered that Tracie had had an adverse reaction to the antibiotic ciprofloxacin and prescribed the antihistamine piriton one hour before the next dose of intravenous ciprofloxacin. The intravenous fluid infusion was increased because of the low blood pressure (it was not written what volume of fluid was to be infused and over how long). Paracetamol was prescribed for the fever and it was noted that the plan was to wait for the sputum sensitivity pattern the following day.

1.76 On the ward round on the 25th (no time given) Tracie was described as unwell. She was afebrile with 99% saturation but continued low blood pressure at 95/45. It was noted that she had had two spikes of temperature overnight after her intravenous ciprofloxacin. The management plan was to change the intravenous to oral ciprofloxacin, to obtain more sputum samples and to liaise with the Microbiologist re treatment.

1.77 At 16.00 hours on the 25th the Senior House Officer noted a temperature of 38.5 degrees that afternoon and documented the blood count picture from the 22nd to the 25th showing a fluctuating pattern but consistently low white cell

count, neutrophil count and platelet count (see Appendix A). Pseudomonas sensitivities were still awaited.

1.78 The management plan was to continue the current antibiotic regimen and also intravenous fluid administration.

1.79 Tracie was later reviewed by the "Team". The low grade temperature, recently raised CRP and ESR were noted. At this point Tracie's antibiotic treatment was flucloxacillin 2 grams four times a day, tobramycin intravenously, ceftazidime intravenously, ciprofloxacin orally, and colomycin nebulised. Tracie was also receiving the antibiotic azithromycin three times a week. The plan was to monitor daily white cell counts until they had returned to normal.

1.80 There is no detailed record of any clinical examination for the 25th of October.

1.81 On the 26th of October the Senior House Officer recorded a discussion with the Microbiologist and information that the pseudomonas growth was sensitive to colomycin but resistant to all other commonly used anti-pseudomonal antibiotics. The situation was discussed with the Cystic Fibrosis Registrar at St. Vincent's Hospital who recommended continuing the same antibiotic treatment i.e. tobramycin, ceftazidime and flucloxacillin intravenously, ciprofloxacin orally, and colomycin by nebuliser. If Tracie had not improved after seven days a change in antibiotic treatment was to be considered.

1.82 Tracie's temperature was still spiking. Her peak flow rate had decreased from 250 to 300 to 150.

1.83 Tracie's condition was discussed with Dr. Foley who advised administering colomycin 2 mega units twice daily intravenously and maintaining the nebulised colomycin. The antibiotic aztreonam and the anti-fungal agent itraconazole orally were also recommended.

1.84 Possibly on the 26th (but the date is obscured) there is a note that Tracie developed urticaria after the dose of aztreonam. The Microbiologist recommended continuing the current antibiotic regimen for the multi-resistant pseudomonas.

1.85 Blood results on the 26th of October showed the ESR maintained high at 24, a fall in the white cell count to 1.9 and neutrophil count to 0.66. The platelet

count remained low at 52. There had been no change in the blood clotting results since the 22nd. Blood calcium was low at 1.74 and albumin low at 18 (see Appendix A).

1.86 No clinical examination details are recorded for the 26th. I could find no clinical record for the 27th of October either in the medical or nursing records. On the 28th of October the only medical note is of a possible urticarial reaction to aztreonam which is also the only record in the nursing notes. There is no record in either the nursing or medical notes for the 29th of October.

1.87 The records for the 30th of October document a pancytopenia, multi-resistant pseudomonas infection but improvement on intravenous colomycin and aztreonam and oral itraconazole. The possibility of aspergillus (fungal) infection with a febrile neutropenia was raised. Clinically air entry had improved but there were crackles in the right mid zone. The management plan was to stop the oral ciprofloxacin, to repeat the chest x ray and to consider bronchoscopy if the temperature continued to be raised.

1.88 On the 30th of October the Physiotherapist documented oxygen saturation of 96% on 2 litres supplementary oxygen with scattered crackles throughout the lung fields and a strong productive cough. However, Tracie was clearing her secretions more easily.

1.89 On the ward round on the 31st of October (no time given) it was documented that there had been no change. Tracie's blood count continued to show a low white cell count, low neutrophil and platelet count and low haemoglobin (see Appendix A). The overnight temperature had been recorded at 38.2 degrees at 23.30 hours but at the time of the ward round had fallen to 36.4. Tracie continued hypotensive at 87/49. Blood results showed a low potassium, low albumin, and low calcium (see Appendix A).

1.90 On the ward round on the 1st of November (no time given) it was noted that Tracie had continued to spike temperatures overnight. The decision was taken to perform a bronchoscopy. The latest microbiology results showed two pseudomonas isolates sensitive to colomycin and aztreonam. There was also a light growth of candida and aspergillus (fungi). Blood cultures had remained sterile.

1.91 It was noted that a bronchoscopy could not be performed until the 5th. Treatment was started with the antifungal agent amphotericin.

1.92 A blood gas result documented pH 7.44, pCO_2 3.47, pO_2 10.18 but the date of this sample is not present. No clinical details were recorded for the 1st of November. Despite the low blood pressure readings, only isolated blood pressure recordings seem to have been taken.

1.93 The clinical records for the 2nd of November note the intermittently raised temperatures. It was queried that Tracie's fever might be drug related or that the PAC might be infected. It was written that there was no evidence for septicaemia. The possibility of invasive aspergillus infection in an immuno-compromised host was considered.

1.94 Tracie's low albumin levels were noted. The response to this was that Tracie's mother would bring in food. Tracie did not wish to have a nasogastric feed.

1.95 Treatment was altered and itraconozole therapy stopped and the antibiotic tazobactan introduced.

1.96 Blood results showed continuing haematological abnormalities and a slight disturbance in blood clotting. Potassium, calcium and albumin levels remained low (see Appendix A).

1.97 I note the Physiotherapist reported blood in the sputum and wrote a plan was to "review on Monday". Apart from blood result entries for the 3rd and 4th of November it appears that Tracie was not re-examined or reassessed over the weekend. The blood results for the weekend showed continuing abnormalities as previously described.

1.98 On the ward round on the 5th of November (time not given) Tracie was described as still unwell. She was spiking temperatures (38.5 at 23.30 hours on the 4th of November). The problems were a multi-resistant pseudomonas infection and a persistently swinging fever despite treatment with intravenous colomycin, aztreonam, tazobactan, ambisone and oral flucloxacillin. The blood tests showed a continuing low neutrophil count, haemoglobin and platelet count. CRP remained high at 100 and blood clotting was showing an increasingly abnormal picture. The potassium remained low (see Appendix A).

1.99 On the ward round (no time given) for the 6th of November Tracie was reported to be unwell with a temperature of 38.9 degrees the previous night. Her temperature at the time of the ward round was 36.2 with oxygen saturation

97% in 2.5 litres. Blood pressure remained low at 90/54. Blood results showed a continuing anaemia, low white cell count and neutropenia and low platelet count. The blood clotting values were slightly more abnormal with an INR of 1.5. Potassium remained low at 2.6 and albumin at 16.

1.100 The management plan was to continue antibiotic treatment and to provide potassium supplements intravenously and orally.

1.101 A bronchoscopy was performed. A stain on a lavage sample for atypical mycobacteria was negative.

1.102 On the 7th of November the ward round led by Dr. Foley documented the persistent spiking of temperatures and the onset of diarrhoea. A sputum sample showed a heavy growth of pseudomonas sensitive only to colomycin. Potassium remained low at 2.6 and albumin at 14. No clinical examination details are given.

1.103 The management plan was to increase the intravenous dose of colomycin to 2 mega units three times a day (the maximum recommended dose), to repeat the chest x ray, obtain a stool sample and an abdominal ultrasound. The report of the series of chest x rays from the 26th of October to the 7th of November documented initial peribronchial thickening in both lower zones and mid zones with no significant change by the 30th of October. The chest x ray of the 7th of November showed more consolidation on the left side.

1.104 The clinical records for the 8th of November document the results of the abdominal ultrasound showing an enlarged liver and a grossly enlarged spleen at 20 cm (page 565). The liver picture was consistent with cirrhosis.

1.105 CT scan of the thorax noted on the 8th of November showed diffuse bronchiectasis with segmental areas of peribronchial consolidation bilaterally. There were patchy areas of ground glass consolidation throughout both lung fields particularly at the bases. There was more dense consolidation in the right middle lobe. The appearances were suggestive of secondary aspergillosis.

1.106 Blood test results showed similar continuing abnormalities. The potassium remained low at 2.3 and the albumin at 15.

1.107 There is no documentation of the details of a clinical examination.

1.108 On the 9th of November the Senior House Officer was called to review Tracie at 04.30 hours. Her saturations had fallen to 85% on 2 litres supplementary

oxygen. Other observations showed blood pressure 117/62, respiratory rate 22, heart rate 95, temperature 37.2. With 100% oxygen supplementation saturations improved to 100%.

1.109 On clinical examination air entry was good but Tracie had crackles all over her chest with a raised jugular venous pressure. An ECG was performed which showed sinus rhythm.

1.110 The Senior House Officer decided to continue with the ongoing treatment regimen and to perform a blood gas result.

1.111 The latter at 04.36 hours showed a pH of 7.28, pCO_2 4.23, pO_2 (difficult to read but appears to state 21.78).

1.112 The Senior House Officer reduced Tracie's oxygen supplement to 39% but at 06.30 hours it was noted that this had resulted in a fall in oxygen saturation to 90%. Even with increasing supplementary oxygen to 100% only 95% saturation was achieved. Tracie was noted to have increasing tachycardia. On examination at 06.30 hours she looked extremely ill with tachypnoea. She was afebrile. Blood pressure 119/59, respiratory rate 28, heart rate 100. Her chest was full of crackles and oxygen saturation was 95% in 100% supplement.

1.113 The Senior House Officer did not involve a Senior Doctor and no chest x ray was taken.

1.114 Blood results for the 9th of November showed a continuing low potassium at 2.3, low calcium 1.87, low albumin 15. Blood clotting showed an increase in the INR to 1.6 and D-dimer to 273. Two blood counts showed haemoglobin respectively 10.0 and 8.3, white cell count 6.8 and 3.6, neutrophil count 3.51 and 1.15.

1.115 The Senior House Officer requested that the Registrar review Tracie but it appears that advice was only given over the telephone and that the Registrar did not personally assess Tracie. The Registrar stated that on the information given the likely diagnosis was cor pulmonale (right sided heart failure secondary to chronic lung disease) and advised treatment with the diuretic frusemide 60 mg, with nebulised pulmicort (corticosteroid), and review by the Respiratory Team in the morning.

1.116 Tracie was reviewed at 09.08 hours on the 9th of November. She was described as "very sick"; heart rate 110, respiratory rate 40, blood pressure

93/49, saturation 100% with 15 litres supplementary oxygen, temperature 36.9, Glasgow Coma Score 15/15. She had coarse crackles bilaterally. Her jugular venous pressure was normal. The plan was to discuss her condition with the Consultant and the family and then to review.

1.117 At a later unspecified time Tracie was reviewed by Dr. Foley. She was critically ill. This entry is difficult to read. Tracie's oxygen saturation was 94% on 100% supplementary oxygen. Dr. Foley had a long discussion with Tracie and her family, noting her deteriorating status and the family's wish for aggressive treatment. It was stated that Tracie should be transferred to St. Vincent's Hospital, that the Anaesthetist should review Tracie before transfer, that the Microbiologist should be consulted about antibiotic treatment and that the albumin should be replaced. No beds, however, were available at St. Vincent's Hospital, or when they were contacted again at 11.30 hours that morning.

1.118 At 13.10 hours on the 9th of November the Anaesthetist noted that Tracie could only speak two or three words before she became breathless. The Anaesthetist thought that Tracie would be in terminal respiratory failure within a few hours. The risks of ventilation were explained to Tracie and she was told that she would only be able to be taken off ventilation if the infection responded to antibiotics.

1.119 It was later noted that the sputum from the 8th of November had grown pseudomonas sensitive to the antibiotics colomycin and tazocin. There had also been a light growth of aspergillus.

1.120 A further entry documented that intravenous therapy was not appropriate at this stage and that Tracie did not want mechanical ventilation. Tracie was given the choice between remaining in hospital or returning home with intravenous antibiotic therapy. It was documented that she was not for resuscitation. The family decided that they wanted to take Tracie home. It was noted that she could not continue with the amphotericin at home as this needed to be given by an infusion.

1.121 The Palliative Care Team was involved and noted that Tracie was in end stage cystic fibrosis. The issues identified by the Palliative Care Team were terminal agitation and marked chest secretions. Contact was made with Tracie's General Practitioner, the Home Care Team and the On Call Nurse.

Tracie was discharged with intravenous antibiotic therapy and palliative treatment.

1.122 Tracie died on the 10th of November. The Death Certificate noted the cause of death as -

a) i) Invasive aspergillosis

ii) Multi drug resistance *Pseudomonas aeruginosa*

as the direct causes of death, and "immunocompromised state as a consequence of cystic fibrosis" as antecedent causes.

1.123 I refer the Court to Appendix B detailing sputum isolates, Appendix C showing the temperature charts and blood pressure and oxygen saturation monitoring and Appendix D showing a summary of treatment received.

1.124 The temperature chart shows a fluctuant temperature pattern which never settled to normal levels. Temperature peaks above 38.0 degrees were frequently noted. The observation charts also show a persistent hypotension.

2. SUMMARY

2.1 Tracie was born on the 28th of April, 1983. She was diagnosed with cystic fibrosis following referral in April 1984 because of failure to thrive, recurrent respiratory tract infections and abdominal distension.

2.2 In the 1980's Tracie had infrequent respiratory tract exacerbations. These initially responded to oral antibiotic therapy but in 1989 intravenous antibiotic treatment was required in January and August. There were no significant chest x ray changes through to 1990 and Tracie remained generally well.

2.3 In the early 1990's Tracie remained generally well requiring occasional courses of oral antibiotic therapy and one to two courses of intravenous antibiotic therapy annually. On examination her chest was usually clear and her chest x ray showed no specific abnormalities. The first pseudomonas infection had been identified in June 1998 and had never been successfully eradicated.

2.4 Through the 1990's Tracie remained physically active. Chest x ray showed minor changes of bronchial wall thickening. Blood tests showed slightly abnormal liver function and Tracie was commenced on ursodeoxycholic acid. She received standard therapy for cystic fibrosis. Adherence to a restricted fat diet had been advised against in 1988. Treatment included the inhaled

mucolytic pulmozyme. Respiratory function varied between 40% to 60% predicted. Weight and height varied between the 10th and 50th centiles. This suggests that Tracie had some fluctuations in her wellbeing but the general pattern was of a well child with intermittent respiratory exacerbations. Tracie continued to respond to intensification of therapy with intravenous antibiotics.

2.5 In February 1999 it was noted that Tracie had been coughing since Christmas and that her chest x ray showed basal changes. She responded to oral antibiotic therapy but required a course of intravenous treatment in May 1999. Tracie was referred to Dr. Gallager in May 1999. By June she was noted to have much less cough with a clear chest and improvements in the chest x ray appearance. Nonetheless it was written in July that there had been a general deterioration over the preceding twelve months, especially over the preceding six months with a chronic cough, shortness of breath, wheeze and the requirement for two courses of intravenous antibiotic therapy. In December 2000 Tracie's respiratory function was 49% predicted.

2.6 I have only seen minimal records through 2000 to 2007. From the information I have available it appears that Tracie continued to require only one to two intravenous antibiotic courses per year.

2.7 In 2007 Tracie required intravenous antibiotic therapy in February and July. It was documented in June that Tracie was well and that her respiratory function had returned to her normal baseline with an FEV_1 of 58% predicted.

2.8 Tracie was admitted on the 22nd of October with complaints of tiredness and a low grade temperature for the previous two days. She complained of increased amounts of green sputum with some blood streaking of the sputum. Tracie had taken a week's course of the oral antibiotic ciprofloxacin two weeks previously without improvement. Her daily treatment regimen was comprehensive and accorded with a standard treatment protocol for cystic fibrosis.

2.9 On admission Tracie was febrile at 38.5 but with normal oxygen saturation of 97% and no respiratory distress. She had decreased air entry at both lung bases. Chest x ray showed infiltration at the apices of the right and left lower lobes.

2.10 Initial blood tests showed a low white blood count (3.7), a low neutrophil count (2.48), and a low platelet count of 57. These results were similar to

those recorded for July 2007 and consistent with splenic sequestration. Tracie was known to have cirrhosis and portal hypertension. Her potassium was marginally low at 3.4.

2.11 Tracie's condition was discussed with the Cystic Fibrosis Registrar at St. Vincent's Hospital and advice was given to administer the antibiotics tobramycin, ceftazidime and flucloxacillin intravenously. Potassium replacement was advised.

2.12 There is very little clinical detail given for the 23rd of October. A deteriorating haematological picture was noted on the 24th when a high C reactive protein of 117, a high ESR of 24 and a low albumin of 15 were also recorded. Tracie was complaining of fever, shivering and shortness of breath.

2.13 The Senior House Officer was asked to review Tracie at 19.00 hours on the 24th following a temperature of 40.0 degrees at 17.00. It was noted that she was hypotensive, 86/48. The Senior House Officer diagnosed a possible reaction to the antibiotic ciprofloxacin, advised paracetamol for the fever, intravenous fluid infusion for the low blood pressure and to await sputum sensitivities. Pseudomonas had been cultured from the initial sample but sensitivities were not yet known. The Microbiologist had advised adding ciprofloxacin therapy.

2.14 Tracie continued unwell on the 25th of October. She was afebrile on the ward round but hypotensive, 95/45. She had spiked temperatures overnight and continued to show an abnormal blood picture. A multi-resistant pseudomonas growth had been cultured, sensitive only to colomycin. Treatment continued with flucloxacillin, tobramycin, ceftazidime, oral ciprofloxacin and nebulised colomycin. The Cystic Fibrosis Registrar at St. Vincent's Hospital was contacted and recommended continuing the same treatment for seven days before considering a change. However, Dr. Foley changed the antibiotic therapy to colomycin 2 mega units twice daily and aztreonam. The antifungal agent itraconozole was introduced to be taken orally. Blood tests remained abnormal although blood clotting values were normal.

2.15 No examination details are given for the 25th. With regard to the abnormal blood tests it was noted that they should be repeated daily until they became normal.

2.16 There is no entry in the records I have seen for the 27th or the 29th. The only entry for the 28th was to document a possible urticarial reaction to the antibiotic aztreonam.

2.17 Throughout Tracie's admission to the 9th of November the clinical records do not document any daily detailed clinical examination.

2.18 On the 30th it was noted that Tracie's blood picture continued to show a pancytopenia and sputum samples continued to culture a multi-resistant pseudomonas. The possibility of aspergillus infection with a febrile neutropenia was raised. Clinical examination showed increased air entry and it was noted that Tracie was clearing her sputum more easily.

2.19 Tracie showed no improvement on the 31st. She remained hypotensive with intermittent spikes of temperature, and oxygen dependent. Blood test results remained abnormal showing significant respiratory and metabolic problems. Her albumin remained low. I have seen no evidence of dietetic intervention.

2.20 No clinical details are recorded for the 1st of November and Tracie's condition continued unchanged. Her blood pressure was not documented. A bronchoscopy was planned.

2.21 On the 2nd of November the possibility of a drug reaction causing her fever was considered as well as a possible infection of the PAC. However, it was documented that there was no evidence of septicaemia. The possibility of invasive aspergillus infection was considered and treatment with ambisone commenced. The full blood count continued to show significant abnormalities. Clotting studies were now also abnormal. The low albumin was noted. The response to this was that Tracie's mother would bring in food. The Physiotherapist documented some haemoptysis.

2.22 The 2nd of November was a Friday. For the 3rd and 4th of November there is no entry in the clinical records apart from documentation of the continued abnormal blood results.

2.23 On the 5th of November it was noted that Tracie continued unwell with a persistent fever despite intravenous therapy with the antibiotics colomycin, aztreonam, tazocin, the antifungal agent ambisone and the oral antibiotic flucloxacillin.

2.24 On the 6th of November it was documented that Tracie remained unwell and continued to have raised temperature with a peak recorded of 38.9. She was

requiring 2.5 litres of supplementary oxygen to maintain her saturation at 97%. She remained hypotensive, 90/54. Her full blood count and blood clotting studies remained abnormal. No further information was obtained from bronchoscopy. No details of her clinical status were recorded. The management plan was to continue the ongoing therapy regimen.

2.25 On the 7th of November there was no change documented in Tracie's clinical condition but no clinical details documented. Her potassium was low at 2.6 and albumin had fallen further to 14. The pseudomonas culture was sensitive only to colomycin. The dose of colomycin was increased to the recommended maximum of 2 mega units three times a day. An abdominal ultrasound was requested. Chest x ray showed increasing left sided consolidation.

2.26 Abdominal ultrasound on the 8th of November showed cirrhosis and an enlarged spleen of 20 cm. CT scan of her chest showed diffuse bronchiectasis with a patchy ground glass appearance suggestive of aspergillus infection and dense consolidation in the right middle lobe. The blood test results were not improved. Nothing else was documented.

2.27 Tracie deteriorated in the early hours of the 9th of November. The Senior House Officer was asked to see her at 04.30 hours as her saturation was 85% on supplement of 2 litres. She had marked crackles in her chest and a raised jugular venous pressure. Blood gas showed a metabolic acidosis with pH 7.287 and pCO_2 4.23. Saturations of 95% only were achieved with 100% oxygen supplement. Tracie was increasingly tachypnoeic. Blood results showed an increasingly abnormal blood clotting, a continuing low potassium, calcium and albumin, and continuing full blood count abnormalities.

2.28 The Senior House Officer requested Registrar review but it appears that the Registrar advised only over the telephone, diagnosing probable cor pulmonale and advising treatment with frusemide (diuretic) and nebulised pulmicort (steroid). Tracie was reviewed by the Team at 09.08 hours and noted to be very sick. On Dr. Foley's ward round she was described as critically ill. The family requested aggressive treatment and at this point transfer to St. Vincent's Hospital was suggested. No beds were available on the morning of the 9th.

2.29 Tracie was reviewed by the Anaesthetist who advised that Tracie would likely be in terminal respiratory failure shortly. Tracie was advised about the risks

and benefits of mechanical ventilation and declined to have this. Home intravenous treatment and palliative care was offered and accepted.

2.30 Tracie died on the 10th of November. The Death Certificate recorded invasive aspergillosis and multi drug resistant pseudomonas infection due to Tracie's immuno-compromised state as a consequence of cystic fibrosis.

3. OPINION

3.1 It is my opinion that Tracie received an inadequate standard of care during her admission from the 22nd of October through to the 9th of November. My reasons for stating this are discussed below.

3.2 During her childhood Tracie had remained generally well. She had moderate cystic fibrosis lung disease. She showed a good response to intensification of therapy with courses of intravenous antibiotic treatment. Although showing increased symptoms around 1999 and respiratory function falling to 49% predicted in December 2000, by June 2007 she was described as well with her respiratory function at 58% predicted. This was described as her baseline measurement.

3.3 As a rule of thumb the criteria for severe cystic fibrosis is a respiratory function value less than 40% predicted, for moderate cystic fibrosis a value of 40% to 75% predicted, and for mild disease a value above 70% predicted. Tracie therefore in June 2007 had moderate cystic fibrosis lung disease. She was also known to have cystic fibrosis associated liver disease with a cirrhotic picture, a large spleen and portal hypertension on ultrasound examination. Her blood picture prior to her admission in October 2007 was consistent with hypersplenism.

3.4 When Tracie was admitted on the 22nd of October nothing in the initial history or examination suggested that she was suffering anything other than a routine pulmonary exacerbation. She had had increased symptoms over the previous two weeks and had not responded to oral antibiotic therapy. She had a low grade temperature and some minor blood streaking of her sputum. Air entry was decreased at the bases and chest x ray showed changes bilaterally but these changes were not gross. She was febrile at 38.5 degrees but had no respiratory distress and her oxygen saturation in air was normal at 97%. The abnormal blood picture showing a low white cell count, neutrophil count and