

Care Standards

The Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care) Rules 2008

Heard on 18 & 19 December 2018 & 10 January 2019 & 20 February 2019 & 3 & 4 April 2019 at the Leeds Magistrates Court
18 April 2019 Panel Deliberation at the Tribunal Centre Manchester

[2018] 3532.EA-MoU

BEFORE

Tribunal Judge - Timothy Thorne
Specialist Member - Mr Michael Flynn
Specialist Member- Dr David Cochran

BETWEEN

Thames Allergy Centre Limited

Appellant

-v-

Care Quality Commission

Respondent

DECISION

The Appeal

1. This is an appeal by Thames Allergy Limited, the Appellant (A) pursuant to section 31 of the Health and Social Care Act against the decision made by a Magistrate on 19th October 2018, to make an order under Section 30 of the Health and Social Care Act 2008 cancelling A's registration

Factual Background

2. A was first registered by the Care Quality Commission (CQC) on 1st October 2010 for the provision of:
 - a. Diagnostic and screening procedures and
 - b. Treatment of disease, disorder or injury.
3. The registered manager is Ms Donna Joanne Paxford. The Airedale Allergy Centre (the "Clinic") was added as a condition of registration on 16th July 2013.

4. A **Focussed Inspection** was undertaken by the CQC on 12th March 2018. This revealed concerns that were set out in a subsequent CQC report which was produced into evidence during the Tribunal Hearing. The concerns are summarised below:

- a. **“Incidents** were recorded in an adverse events book which was stored in the office. Since 2013 there had been five recorded incidents. Two related to incorrect doses of treatments being given. Two related to adverse reaction to treatments and one related to a treatment not being available when a patient attended for their appointment.”
- b. **Environment and equipment** “We looked at a number of sterile items in the treatment room, such as needles and syringes. We found a large number of these to be past their expiry date by as much as nine years. These included; ▪ a butterfly needle which expired in December 2013, ▪ Twelve orange needles which had expired, six in September 2017, ▪ Three orange needles which had expired in May 2014 and a further three in March 2009. A needle which expired in February 2015 ▪ A syringe which expired in December 2016. ▪ We found items in the first aid box had also expired: ▪ This included four bandages which had expired, two expired in March 2014 and two expired in March 2016. • We also found two boxes of plasters which expired in February 2018. This meant these items may no longer be sterile and there may be a risk of infection if they were used.”
- c. “There was no defibrillator on site, as staff would not be expected to use one in an emergency.”
- d. “We saw that the electrical safety testing of all equipment had last taken place in 2013”
- e. **Medicines** “There was a lack of systems, processes and policies in place to support safe management and administration of medicines. For example, we asked how the clinic dealt with medicines alerts, medical device alerts, and other patient safety alerts, such as those issued by the medicines and Healthcare products Regulatory Agency. The registered manager told us the clinic did not receive these alerts. This meant patients could be at risk of harm if they had been given a medicine

or excipient which was subject to a recall or safety alert. An excipient is an additive to a medicine which does not exert any therapeutic effect on the patient.”

- f. “We checked five refrigerators which contained medicines and pharmaceutical excipients and found staff did not monitor temperatures in accordance with national guidance because only the current temperature was recorded. In addition, temperatures were only checked once each week. On the day of our inspection, all five thermometers showed a maximum temperature which was greater than the recommended range for storing medicines, and four thermometers showed a minimum temperature which was lower than the recommended range. This meant we could not be sure medicines and excipients stored in these refrigerators were safe to use.”
- g. “We also found a bottle of benzyl alcohol used to make the vaccines which had expired in 2015, this meant it may not still be safe to use.”
- h. **Records** “We spoke with the clinic nurse who was manufacturing vaccines. The nurse did not keep records of the batch number or expiry date of the excipients they had used to manufacture the vaccines, or details of the batches of vaccines themselves. This meant it would not be possible to identify which patients had received which batch of vaccines in the event of a medicine needing to be recalled.”
- i. **Safeguarding** “We requested training data which showed the nurse last undertook children’s safeguarding training in 2012 and adults training in 2013. The registered manager had last undertaken training in 2013, it was not specified if this was adults or children. We were told the safeguarding training was at a ‘basic level’ and that refresher training was being arranged, however no dates were provided as to when this would be. This meant staff were not up to date and may not recognise a safeguarding concern or know how to manage this.”
- j. “We were concerned about children being treated at the clinic with regards to safeguarding”. The Safeguarding children and young people: roles and competences for health care staff intercollegiate document states that level three training should be undertaken by; ‘all clinical staff working with children, young people and/or their parents/ carers and who

could potentially contribute to assessing, planning, intervening and evaluating the needs of a child or young person'. Level three training had not been undertaken by any staff at the clinic.

- k. **Mandatory training** "Information on training compliance could not be provided as training records were not kept at the clinic. Training data was sent following the inspection....The data showed training was sporadic and inconsistent between all staff members. We were unsure if the training data that was provided to us was a complete record of staff training. ...We were unclear what training was mandatory for staff and how often it was expected to be completed....Fire safety had only been undertaken by one staff member and this had last been done in 2014."
- l. **Assessing and responding to patient risk** "We were not provided with training data in relation to staff training for the management of anaphylaxis. Therefore we were not assured that staff were up to date with the current guidance on how to treat anaphylaxis. This is a potential risk in the management and treatment of allergies. The service did not have a clear process for monitoring patients after treatments to observe for signs of a reaction
- m. **Informed Consent** "We lacked assurance about consent processes; we were concerned that consent was not always sought, and that concerns about patients' capacity to consent to treatment may not be identified or managed in an appropriate way. This was because training was not provided to staff on mental capacity and our discussions with staff showed limited understanding. This meant that there was a risk that patients were potentially receiving treatment they did not fully understand or had not consented to".
- n. **Nursing staffing** "There was one nurse who worked at the clinic. They prepared and administered the vaccines and infusions. We requested training records for this member of staff, these showed the only training provided specific to their clinical role was intravenous and cannulation therapy. This training had been provided by an external firm in July 2016. There was no training specifically on allergy treatments or the manufacturing of vaccines. We therefore lacked assurance about their skills and competence to provide the treatments being given."

- o. “We were particularly concerned about the manufacturing and administering of vaccines. This was not being done in line with regulations and specialist training for the administration of these products had not been undertaken. We were also concerned that there was a lack of systems, processes and guidance for the administration of medicines.”
5. These findings resulted in a **Warning Notice** under Section 29 of the 2008 Act (“the Notice”) being served upon the Appellant by the CQC. The Notice was dated 20 March 2018 and served on the Appellant on 22 March 2018. A was also referred to the Medicines and Healthcare products Regulatory Agency (“MHRA”). A made representations in response to the Notice but a decision not to uphold was taken on 18 May 2018.
6. On 16 October 2018, an announced **Comprehensive Inspection** was undertaken by the CQC. The inspectors on that occasion were:
 - a. Mrs Joanne Cansfield - a CQC inspector
 - b. Mr Kieron Jones - a CQC Pharmacist Specialist
 - c. Ms Lisa Cook – a CQC inspector from the Acute Hospitals Directorate
 - d. Dr John Robert Spain - a GP Specialist advisor the CQC.
7. The findings of this inspection are set out below. As a result of this inspection, the decision was made on 18 October 2018 to cancel the Appellant’s registration pursuant to Section 30 of the 2008 Act, due to the alleged serious risk of harm. A hearing took place at the Leeds Magistrates Court on 19 October 2018 as a result of which a Magistrate cancelled A’s registration.
8. In summary, A denies that there ever was a serious risk of harm at the clinic and in any event reforms have been undertaken which meet all the concerns outlined by the CQC. In addition A claims that they were not given adequate notice of the hearing before the Magistrate and were therefore not able to make representations against such a course of action.

Representation

9. Before the Tribunal, A was represented by Mr David Pojur and the CQC by Mr. Armardeep Dhillon.

Restricted Reporting Order

10. The Tribunal makes a restricted reporting order under Rule 14(1) (a) and (b) of the 2008 Rules, prohibiting the disclosure or publication of any documents or matter likely to lead members of the public to identify the users of the service in this case so as to protect their private lives.

Late Evidence

11. At various stages during the proceedings, the Tribunal was asked to admit additional evidence by the A and the CQC. This consisted of the following:

- a. An Inspection Report on the Burghwood Clinic issued by the CQC relating to an inspection carried out on 14/11/18.
- b. Further witness statements of Dr Econs
- c. Counsel's Attendance Note of the hearing at the Magistrates Court on 19/10/18
- d. Email correspondence relating to the hearing at the Magistrates Court on 19/10/18

12. In relation to all of this new material, the Tribunal applied rule 15 of the Tribunal Procedure (First Tier Tribunal) (Health Education and Social Care Chamber) Rules 2008 and took into account the overriding objective as set out in rule 2 and admitted the late evidence (as and when such applications were made) as it was relevant to the issues in dispute.

The Hearing

13. The Tribunal took into account all the documentary and oral evidence that was presented. The Tribunal heard evidence from a number of witnesses on behalf of the Respondent and Appellant. The following is a precis only of what was said.

14. The Tribunal first heard oral evidence from **Mrs Joanne Cansfield**, the CQC inspector from the West Yorkshire Team. She adopted her witness statements which indicated that she was a registered nurse took part in the inspection of the clinic on 16th October 2018. Her statement recorded the following concerns which she and her colleagues identified:

- i. The vaccine preparation room was accessible to patients. It was not locked
- ii. The vaccines were not locked away
- iii. Morphine and Fentanyl, (controlled substances under the Misuse of Drugs Act 1971), were present and not subject to the mandatory checks required;
- iv. Clopixol was found that had expired in 2013;
- v. Fluanxol was found that had expired in 2016;
- vi. A number of sterile items within the clinic, including syringes, had expired;
- vii. Labels on other medicines had expired and appeared to be tainted with mould;
- viii. A's employees did not take emergency medicines or oxygen to home visits for treatment;
- ix. There was no defibrillator on the premises;
- x. It was not clear that the Appellant had a system to receive MHRA, and other safety alerts;
- xi. There was no evidence that staff had had the relevant safeguarding training, especially in relation to children;
- xii. There was no up to date Fire Risk Assessment, nor was there a fire alarm system;
- xiii. There were no checks on smoke alarms or the emergency lighting;
- xiv. There were no checks on the water system;
- xv. The refrigerators used to store solutions and vaccines were consistently out of temperature range;
- xvi. There was no evidence that proper cross-infection control systems were in place, both in relation to the preparation of vaccines and in relation to general hygiene, including the cleaning of the fridges;
- xvii. There was not always a medical doctor on the premises to support the nurse when preparing vaccines and administering solutions;
- xviii. There was a mercury sphygmomanometer on the premises

without the necessary kit to deal with breakage.

- xix. There were no records to show that the Appellant had ensured that staff were fit to practice and work, including the locum nurse present; and
- xx. The Indemnity insurance did not cover the manufacture of vaccines and was limited to £1,000,000.

15. All of these deficiencies were included in a CQC report dated 16th October 2018 which was served on the Appellant. The Appellant did not submit a response questioning the factual accuracy of any of the findings.

16. In cross examination she gave further details of her involvement with the Management Review Meeting (MRM) held on 18/10/18 and why they sought to pursue Section 30 closure. She also outlined her efforts to inform Dr Econs of the hearing at the Leeds Magistrates Court. She was shown an email exchange between the CQC and Dr. Econs. An agreed chronology of emails relevant to this issue was produced and appears at **Appendix 1** of this decision. She explained that the first email giving notice of the hearing was sent to the registered manager as that was the contact details specified by A and was the one she always used to contact A.

17. She said that she could not remember when she found out the exact time and court room that the hearing was due to take place in. She said that “we made every effort” to tell A as soon as they knew. She said that she “had not done a section 30 case before.” She said that she gave evidence before the magistrate and the hearing was listed at 2pm and took about 40 to 45 minutes.

18. The panel was also shown a copy of the CQC’s Counsel’s Attendance Note of the hearing at the Magistrates Court on 19/10/18 and it appears at **Appendix 2** of this decision.

19. In cross examination it was put to Ms. Cansfield that all the concerns raised by the CQC had now been complied with. She said that she did not know as no further inspections had been conducted as the clinic was not operating.

20. She was shown the following documents:

- a. Fire risk assessment dated 08/02/16 (p347) which she said was out of date but did refer to electrical checks in 2018.
- b. a Legionella Risk Assessment (p.361). She said that they were not available at the inspection and when she spoke to Ms. Paxford she said that there was no legionella risk assessment. However she accepted that it existed now.
- c. Cleaners Schedule (p356). She said that they were not available at the inspection and when she spoke to Ms. Paxford she said that the cleaner had taken them home. However she accepted that it existed now.
- d. Patients Questionnaire (p363) which she said appeared adequate.

21. The Tribunal next heard oral evidence from **Lisa Cook** who adopted her witness statement that indicated she was a CQC inspector from the Acute Hospitals Directorate. She attended the 1st inspection on 12th March 2018 and stated that there was a lack of policies and procedures to support safe medicine management and how the clinic responded to patient risk. In addition sterile equipment was found that was past its expiry dates. A warning notice was issued with a date of expected compliance set for 30th April 2018.

22. She also attended the 2nd inspection on 16th October 2018. Her findings can be summarised as follows :

- a. Glass vials were not locked away in the kitchen next to the treatment room.
- b. There were 6 vials of 20% potassium chloride in the kitchen not locked away.
- c. 13 boxes of phosphate dicoline were stored in the fridge in the kitchen. The instructions were not in English and the nurse working in the clinic did not know what it was.
- d. The fridge contained magnesium chloride which had expired on 11/04/18
- e. The fridge contained insulin which had expired on 12/05/18
- f. The fridge contained a box of 20 vials of potassium chloride.
- g. Downstairs on a trolley was a suction tube out of its sterile packaging.
- h. In the vaccine preparation room was an over-filled sharps container

- i. A fridge in the treatment room contained 4 vaccines that had labels indicating they were past their expiry date.
- j. A fridge in the treatment room contained 4 vaccines that had torn labels so that their expiry date could not be seen.
- k. A fridge in the treatment room contained 6 vaccines that had labels that were completely illegible.
- l. A fridge in the treatment room contained vials of morphine and fentanyl with labels stating they had been made on 12 September 2016. The room and the fridge were not locked.

23. In cross examination it was put to her that all the concerns raised by the CQC had now been complied with. She said that she did not know as no further inspections had been conducted as the clinic was not operating.

24. She also said that she had a conversation with the members of staff who were present about the processes followed by the clinic. Dr. Econs was not present. She said that the concerns of the CQC were with the systems and processes of how the vaccines were administered and not the underlying science behind the vaccines.

25. The Tribunal next heard oral evidence from **Mr Kieron Jones**, the CQC Pharmacist Specialist, who adopted his statement in which he recorded the following concerns identified during the inspection on 16th October 2018:

- i. There were no standard operating procedures for the manufacture of vaccines;
- ii. There was no evidence that staff had been properly trained in the preparation of vaccines;
- iii. There were no quality control processes in place to ensure the sterility of the vaccines prepared;
- iv. There were out of date stock solutions, which were being used to prepare vaccines;
- v. No scientific justification has been provided to support the Appellant's contention that the vaccines were safe as a result of the glycerine utilised;
- vi. There was no record keeping in relation to the preparation of the

vaccines, such as batch numbers used and administered to patients;

- vii. Controlled drugs, Morphine and Fentanyl, were stored on the premises in unlocked and unsupervised rooms;
- viii. Concentrated potassium chloride supplies were present, which was the subject of a national patient safety alert in 2002; and
- ix. There were not proper processes in place to protect vulnerable patients, including children, with relation to identification and confirmation of parental responsibility.

26. In cross examination it was put to him that all the concerns raised by the CQC had now been complied with. He said that he did not know as no further inspections had been conducted as the clinic was not operating. However he accepted that the risks arising from the mercury blood pressure monitor had now been mitigated.

27. He was cross examined in detail about his qualifications and experience. He confirmed that he was a practicing pharmacist with a Master's in Pharmacy and a post graduate diploma in clinical pharmacy. He said that he had experience of making vaccines and understood the scientific basis behind the vaccines. He accepted that he had not personally made the type of low dose immunity (LDI) vaccines that Dr. Econs made but he had dealt with similar clinics as a regulator.

28. He accepted that normally LDI vaccines carried a low risk of allergic reaction and carried little risk generally but only if prepared and produced correctly with appropriate sterile conditions.

29. He said that glycerine and benzyl-alcohol can inhibit the growth of bacteria but how long it preserves the vaccines depended on a number of factors including how it was prepared and stored, the nature of the ingredients. In addition the preservative properties of the glycerine and benzyl-alcohol reduces over time. That was why the vaccines had expiry dates. He was asked about the Allergen Immunotherapy Extract Preparation Manual produced in the USA (Exhibit KJ01). He said that the US document dealt with the same sort of vaccines produced by Dr. Econs i.e. serial dilutions at p129 of the exhibit and it

recommended that such vaccines should be used within 6 years.

30. He said that the process used by Dr. Econs was that the drug or ingredient is mixed and turned into a concentrate solution and then diluted in a series of steps, but there was no way of knowing how much weaker it was than the original substance. He said that the clinic's documentation contained the process for making dilutions but not concentrates. He said that in addition the instructions produced by the clinic were unclear and appeared to relate to inhalants only. It was not possible by referring to the document to work out how much weaker each dilution was than the original substance. He did not know if concentrates had longer expiry dates than dilutions. He knew of no evidence which indicated that vaccines only expired after 20 years as claimed by Dr. Econs.
31. He said that the vaccines were not licenced medicines and that therefore no prescription standards applied. With repeated dilutions the risk of anaphylactic shock reduced but the risk of contamination increased with every dilution. That was why a thorough system of sterilisation and cleanliness was so important.
32. He also said that there were inadequate records of batch numbers for the ingredients so that if there was a manufacturing recall the clinic would be unable to identify which patients had had which batch.
33. In relation to the potassium chloride it was suggested that it was only on the premises because a patient wanted it for a particular purpose and the patient was well qualified to assess the risk to himself. The witness replied that it was incumbent on the doctor prescribing and administering substances to ensure they are safe and not for patients to decide what is safe for them. He said that the presence of undiluted potassium chloride constituted a serious risk to patients and that was why a NHS safety alert had been issued.
34. He produced a copy of the relevant **NHS safety alert** which had been issued on 23/07/02 and remains in force. The relevant parts read as follows: "*Research in UK and elsewhere has identified a risk to patients from errors occurring during intravenous administration of potassium solutions. Potassium chloride*

concentrate solution can be fatal if given inappropriately.

1.1 Potassium chloride concentrate solutions should be restricted to pharmacy departments and to those critical care areas where the concentrated solutions are needed for urgent use. Potassium chloride concentrate and other strong potassium solutions should be removed from routine stock in wards and clinical departments.

1.2 Potassium chloride concentrate solutions should be stored in a separate locked cupboard away from common diluting solutions such as sodium chloride (normal saline) solution.

1.3 Potassium chloride concentrate solutions should not be transferred between clinical areas. All supplies should be made directly from the pharmacy department. Documentation should follow the pattern for controlled drugs and should record the requisition, supply, receipt and administration of potassium chloride concentrate solution.

2.1 Commercially prepared ready to use diluted solutions containing potassium should be used wherever possible.

4.1 A second practitioner should always check for correct product, dosage dilution, mixing and labelling during the preparation of and again prior to intravenous administration of solutions prepared from potassium chloride concentrate and other strong potassium solutions

5.1 Risks associated with the storage, prescribing, preparation and administration of potassium chloride concentrate should be highlighted in patient safety induction training for all staff involved in the medication process and should also feature in specific training in intravenous drug preparation and administration. This includes induction schemes for locum staff.”

35. Mr. Jones also said that he also reviewed the medical notes of “patient X” at pages 189 to 191 and was concerned that Dr. Econs had not undertaken an adequate mental capacity assessment. He denied the suggestion that he had misled the magistrate about this.

36. In patient X’s medical notes, it was recorded that on 11/07/17, the patient had attended the clinic “to neutralise troublesome chemicals [but] did not seem aware of why she was here, very vague. Demonstrated adequate self-injecting

technique". There was further records of testing on her and then on 26/09/18, it was recorded that she had told her other doctors about her problems but they did not believe her and wrongly ascribed it to mental health problems. Dr. Econs recommended further LDI treatment and recorded, "sounded coherent with no delusional ideation."

37. The panel also saw correspondence between Dr Econs and patient X's GP. Dr. Econs wrote to the GP on 16/06/17. In a letter dated 23/06/17 the GP informed Dr Econs that patient X had failed to disclose to Dr Econs that she was suffering from Bipolar Affective Disorder and was not complying with her anti-psychotic medication. She was under the care of the community mental health team "who are trying to safeguard her against over testing." On 21/09/17 Dr. Econs wrote to the GP saying that he was carrying on with LDI testing and treatment and that patient X was responding well.

38. The Tribunal next heard oral evidence from **David Ross** the CQC Inspection Manager, who adopted his statement in which he explained the inspection methodology adopted by the CQC and its enforcement policy. This was supported by a "Decision Tree" which was "a 4 stage structured decision making process which drives consistency and proportionality when considering enforcement action against a provider".

39. In evidence in chief and in cross examination he gave further details of his involvement with the Management Review Meeting (MRM) held on 18/10/18 and why they sought to pursue Section 30 closure. He explained in detail during his evidence why the CQC had decided that urgent cancellation was necessary in this case as opposed to the alternatives of urgent suspension or the urgent imposition of conditions. He explained that in light of all the findings of the inspectors he had concluded that "patients were at serious risk of harm if CQC did not cancel registration."

40. He also outlined the efforts to inform A and Dr Econs of the hearing at the Leeds Magistrates Court. He was shown an email exchange between the CQC and the Clinic and Dr Econs which is referred to at Appendix 1 of this decision.

41. The Tribunal next heard oral evidence from **Beverley Cole** the CQC Head of Inspection, who adopted her statement in which she said that she was a registered Nurse and had 14 years of regulatory experience. She explained how the “Decision Tree” worked and the details of her involvement with the Management Review Meeting (MRM) held on 18/10/18 and why she had decided that urgent cancellation was necessary in this case as opposed to the alternatives of urgent suspension or the urgent imposition of conditions.
42. In oral evidence she was shown the Inspection Report on the Burghwood Clinic issued by the CQC relating to an inspection carried out on 14/11/18. Dr. Econs owned that clinic. The report indicated that the clinic was providing safe, effective, caring and responsive services but that “this service was not providing well-led care in accordance with relevant regulations.”
43. She was asked to comment on the report and said, “I’ve seen many times when a provider has more than one location and the clinics are very different. Sometimes they fail to meet regulations on one location but can in others.” She added that the findings in relation to the Burghwood clinic have “no bearing on our decision. We didn’t know of this report until after we made our decision about [A]. This is something we see on a regular basis. It all depends on staff and the registered manager.
44. She was cross examined at length about why she had decided that urgent cancellation was necessary as opposed to the alternatives of urgent suspension or the urgent imposition of conditions. She explained that it was a group decision but she had “signed off on it.” She reiterated that the Decision Tree was followed and A’s past history, failure to comply with regulations despite warnings, the number and seriousness of the breaches and the dismissive attitude of the provider towards the regulations were all taken into account. She also explained that the maximum time for a suspension was between 3 and 6 months and the CQC did not believe that A “would be able to turn it around in time.” She further explained that they concluded that conditions were not appropriate because “there were too many of them and it wouldn’t be possible for [A] to meet them.” The risk to patients was paramount.

45. She was also asked about the efforts to inform Dr Econs of the hearing at the Leeds Magistrates Court and was shown the email exchange between the CQC and Dr. Econs which is referred to at Appendix 1 of this decision.
46. In addition she was asked whether she understood the nature of the treatment provided by A. She said, “I am aware of the highly specialised nature of the services.” She also said, “We don’t have a problem with the treatment, it’s all the things around it.”
47. The Tribunal then heard evidence from **Dr. Appelles Econs** who adopted his witness statements and indicated that he was the sole director of A which operates the Clinic. When it operated he attended the clinic 2 days a fortnight. The other members of his team were:
- a. Dr. Alisa Care – Associate Consultant
 - b. Donna Paxford – Administrator & Registered Manager.
 - c. Ky Clarke – Allergy Nurse
 - d. Hazel Econs – Communications Marketing Director.
48. He explained that the treatments offered by the Clinic “are forms of immunotherapy including low dose immunotherapy, intravenous infusions which are comprised mainly of nutrients and occasionally drugs. The treatments are not available to patients on the NHS.”
49. Dr. Econs evidence in chief and cross examination can be summarised under the following headings:
50. **Production of Vaccines** In his witness statement he stated that “Airedale has been in operation for approximately 40 years. Our safety record is exceptional and no serious adverse events have ever occurred. The method used to produce the vaccines was first put to extensive use in the early 1980s when Airedale was the only 'Environmental Medical Unit' in Western Europe and most of its work was funded by the NHS. The method was established by the previous director, Dr Jonathan Maberly (Consultant Respiratory Physician). This type of vaccine has been used by over 30 million people, mainly in the USA, since the 1980s. The methodology for producing the vaccines has remained

totally unchanged throughout this period and I provided in-house training to my nurse, Ky Clarke, when she joined the clinic. The production of vaccines is a very simple process but it is important to ensure that the nurse understands the theory and practical implications....[T]he vaccines are low dose which means that they are very weak and incapable of causing a severe reaction.” He expanded upon the process in his examination in chief and said that because the solutions were so diluted there was only “negligible risk” to patients. The patients were given the heavily diluted finished product to take home and self-administer. He said that the dilutions lasted for 3 months. He added that the process of producing the vaccines was so simple that “we can teach a 12 year old child in minutes how to do it as long as they are numerate.”

51. In cross examination It was put to him that the March 2018 inspection highlighted problems with the production of vaccines. He replied, “I don’t accept this. It was based on assumptions that we were using a different form of immunotherapy.....I don’t think that Mr. Jones understood.” He added “I don’t accept these are valid concerns.” It was put to him that he did not have standard operating procedures for the manufacture of vaccines. He replied, “I don’t need them, but in 40 years we have used a standard process.” He added that there were instructions on the noticeboard which he alleged Mr. Jones didn’t take any notice of. It was put to him that the claim that there were instructions on the noticeboard was not in his witness statement. He replied, “Why should it be? The CQC were talking about a different type of immunotherapy and I couldn’t get it through to them.” He also said that the “standard operating procedures don’t apply to us.”

52. He also said in cross examination that Mr. Jones “doesn’t understand the process of low dose immunotherapy. He was clueless about what he was inspecting.”

53. In re-examination he said that now the clinic kept “full records of all the food and inhalant and the dilutions and a record for the concentrate.”

54. **Sterility of vaccines** In his witness statement he stated that “in relation to the long expiry dates where glycerine and benzyl alcohol are concerned, I attach

two studies at [AE12]. The GILL study shows that the allergenicity of concentrates made up of glycerine protects them against infections. Glycerine has antibacterial risks of close to zero. In addition, we also add benzyl alcohol as a double protection against infection and so we can give this an expiry date of 20 years. For subsequent dilutions, we add additional benzyl alcohol as a further single protection.”

55. In cross examination he was asked about the Allergen Immunotherapy Extract Preparation Manual produced in the USA (Exhibit KJ01) which recommended that such vaccines should be used within 6 years. Dr. Econs refused to accept the findings of the report saying that he believed that vaccines could be used for 20 years. He added that the manual only referred to the FDA and conventional immunotherapy. “I rely on my experience and feedback from patients” he said.

56. He said that as a doctor “I can prescribe anything I deem appropriate for my patients even if its potatoes or cucumbers without any issues about sterility or efficacy.” He added that the “bacteriostatic properties of glycerine and benzyl-alcohol minimizes the risk of contaminants building up in the concentrate” but he then said, “There is no food that is devoid of bacteria” and “we say it’s safe, we don’t say its sterile” and “they are safe for 20 years. I didn’t say they were sterile for 20 years.”

57. He was asked whether he had any scientific justification for what he was saying and replied, “I don’t need any. It’s my experience that counts. I have a unique approach and we treat people not helped by conventional medicine. I think the CQC have difficulty with the science behind our treatments.” He was later again asked whether he had any scientific proof for his claim that vaccines could be used for 20 years. He said, “I don’t have to prove it.” He also said that he sent evidence to the CQC which they never read. In re-examination he said that “I submitted 38 studies to the CQC because they didn’t understand what they were inspecting.”

58. He added that “we are now in the process of doing sterility testing on concentrates. We used to do random tests and mostly they were OK. We check when we suspect that concentrates are non-sterile.” He later said that “we only

tested rarely. This is unlicensed medicine. Therefore I don't have to test vaccines for sterility." In re-examination he said that it was impossible to be sterile when dealing with foods and "I am allowed to do what I think is in the patient's best interest."

59. He was asked why the clinic was not able to produce an infection control policy for the October 2018 inspection. He replied, "This information was available. It's not my problem that the inspectors didn't see it."

60. **Quality Control & Expired products** He also said in his witness statement that "the vaccines pose no serious risk to the life, health or wellbeing of patients because they contain highly diluted allergens" and "Ky Clarke had been manufacturing the vaccines, [and] she had been doing so in accordance with a detailed guidance document which had been produced internally within Airedale. A copy of this document has been enclosed at [AE1]. He added that "We have amended our procedures in light of the MHRA guidance and a doctor will administer vaccines at Airedale going forward, subject to the outcome of this process."

61. In addition, in his witness statement Dr. Econs added: "The deficiencies found in quality control processes were the result of the inspectors being confused between concentrates and dilutions. Concentrates usually have expiry dates of 20 years and they are secured by the presence of glycerine as an anti-contaminant and to conserve allergenicity and benzyl-alcohol to secure their integrity against contaminants in dilutions which contain less glycerine. Dilutions are produced using a small amount of the concentrate which is - as the name suggests - repeatedly diluted. Dilutions are given a shorter shelf life as when they are sent to patients, they will not be kept at controlled temperatures as they are at Airedale and so we recommend that the dilutions should be used within 3 months."

62. In cross examination he accepted that inspectors had found a bottle of benzyl-alcohol that had expired in 2015, however he did not accept that using it in the production of the vaccines was unsafe. He said, "I don't accept its not effective after the expiry date. It can remain potent like old wines" but then added, "expiry

dates are given by the manufacturers. I don't know if we were using it. We have now sorted it out....I don't think it loses potency. I don't dispute there needs to be expiry dates."

63. He also accepted that an amount of other expired material were found by the inspectors. His explanation was: "We have rectified that all 100%. We were overworked and struggling with the amount of regulations we had to meet." He added that "We had been naïve that what we had done for years" was acceptable. He later added that "Our ignorance or lack of guidance was the problem."

64. It was put to him that there were inadequate records concerning the batch numbers and prescriptions relating to each vaccine. He said that "they were available but the inspectors didn't ask for them." It was pointed out that this was not correct and he responded by saying "I am a doctor entitled to produce unlicensed medicines. Therefore I don't need to keep records." He added "There is no risk because we are providing dilutions. The risks in my job are negligible. There were no fatalities. There is no harm to the public." He went onto say "The CQC can concentrate on auditing but they should make allowances for our set up where there has been decades of absence of harm, and now I have to defend myself about negligible harm."

65. He was asked about audits in the clinic and said that "I accept that they were not done as they should have been done". He later said, "they were partly done but not available."

66. He was asked about the lack of training provided for the nurse who made the vaccines and he explained, "there is no training for this sort of immune therapy in the western world. There is no authority that can train someone to do this kind of dilution." He also said that the process used at his clinic does not require "high sterility and training."

67. He was asked about the Clopixol found that had expired in 2013 and the Fluanxol found that had expired in 2016. He said, "We had no reason to have it." Then he said "Yes we have a reason. The NHS sometimes ask us to prepare vaccines to provide such dilutions to de-sensitise patients." It was pointed out

that these two items were not diluted. He replied, “No. That was an omission on my part.” He later said, “they were forgotten.” It was put to him that he could not explain why he was storing medicines at the clinic. He replied, “I can explain most of it most of the time.”

68. He was also asked about why the fridge contained magnesium chloride which had expired on 11/04/18 and insulin which had expired on 12/05/18. He replied, “that was an oversight.” He was asked why the clinic was storing insulin at all. He replied, “I don’t know. There must have been a reason.”

69. He accepted that by October 2018 the clinic still did not have a system in place to deal with expired drugs. It was put to him that having expired drugs at the clinic was a risk to patients. He disagreed saying, “it is highly unlikely that this would happen...we have 2 people checking these things when they are used. This is the system now, since October 2018”. He was asked why the clinic did not have a such a system in place before and he said, “I relied on my staff to do it.”

70. It was also pointed out to him that in the March inspection a number of pieces of expired equipment was found that were still present at the time of the October inspection. He said, “I agree they shouldn’t be there.” He added, “that was a great omission by my staff. We have now taken all the necessary steps.”

71. He accepted that the fridges in the clinic were found to be out of range during the March inspection and were still out of range at the October inspection. He agreed that it should have been remedied earlier. However he did not accept that there was mould on some of the labels on products in the fridges. He said, “sometimes labels are discoloured, that’s common.”

72. He was asked about the 13 boxes of Phosphatidyl Chlorine which were stored in the fridge in the kitchen and why the instructions were not in English and the nurse working in the clinic did not know what it was. He said it was a nutrient and he had translated the instructions into English. It was impossible to buy it in the UK, only in the USA, Ukraine or Russia. He was asked where he got it from and said, “Not on Ali Baba.....we buy it from reputable dealers.” He added “I knew what it was. I don’t know why my staff did not. They use it on a weekly

basis. They should know what it is”

73. He was asked about the 4 vaccines that had torn labels so that their expiry date could not be seen and the 6 vaccines that had labels that were completely illegible found in the fridge in the treatment room. He said, “I don’t know about this. There are a number of possibilities.” It was put to him that there was no excuse for this. He replied, “It depends if they were meant to be sent some time ago.” He added, “It’s an oversight by my staff. It shouldn’t be there but unlicensed medicines are exempt from regulations.”

74. It was put to him that the problems with the clinic were systemic. He replied, “There were problems but not systemic. The CQC find it hard to understand that some clinics have low risk. They have invented and magnified risks and we have learnt from this.”

75. **Management of controlled drugs** In his witness statement he made no mention of fentanyl found at the clinic but in relation to the morphine he stated that “The substance in question was morphine which had been diluted 100 times. This is not the same as morphine in its non-diluted form. It had been procured for a patient to help them tolerate some medication and it was the first and only time the solution had been kept on the premises.....The CQC inspector’s claim that this posed a serious risk to life, health and wellbeing of patients is grossly exaggerated. The dilutions contained within the fridges are extremely low risk.”

76. In examination in chief he said that “the controlled drugs entered my clinic as the result of a request by an anaesthetist colleague who was about to take a patient who had multiple chemical sensitivity.....We sent vials containing saline and someone at the Morecombe Hospital, I can’t remember names, added a small amount of the drugs into the saline. We used it as an extract for serial dilution for testing.” He said that there was no risk to patients because the drugs had been so diluted that “they lose their pharmacological value and are likely to lose their street value.”

77. In cross examination he was asked if there were any prescriptions or other

records from the hospital concerning the controlled drugs. He said there was email correspondence but none was produced. He said “it was not an illegal obtaining. The anaesthetist knew.” Dr. Econs said that he did not believe the fentanyl and morphine were still controlled drugs after they had been diluted.

78. He was asked how the drugs were transported to his clinic and he said, “I don’t know I’m not cognisant of every detail.” He later said that it might have been brought to the clinic by the patient “or a spouse. I can’t remember.” He said that he had no register or record of the drugs. He said that he did not need to because “we only deal with dilutions.”

79. He was asked whether he accepted that having controlled drugs in unlocked premises constituted a risk. He said, “No. They are dilutions not pure medications. It is ridiculous that anyone would come to harm if they touched my vaccines.” He was asked what proportion of the drugs were in the saline dilution and he said, “I can’t be specific.” In response to questions from the panel he said “all these things happened under a lot of pressure. I assumed standard concentrations were used.”

80. In re-examination he said that he was sure the dilutions of the controlled drugs were “below pharmacological effect.” He was also asked if the vaccination room was now always locked and he replied, “yes, to deal with the exaggerated concerns of the CQC.” He then added that the “fridges are not locked but the room is.” Arrangements were made to destroy the drugs but they were still there on the premises for evidential reasons.

81. **Concentrated potassium chloride solutions & Patient Safety Alerts** In his witness statement he stated that “Potassium Chloride was administered to one patient who had difficulty dealing with sulphur and sulphur containing compounds. We do not normally deal with Potassium Chloride however, the patient had specifically requested that we use it.....The patient in question has a first class honours degree in chemistry and a PhD in chemistry with a specialist field of organic synthetic chemistry. He had also worked as a forensic toxicologist for 8 years and so was very familiar with sulphates. The ordinary dilution of Potassium Chloride in line with BNF or NICE guidance is 50 – 70

times. However, in this particular instance it was diluted 200 times and so the likelihood of harm arising was extremely low.”

82. In cross examination he said that he accepted that at the time of the October inspection the registered manager of the clinic did not receive Patient Safety Alerts but he did. He did not think it necessary to pass them onto the registered manager because 95% of them had nothing to do with the clinic.

83. He accepted that the Potassium Chloride was kept next to the substances used to make the vaccines. He was asked whether he accepted that this was not in accordance with the relevant Patient Safety Alert. He said “yes, but I relied on guidance by NICE & BNF. They didn’t raise the need for separate storage. The CQC inspector didn’t bother looking at it he just made a sweeping statement.” It was put to him that storing the substance in this way could cause a problem and he responded by asking counsel a rhetorical question: “explain to me how this can harm patients?” It was put to him that an accidental injection could occur. He said, “I don’t accept this could happen.” He was asked whether he accepted that the relevant Patient Safety Alert applied to his clinic. He said, “yes but you can’t confuse them unless you are blind.” He later said that the accidental injection of the Potassium Chloride was “very unlikely” and there would only be a risk if “someone did it on purpose.” He later said, “I know damn well how to use Potassium Chloride.”

84. In re-examination he said that “99.9% of alerts are irrelevant to my work and I was surprised that I was chastised that I was receiving them but not my registered manager.” The registered manager now did receive them he said.

85. **Patient X** In his witness statement he stated that “The patient had a history of depression because nobody believed her that she was chemically sensitive. The CQC failed to point out that fact. In accordance with the General Medical Council's guidance for communicating with colleagues, (Exhibit [AE2]), I contacted the patient's GP and explained the condition of Multiple Chemical Sensitivity to them. It is an extremely frustrating condition which can lead to patients becoming withdrawn and depressed and so being treated by psychiatrists with psychotropic medications which fail to address the underlying

problem can exacerbate the patient's condition.....I had also made a note to say that the patient was coherent and not delusional and I assessed that she did have capacity to consent to treatment.”

86. In cross examination he defended his decision to continue treating patient X by saying, “she had the classic history of a psychiatrist not believing her. Therefore accepting at face value what was said is like me not doing my duty to my patient.” He added that he did not have to have permission from the GP to continue treatment and “none of the treatment we offer would undermine her psychiatric treatment.”

87. It was put to him that he never made a mental capacity assessment of patient X. He said that “it was sufficient in the circumstances” and added, “I am not a psychiatrist.” He later said that she had been “fobbed off by the NHS. If that’s failure to provide consent then this is totally misguided as my duty is to the patient.”

88. In re-examination he said that he could see no risk in how he treated patient X. He added, “I don’t believe it was a figment of her imagination.” He was asked whether the treatment was effective and he replied, “she said so.”

89. **Safeguarding patients, including children** In his witness statement he stated that “Staff training has now all been refreshed.....In addition, the Clinic's identification procedures have been updated so that patients will be asked for identification documents or proof of guardianship in respect of children prior to treatment being commenced..... Staff training has been updated with the exception that I will be completing my Fire Safety training, Infection Control and Children Level 3 refresher training this weekend (8-9 December 2018).”

90. In cross examination when the lack of training for staff was put to him he said “It’s ridiculous for the CQC inspector to tell me that my nurse is a danger to the public or is a child abuser. It is unacceptable for the CQC to say this just because she hadn’t had training for 3 years.”

91. He admitted there were gaps in staff training but insisted that his own training was up to date. It was put to him that he was unable to provide the inspectors with documentary evidence of this and he explained, “they were in my other clinic and they did not ask me to provide them.” He was asked why he had never said that before and why they had not still been provided today. He replied, “Its straight forward to comply with these gaps and we meet the standards.”
92. In relation to the need for staff training he later said “I now know they are almost mandatory. Training before was optional and periodic. This is all new to me.” He later said, “It has now dawned on me that the inspectors have looked at everything.” He also said that “my nurse, she didn’t need particular training because vaccines are not dangerous.”
93. It was put to him that he only had his safeguarding children training in December 2018, and he had no valid certification at the time of the last CQC inspection. He agreed but said, “there were some lapses, but I’m not sure how that makes me a dangerous person to the public.” He later said, “My safeguarding certificate had expired in August but that didn’t mean I was a danger to the public.”
94. He was asked about the fact that in the March 2018 inspection it was discovered that the vaccine preparation room was accessible to patients as it was not locked and the vaccines were not locked away. He replied, “they didn’t need to be.” He said that although the room had a lock and within it were lockable cupboards, the locks were never used because the vaccines were harmless. He said, “It is unthinkable that a child or adult would come to harm.” He added, “We now lock everything” but also said, “But I can’t see how vaccines are dangerous.”
95. It was put to him that checking staff history and carrying out DBS checks was vital and he was asked why no checks were done in relation to the locum nurse employed by the clinic. He said, “the field of our work is very specialised. I know the nurse very well. Yes for the sake of the inspections it was an omission on my part but we are splitting hairs.” He added, “I knew the level of her skills and I trusted her. Your talking tick boxes.” He said that he only became aware recently of the need to undertake DBS checks.
96. **Steps taken by Airedale after the March 2018 Inspection** In his witness

statement he stated that the following steps were taken:

- a. "With regard to the refrigerators, we commenced monitoring of the temperatures on a daily basis, on working days, and this is now logged".
- b. "The emergency trolley was reviewed and is now inspected on a monthly basis along with the general solutions, dilutions and medical equipment".
- c. "expiry dates on the medicines and medical equipment are reviewed"
- d. "In relation to the room containing the vaccines, whilst it has always been lockable using a key, it is admitted that previously it was often left open. The solutions contained within the room are all extremely diluted and it is denied that they would cause any harm to the health and wellbeing of our patients. However, a coded lock has been obtained in order to ensure that the room is always secure."

97. Steps taken by Airedale after the October 2018 Inspection In his witness statement he stated that the following steps were taken:

- a. A Fire Risk Assessment was completed by our Practice Manager. The smoke alarms in the building are checked on a monthly basis and the tests are logged."
- b. The instruments at the Clinic have all been calibrated by an external provider"
- c. "The mercury monitor is currently still on site and we have contacted a specialist and arranged for it to be safely disposed of."
- d. "A formal schedule is in place for the cleaning regime at the Clinic.....The products used need to be suitable for our chemically sensitive patients and so harsh products cannot be used at the clinic."
- e. "Staff training has been updated with the exception that I will be completing my Fire Safety training, Infection Control and Children Level 3 refresher training this weekend (8-9 December 2018)."
- f. "A Legionella risk assessment has been produced"
- g. "An updated medical questionnaire has been produced".
- h. "We have also changed our consent forms so that the patients have to have their capacity checked during each attendance at the clinic.
- i. "Dispensing labels have been updated"
- j. "audits have been carried out on patients who are undergoing Low Dose

Immunotherapy treatments to ensure patient satisfaction. A copy of the most recent audit has been attached at [AE11].”

- k. “In respect of sterility tests, a local NHS Laboratory has been contacted in order to undertake these tests”
- l. “In terms of safeguarding and in particular safeguarding children, we intend to ask for proof of ID and for proof of legal guardianship of any children attending the clinic or attending a Skype consultation”.

98. In cross examination it was put to him that by the October 2018 inspection the clinic had still not rectified all the problems identified in the March 2018 inspection. He said, “Yes, I accept that” but added, “we had the view that our processes were safe, especially compared to all other medical set ups. We felt we could withstand the scrutiny. Our safety record is impeccable.” He later explained, “We didn’t expect this harsh analytical scrutiny; it’s the most I’ve had in my career.....We had no experience of how detailed the inspections would be.” He also said “We felt that the CQC were referring to the wrong treatment. I disagreed with what they said.”

99. It was put to him that he was not keeping up to date with the relevant regulations set by the CQC and the MHRA. He replied, “The regulations have changed since I started producing compounds.” He added, “This treatment is to help patients. This is hindered by the complexity of the regulations that happen to exist at the moment.”

100. He later said, “the regulations take a university degree to go through. I didn’t know everything. There was only a remote risk of harm.”

101. In cross examination he was also asked about the general cleanliness of the clinic. He said that “you don’t need to sterilise. I was amazed at how ignorant the CQC inspectors were about our air filters. The floor is taken care of by vinegar and bicarbonate.” It was pointed out to him that he had never mentioned the air filters before. He replied, “I didn’t think I had to bring it the attention of the CQC.” He added, “I don’t have to provide a sterilised environment.” It was put to him that if the environment is not clean there would be a serious risk to patients. He replied, “If it was there would have been a

number of deaths.” He was asked if that was how he gauged it and he replied, “no, it’s on the basis of feedback from patients.”

102. **Insurance** In cross examination he was asked why the clinic did not have insurance for manufacturing the vaccines. He replied, “It was low dose immunotherapy. I don’t accept that insurance of that level was necessary. I don’t accept that my indemnity did not cover the manufacture of vaccines because we were producing unlicensed medicines”.

103. **EPD Audit & Consent forms** In cross examination he was asked about the Audit Review of Enzyme Potentiated Desensitisation (EPD) dated November 2018 produced by the clinic to show compliance now. He said that the audit went back many years even though the document said on its face that it was conducted between January 2018 and October 2018. It also recorded that 6 doses of EPD administered to patients were “undocumented”. He was asked what this meant and replied, “It’s a minor processing issue which appears to the CQC as a glaring error.” He added that he thought the term “undocumented” meant the clinic had not recorded the patient’s response but then said, “I need to find out what “undocumented” means.” It was put to him that his answers were ambiguous and he replied, “Ambiguity is part of human life.”

104. It was also pointed out that in relation to the survey of whether patients had found the treatment successful and whether they opted to continue, in 13 cases it was recorded as “Unknown / Undocumented.” Dr. Econs said “perhaps its patients who are too early in the treatment” or “they may have dropped out”.

105. It was put to him that the audit showed nothing of value. He responded angrily to counsel by saying, “for someone who doesn’t understand the treatment like you. We don’t speak the same language.” He was asked why the audit did not refer to any learning outcomes and he replied, “I don’t have to learn anything. I’ve learnt.”

106. In re-examination he said that the purpose of the audit was “to try and meet

the concerns of the CQC. This was not a priority to me as I assess patients on an individual basis.”

107. In cross examination he was also asked about the need for consent forms. He said that the clinic now used them but “this is never necessary, its only to meet the needs of the CQC. The inspectors didn’t understand that EPD is not dangerous.”

108. **Procedure in the Magistrates Court** In his witness statement he stated that “I was unfortunately unable to attend the Magistrates Court hearing as I was informed that the hearing would be taking place at 10:00am. I was not told what time it would take place or where it would take place until 12:40pm that day. I drafted a response to the CQC's Statement of Reasons which was sent to the CQC at 13:50pm. However, my response was not provided to the Magistrate and the hearing commenced at 14:00pm.”

109. In cross examination he accepted that he was in fact informed of the hearing at 9am on the morning. He was asked why he made no attempt to get to the magistrates court and he replied, “I was flabbergasted. I thought the CQC had gone crazy. My head was not to attend the magistrates court. I was waiting to be told where and when. I didn’t know which magistrates court.”

110. It was pointed out to him that he was informed of the location of the hearing at 12.48 am by email. He said that he could not remember and “I was not welcome to attend the hearing.” He was asked if he did anything to try and attend and he said, “I had clinical responsibilities.”

111. He was asked whether he tried to contact his lawyers. He said “Its difficult and I didn’t have a contingency plan. I must have been a very dangerous man to the public.” He also explained that “I didn’t know if I was insured” to have a lawyer.

112. In re-examination he said that before this experience he had always thought of the CQC as his friends and that when he heard of the application to cancel his registration he was “paralysed and couldn’t instruct my lawyer.”

113. **Other Matters** In his witness statement, Dr. Econs stated in that in his opinion, “Airedale provides an invaluable service as has been evidenced by the statements provided by some of our patients. The impact of the immediate withdrawal of treatment has been significant and in the event that the clinic is not reinstated, the detrimental impact upon patients' quality of life will be severe. Airedale has an exceptional safety record and the treatments provided are considered to be extremely low risk. However, it is acknowledged that there were some failings in Airedale's practices previously, all of which have now been rectified or are in the process of being rectified ready for the clinic to be reopened.”

114. He added, “I believe that the action taken by the CQC was disproportionate and it has caused a significant amount of harm and distress to patients. There are no other similar providers in the area and without Airedale, patients will not have access to their treatment which will severely impact upon their quality of life.”

115. In response to questions from the panel about his attitude towards regulation by the CQC he became visibly upset and said, “I have no problem with regulation from rogue traders and dangerous individuals. I have always been sensitive to what they are saying but I have serious reservations about how regulations are interpreted by individual inspectors for example keeping premises clean; it depends. I don't wish to misquote but I think they have failed to place the patient at the heart of all our decisions and actions. I don't think it happened on this occasion. They say they would find an alternative service for my patients. I would like to know when and how. The CQC say they respect our human rights and safeguard against abuse. I don't think they have.”

116. The panel then heard oral evidence from **Dr. Alisa Care** who adopted her witness statement which indicated that she was the Associate Consultant for the clinic. She was an experienced GP and came to know Dr. Econs when she was his patient in 2008. She believed that he had cured her using his vaccines when conventional medicine had failed her. She therefore went to work at the clinic under his guidance in 2015 as well as continuing as a partner in an established general practice. She described Dr. Econs as her “mentor”.

She attended the clinic every Thursday to conduct consultations.

117. She took no part in the production of the vaccines and could not comment on the findings of the CQC inspections about out of date products. She later said that when she attended the clinic the vaccines were “all ready for me” and she was not responsible for their storage. She thought that the treatments offered by the clinic were extremely low risk. She also said in her witness statement that “with regard to intravenous infusions, any time you puncture skin there are always risks involved around Infection which means strict aseptic technique needs to be used both when making up the IV infusions and when cannulating the patient.”

118. She added that the clinic had always obtained patients’ consents for treatment and now written consent would be taken for each instance of treatment. Everyone had now undertaken safeguarding and mental capacity training.

119. She added that if the clinic was not re-opened there would be “wide ranging and long lasting impact on the safety, health and wellbeing of our patients.” She also said that “to the best of my knowledge there are no outstanding elements of compliance left.”

120. In cross examination she did not accept that the presence of Potassium Chloride posed a risk as it was contained in plastic vials whereas the saline used in the clinic was contained in large IV bags. She knew the alert applied to the clinic and “from now on it will be stored separately”.

121. She also said that she did not know how the controlled drugs came to be in the clinic but found “nothing odd” about the explanation that she had heard Dr. Econs give in oral evidence.

122. The panel then heard oral evidence from **Donna Paxford** who adopted her witness statement which indicated that she was the Administrator & Registered Manager for the clinic and set out her employment history.

123. She took no part in the production of the vaccines and thought that they were

“akin to a homeopathic approach.” She thought that the treatments offered by the clinic were extremely low risk.

124. She said that since the inspections all personnel files are kept in the clinic and all staff training is up to date. The expiry dates of all stock is now checked monthly and she produced a log of those checks as exhibit DP/1. They also now checked fridge temperatures daily and had appropriate labels.

125. She added that the clinic obtained patients’ consents for treatment and now written consent would be taken for each instance of treatment. Everyone had now undertaken safeguarding and mental capacity training. They also now carried out patient audits which they had not done before.

126. She said that if the clinic was not re-opened there would be significant effects on patient health and wellbeing.

127. In cross examination she also said that prior to the March 2018 inspection she had not fully read the CQC regulations. In relation to the making of vaccines, there were 2 operating procedures. One was contained on a single piece of paper at Exhibit AE1 and the other was on a board which was never produced to the Tribunal. She said that the process for manufacturing “was so simple I would let my 13 year old daughter do it.” She thought that there was no need to update the operating procedures. She said that she was not qualified to opine on how long the dilutions and concentrates could be used for. From now on Dr. Econs would alone make the vaccines if the clinic was reopened.

128. In relation to the expired medicines found during the inspections she had no knowledge of why insulin was in the clinic at all. “We obviously missed it” she said. In relation to the expired equipment still in the clinic at the time of the October 2018 inspection she explained, “They must have dug at the back of a very old drawer.”

129. In relation to staff checks she was asked about the employment of the locum nurse and asked whether she thought it necessary to undertake DBS checks on her. She said, “No. It was Dr Econs who took the lead. He knew her for a

long time and I went on his judgement.” It was put to her that it was her duty to check these things. She replied, “If Dr. Econs feels it’s OK, I accept that. He knew her for years.” She then added that checks were only necessary for “regular staff”, in relation to locum staff “it’s up to Dr. Econs.”

130. She also said that the clinic was fully insured and did not know why the CQC did not believe this. She suspected it was because they “didn’t understand low dose immunotherapy.” She added, “they didn’t know what they were inspecting” and they were “very heavy handed.” However, she later added in examination in chief, “We learnt a lot from the inspections and we now know what is demanded of us to operate.”

131. In relation to the controlled drugs she explained in her witness statement that a patient “had requested that Airedale make up dilutions...she [the patient] managed to obtain half a millilitre of the controlled drugs in question which she had picked up from the anaesthetist and dropped at the clinic in order for us to make the dilutions.” They still had the drugs on the premises at the time of the October inspection “in case that one patient needed to request more dilutions later.”

132. However in her examination in chief she said that the controlled drugs were “delivered by the patient’s father in the vials we sent with the saline solution to the anaesthetist”. She later explained “there was an email from the anaesthetist to the patient what drugs he was going to use and I spoke to the theatre manager after the patient brought the email to the clinic. She said that the anaesthetist was happy for allergy testing.” She added “I physically took them off the patient’s father.” She could not explain why the email from the anaesthetist was not produced before the Tribunal or why the hospital could not use their own saline to make the dilution.

133. She further explained in response to questions from the panel that the patient had not been seen by a doctor at the clinic before the request to the hospital was made. Ms. Paxford said that she sent the vials of saline in the post to the hospital with a request that they add half a millilitre of the controlled drugs to each. She also arranged for the patient’s father to pick them up from the

hospital and bring them to the clinic. There were no written records of any of this process. She accepted that there was no audit trail of the batch numbers of the controlled drugs from the hospital or a record of the amount of drugs added to the vials. She said, "I assumed the anaesthetist had put the right amount of drugs in the saline."

134. The panel read witness statements from the following **patients of the clinic** (all written in December 2018) who all spoke very highly of the treatment they had received from the clinic and were very worried that if the clinic remained closed they would not be able to access the specialised treatment that they believed they needed and only the clinic could supply. The following patients have been anonymised:

- a. H W (who also handed in an additional letter dated 03/04/19 to the Tribunal)
- b. Dr J A (who had requested the treatment with the Potassium Chloride found in the clinic)
- c. Dr P (who said that he was unaware of any medical malpractice at the clinic)
- d. N W
- e. C R
- f. B C
- g. R D PhD

135. The panel later received **written submissions** from both representatives which we noted and have taken into account.

Legal Framework

136. Section 30(1) of the 2008 Act states:

"(1) If–

(a) the Commission applies to a justice of the peace for an order cancelling the registration of a person as a service provider or manager in respect of a regulated activity, and

(b) it appears to the justice that, unless the order is made, there will be a serious risk to a person's life, health or well-being,

the justice may make the order, and the cancellation has effect from the time

when the order is made.”

137. An appeal against a decision of a Justice of the Peace is made pursuant to section 32(1)(b) of the 2008 Act and must be brought within 28 days of the decision (section 32(2) of the Act). On consideration of the appeal First Tier Tribunal may confirm the decision or direct that it is not to have effect (section 32(4) HSCA 2008).

138. The case of **Chulu & Smart Care Plus Ltd -v- CQC [2016] 2684 & EA[2016] 2685.EA** Makes it clear that “The powers of the Tribunal are set out in section 32 and it stands in the shoes of the decision maker so that the question for the Tribunal is whether at the date of its decision it reasonably believes that unless the order is made, the continued provision of the regulated activity by the registered provider will present a serious risk to a person’s life, health or well-being.”

The Burden and Standard of Proof

139. The case of **Rachel Corrigan v Care Quality Commission [2017] 3126.EA-MoU** makes it clear that “In so far as any past facts in issue the Respondent bears the burden of proof and the standard is the balance of probabilities.....The draconian nature of a cancellation order is such that a much higher threshold is required than in other parts of the Act i.e. such as that engaged in the power to suspend. The ultimate issue involves a judgement as to the significance of risk on the basis of all the material before us, including any findings we may make in relation to past facts. The Respondent bears the burden of satisfying the Tribunal that “it appears that, unless the order is made, there will be a serious risk to a person's life, health or well-being.....Section 30 makes clear that serious risk to well-being (as an alternative to risk to life or health) is sufficient to engage section 30.”

140. The case of Corrigan also makes it clear that “we are required to determine the matter de novo and make our own decision on the evidence as at today’s date. This can include new information or material that was not available to the District Judge. It is, for example, open to any appellant in any given case to rely on evidence to show that the evidence was wrong and/or that the issues have since

been addressed.”

141. The case of *Corrigan* also provides the following guidance: “It is important to recognise that an urgent cancellation order lies at the top of the hierarchy of possible steps that can be taken under the Health and Social Care Act 2008. That, in itself, is recognised by the requirement that a cancellation order can only be made if it appears to us that serious risk of harm to life, health or well-being exists. It is agreed that this is a high threshold. Applying the case of **Jain and another v Trent Strategic Health Authority [2008] QB 246**, the overarching question involves making a judgment on a number of matters. In our view in the circumstances of this case this must include consideration of the vulnerability of the service users, the seriousness of the alleged shortcomings in the service provided by the Appellant, and whether the risks had (or could have) been mitigated within the time scale involved by other less draconian measures. Applying *Jain* this last aspect, in particular, may require consideration of the circumstances underpinning any facts that we have found proved, as well as consideration of matters such as [A]’s response to the matters raised as well as her willingness and/or her capacity to address concerns.”

Conclusions & Reasons

142. For reasons given below the panel concludes that the Respondent has proved to the requisite standard that (following the guidance in *Chulu & Smart Care Plus Ltd*) as at the date of our decision unless the order for cancellation is made, the continued provision of the regulated activity by the registered provider will present a serious risk to a person’s life, health or well-being.

143. In addition (for reasons given below) the panel concludes on the balance of probabilities that the Magistrate made the correct decision on the basis of the evidence before her and that the proceedings before her were in accordance with the law and natural justice and fairness. The panel is satisfied on the evidence that at the time the Magistrate made her decision to cancel the registration the continued provision of the regulated activity by the registered provider would have presented a serious risk to a person’s life, health or well-being.

144. Moreover (for reasons given below) the panel also concludes on the balance

of probabilities that in the light of all the evidence available then and now that continued provision of the regulated activity by the registered provider would still present a serious risk to a person's life, health or well-being.

145. The panel was impressed by the credibility and reliability of the CQC's witnesses and are satisfied that the inspections of the Clinic carried out in March and October 2018 were undertaken fairly, professionally and proportionately. We accept that the findings as recorded in the 2 CQC reports (and as explained to us under oath and supported by photographic and documentary evidence) were accurate, fair and reliable.

146. The findings of the first inspection in March 2018 paint a very concerning picture of a lack of basic care and safety. We are satisfied on the balance of probabilities that the following evidence of particular concern was found. We intend to deal with the evidence and our findings in turn:

- a. A large number of sterile items in the treatment room, such as needles and syringes and items in the first aid box were past their expiry date by as much as nine years. We accept the professional opinion of the CQC inspectors that this meant that these items may no longer have been sterile and there may have been a risk of infection if they were used.
- b. There was inadequate evidence that the clinic received medicines alerts, medical device alerts, and other patient safety alerts. We accept the professional opinion of the CQC inspectors that this meant patients could have been at risk of harm if they had been given a medicine or excipient which was subject to a recall or safety alert.
- c. We accept the professional opinion of the CQC inspectors that there was a lack of systems, processes and policies in place to support safe management and administration of medicines.
- d. Staff were not monitoring temperatures of the five refrigerators in the clinic which contained medicines and pharmaceutical excipients in accordance with national guidance. We accept the professional opinion of the CQC inspectors that this meant no one could be sure that medicines and excipients stored in these refrigerators were safe to use.
- e. There was a bottle of benzyl alcohol used to make the vaccines which

had expired in 2015. We accept the professional opinion of the CQC inspectors that this meant it may not have been safe to use.

- f. The nurse did not keep records of the batch number or expiry date of the excipients they had used to manufacture the vaccines, or details of the batches of vaccines themselves. We accept the professional opinion of the CQC inspectors that this meant it would not be possible to identify which patients had received which batch of vaccines in the event of a medicine needing to be recalled.
- g. The training data showed the nurse and registered manager had no up to date training in adult and child safeguarding. The necessary level three training had not been undertaken by any staff at the clinic. We accept the professional opinion of the CQC inspectors that this created a risk for patients.
- h. Mandatory training was sporadic and inconsistent between all staff members. We accept the professional opinion of the CQC inspectors that this created a risk for patients.
- i. There was inadequate evidence that informed consent was always sought, and that mental capacity was taken into account. We accept the professional opinion of the CQC inspectors that this meant that there was a risk that patients were potentially receiving treatment they did not fully understand or had not consented to.
- j. There was inadequate evidence that the nurse who prepared and administered the vaccines and infusions had appropriate and up to date training. We accept the professional opinion of the CQC inspectors that this meant that she might not have had the skills and competence to provide the treatments being given.

147. In those circumstances (and bearing in mind that the Appellant made no submissions against the factual accuracy of the contents of the report) the panel is satisfied that the CQC were entirely justified in serving the Warning Notice under Section 29 of the 2008 Act upon the Appellant and expecting that the shortcomings outlined above should be rectified in time for the announced Comprehensive Inspection on 16 October 2018. However, the panel is also satisfied that these shortcomings were not rectified by that date. In particular

items 2-6 and 8-11 of the Warning Notice had not been complied with. Moreover, other serious lapses were identified during the inspection.

148. We are satisfied on the balance of probabilities that the following evidence of particular concern was found during that second inspection. We intend to deal with the evidence and our findings in turn under the following headings.

Vaccine Production, Sterility Expired Medicines and Equipment and Labelling

149. The panel notes that the CQC have not said that the process of LDI or EPD is inherently dangerous and the science behind it is not on trial. It was the way in which the clinic delivered its services which were said to put patients at serious risk. As Lisa Cook put it, the concerns of the CQC were with the systems and processes of how the vaccines were produced and administered and not the underlying science behind the vaccines. In addition Beverly Cole specifically said, "We don't have a problem with the treatment, it's all the things around it."

150. The panel was particularly impressed by the evidence of Mr Kieron Jones, the CQC Pharmacist Specialist. The panel considers that he has adequate qualifications and experience to be able to understand the process behind the manufacturing of the vaccines and to be able to pass judgement on whether shortcomings in the process concerning sterility, labelling and training constitute a serious risk to patients. The panel accepts that he was a practicing pharmacist with a Master's in Pharmacy and a post graduate diploma in clinical pharmacy and had experience of making vaccines and understood the scientific basis behind the vaccines. He accepted that he had not personally made the type of low dose immunity (LDI) vaccines that Dr. Econs made but he had dealt with similar clinics as a regulator and fully understood the process.

151. The panel accepts that it has been established on the balance of probabilities that patients were put at serious risk because the clinic had no adequate procedures for the manufacture of vaccines to ensure their sterility and out of date stock solutions were being used to prepare vaccines.

152. The panel does not accept Dr. Econs' and Ms. Paxford's claims that CQC Pharmacist Specialist could not understand the manufacturing process adopted

by the clinic and was somehow confused between concentrates and dilutions. The panel concludes that he could understand the process and that he did. It would be very surprising if he did not as the opinion of Dr. Econ was that the process of producing the vaccines was so simple that “we can teach a 12 year old child in minutes how to do it as long as they are numerate.” The opinion of Ms. Paxford (who is not a medical professional) was that the process for manufacturing “was so simple I would let my 13 year old daughter do it.”

153. In addition the panel concludes that Dr Care’s evidence was of limited value as she was not involved in the manufacture of any of the vaccines or dilutions.

154. The panel accepts Mr. Jones’ evidence that normally LDI vaccines carried a low risk of allergic reaction and carried little risk generally but this was only the case if prepared and administered correctly with appropriate sterile conditions. This was corroborated by Dr. Alisa Care who in her witness statement said that “with regard to intravenous infusions, any time you puncture skin there are always risks involved around Infection which means strict aseptic technique needs to be used both when making up the IV infusions and when cannulating the patient.” The panel also accepts Mr. Jones’ evidence that with repeated dilutions the risk of anaphylactic shock might reduce but the risk of contamination increased with every dilution. That was why a thorough system of sterilisation and cleanliness was so important.

155. In addition, the panel accepts Mr. Jones’ evidence that glycerine and benzyl-alcohol can inhibit the growth of bacteria but how long it preserves the vaccines depended on a number of factors including how it was prepared and stored and the nature of the ingredients. In addition we accept that the preservative properties of the glycerine and benzyl-alcohol reduces over time and that was why the vaccines had expiry dates.

156. The panel also accepts that the Allergen Immunotherapy Extract Preparation Manual produced in the USA (Exhibit KJ01) does relate to the same sort of vaccines produced by Dr. Econs i.e. serial dilutions and does provide scientific support for the recommendation that such vaccines should be used within 6 years.

157. The panel notes that in his witness statement Dr. Econs stated that “in relation to the long expiry dates where glycerine and benzyl alcohol are concerned, I attach two studies at [AE12]. The GILL study shows that the allergenicity of concentrates made up of glycerine protects them against infections. Glycerine has antibacterial risks of close to zero. In addition, we also add benzyl alcohol as a double protection against infection and so we can give this an expiry date of 20 years. For subsequent dilutions, we add additional benzyl alcohol as a further single protection.” However the figure of 20 years does not appear in the GILL study and is Dr. Econs’s own opinion extrapolated from the data in the report. The panel was concerned about how Dr. Econs dismissed the findings of the US report by merely saying that “I rely on my experience and feedback from patients”. As such the panel prefers the evidence relied upon by the CQC that such vaccines should be used within 6 years.

158. The panel is also satisfied on the evidence that the clinic did not keep adequate records of batch numbers for the ingredients for the vaccines. The panel also accepts Mr. Jones’ evidence that therefore if there was a manufacturing recall the clinic would be unable to identify which patients had had which batch.

159. In the judgement of the panel the inspections conducted in March and October 2018 provide evidence which establishes on the balance of probabilities that there were serious issues with sterility, expired medicines and equipment and labelling which placed patients at serious risk of harm.

160. The cleaning regime which was based on vinegar and bicarbonate of soda was unorthodox and there was limited evidence of its efficacy. There was inadequate evidence of air ventilation systems.

161. The panel is satisfied that mould was discovered on labels on some of the dilutions. In the opinion of the panel, this means that storage was inadequate and it makes labels difficult to read and shows a lack of care and a reckless disregard for patient safety.

162. The panel is satisfied that the benzyl alcohol found had expired. In the opinion of the panel, this means that it no longer had adequate sterile properties. It also shows a lack of care and a reckless disregard for patient safety.

163. The panel is also concerned that the staff at the clinic were unable to explain why the benzyl alcohol and other substances had expired but were still present on the premises. The panel is satisfied that Clopixol was found that had expired in 2013, Fluanxol was found that had expired in 2016, magnesium chloride had expired on 11/04/18 insulin had expired on 12/05/18, a fridge in the treatment room contained 4 vaccines that had labels indicating they were past their expiry date, a number of sterile items within the clinic, including syringes, had expired and labels on other medicines had expired. No one seemed to know why the insulin was there at all. When it was put to Dr. Econs that he could not explain why he was storing medicines at the clinic, he gave what in the opinion of the panel was a most unsatisfactory reply: "I can explain most of it most of the time." In the opinion of the panel all of the foregoing also constituted a serious risk to patients.

164. Linked to these failings was the inadequate labelling of bottles and vials stored in fridges (including 4 vaccines that had torn labels so that their expiry date could not be seen and 6 vaccines that had labels that were completely illegible) as well as the presence of the substance in the clinic that was labelled in a foreign language, with staff not being aware of its nature and purpose. The panel notes that Dr Econ stated that it was a form of nutrient (Phosphatidyl Choline), but no adequate independent evidence of this has been submitted.

165. The panel accepts the submissions of the respondent that that the presence of compounds in a foreign language, with staff being unaware of its purpose, as well as inadequately labelled items, expired items and non-sterile substances did pose a serious risk of harm and is further evidence of a chaotic system within the clinic.

166. The panel was told by Dr. Econs and Ms. Paxford that the clinic intended to up-grade its processes and that patients would not be at serious risk in the future. However the panel was concerned by Dr. Econs' attitude and that of other members of staff about the whole question of the safety of the production of the vaccines and the surrounding problems highlighted above. In particular Dr. Econs seemed arrogant and combative in his approach to the findings made by the CQC and appeared to hold them in contempt. In cross examination It was put to him that the March 2018 inspection highlighted problems with the production of vaccines. He replied, "I don't accept this. It was based on assumptions that we were using a different form of immunotherapy.....I don't think that Mr. Jones understood." He added "I don't accept these are valid concerns."

167. Dr. Econs went on to say "the CQC were talking about a different type of immunotherapy and I couldn't get it through to them" and Mr. Jones "doesn't understand the process of low dose immunotherapy. He was clueless about what he was inspecting." He also said that the "standard operating procedures don't apply to us."

168. In oral evidence, Dr. Econs also appeared to downplay the need for proper sterilisation procedures in the process of manufacturing the vaccines. He said that because the solutions were so diluted there was only "negligible risk" to patients. He also said that as a doctor "I can prescribe anything I deem appropriate for my patients even if its potatoes or cucumbers without any issues about sterility or efficacy." He also said "this is unlicensed medicine. Therefore I don't have to test vaccines for sterility" and "I am allowed to do what I think is in the patient's best interest."

169. He gave contradictory evidence about the need for sterility saying, "there is no food that is devoid of bacteria" and "we say it's safe, we don't say its sterile" and "they are safe for 20 years. I didn't say they were sterile for 20 years." However, he later said that that "we are now in the process of doing sterility testing on concentrates. We used to do random tests and mostly they were OK. We check when we suspect that concentrates are non-sterile." He later said that "we only tested rarely."

170. The panel concludes that the evidence establishes on the balance of probabilities that Dr. Econs has shown a lack of appreciation and attention to proper cross-infection policies in a clinic that undertakes IV infusions and subcutaneous injections regularly and in the opinion of the panel this constituted and continues to constitute a serious risk of harm to patients.

171. Dr Econs also gave contradictory evidence about whether benzyl-alcohol lost its potency after the expiry date. In cross examination he accepted that inspectors had found a bottle of benzyl-alcohol that had expired in 2015, however he did not accept that using it in the production of the vaccines was unsafe. He said, "I don't accept it's not effective after the expiry date. It can remain potent like old wines" but then contradicted himself by saying, "expiry dates are given by the manufacturers. I don't know if we were using it. We have now sorted it out....I don't think it loses potency. I don't dispute there needs to be expiry dates."

172. In the opinion of the panel Dr. Econ's evidence exhibited on many occasions a defensive, combative and dismissive approach and contempt for the CQC. In particular this was displayed in the following exchange when he was asked whether he had any scientific justification for what he was saying and he replied, "I don't need any. It's my experience that counts. I have a unique approach and we treat people not helped by conventional medicine. I think the CQC have difficulty with the science behind our treatments." He was later asked whether he had any scientific proof for his claim that vaccines could be used for 20 years. He said, "I don't have to prove it." He also said that he "submitted 38 studies to the CQC because they didn't understand what they were inspecting." However these were not submitted to the Tribunal in evidence.

173. His dismissive, defensive and combative approach was also displayed when he was asked why the clinic was not able to produce an infection control policy for the October 2018 inspection and he replied, "this information was available. It's not my problem that the inspectors didn't see it."

174. This attitude was also on display when it was put to him that there were inadequate records concerning the batch numbers and prescriptions relating to each vaccine. He said that "they were available but the inspectors didn't ask for

them.” When it was pointed out that this was not correct he responded by saying “I am a doctor entitled to produce unlicensed medicines. Therefore I don’t need to keep records.” He added “There is no risk because we are providing dilutions. The risks in my job are negligible. There were no fatalities. There is no harm to the public.” He went on to say “The CQC can concentrate on auditing but they should make allowances for our set up where there has been decades of absence of harm, and now I have to defend myself about negligible harm.”

175. In the opinion of the panel another example of this attitude towards being regulated by the CQC was when it was put to Dr. Econs that the problems with the clinic were systemic. He replied, “There were problems but not systemic. The CQC find it hard to understand that some clinics have low risk. They have invented and magnified risks and we have learnt from this.” In addition when he was asked why the vaccine preparation room was not locked and the vaccines were not locked away, Dr. Econs replied, “they didn’t need to be” but “now we lock everything” but he still maintained, “but I can’t see how vaccines are dangerous.”

176. The panel is also concerned by Dr. Econs past ignorance of the CQC regulations and his continuing attitude towards regulation now and into the future. He said in oral evidence “This treatment is to help patients. This is hindered by the complexity of the regulations that happen to exist at the moment.” He later said, “the regulations take a university degree to go through. I didn’t know everything. There was only a remote risk of harm.”

177. The panel is also concerned by Dr. Econs present attitude towards providing a clean and sterile environment for the manufacture of vaccines if the clinic were to re-open. In cross examination he said that “you don’t need to sterilise” and “I don’t have to provide a sterilised environment.” It was put to him that if the environment is not clean there would be a serious risk to patients. He replied, “If it was there would have been a number of deaths.” He was asked if that was how he gauged it and he replied, no, it’s on the basis of feedback from patients.” In the opinion of the panel this shows a cavalier attitude towards patient safety going forward.

178. This attitude of contempt was mirrored by Ms. Paxford who opined that the CQC “didn’t understand low dose immunotherapy.” She added, “they didn’t know what they were inspecting” and they were “very heavy handed.” However, she later contradicted herself by saying, “We learnt a lot from the inspections and we now know what is demanded of us to operate.” In the opinion of the panel this indicates a misunderstanding of the concerns raised and the mere paying of lip service to the need to follow regulation purely so that the clinic can re-open rather than a recognition that they are required to promote patient safety.

179. Dr. Econs said something similar in relation to why the clinic now has audits and uses upgraded consent forms. He said that the purpose of the audit was “to try and meet the concerns of the CQC. This was not a priority to me as I assess patients on an individual basis.” In relation to the consent forms he said that the clinic would now use them but “this is never necessary, its only to meet the needs of the CQC.” In the opinion of the panel this also indicates a misunderstanding of the concerns raised and the mere paying of lip service to the need to follow regulation purely so that the clinic can re-open rather than a recognition that they are required to promote patient safety.

180. In addition he was asked why the audit did not refer to any learning outcomes and he replied, “I don’t have to learn anything. I’ve learnt.” In the opinion of the panel this indicates an inability or a lack of desire to learn lessons from the inspections.

181. In light of these attitudes (and other evidence dealt with elsewhere) the panel concludes that there remains a serious risk to a person's life, health or well-being. In the opinion of the panel all of the foregoing were examples of how the way in which the clinic delivered its services (and is likely to do so if allowed to operate in the future) put people at serious risk.

Controlled Drugs

182. The panel considered written skeleton arguments from the appellant’s counsel and the respondent’s counsel about the legal characteristics of the substances

found at the clinic. There is no dispute that the 2 vials contained Fentanyl and Morphine albeit in some form of dilution. There is no dispute that Fentanyl and Morphine are controlled drugs. We accept the Respondent's submissions that dilution of Fentanyl and Morphine does not alter the fact that they remain controlled drugs even if they are diluted. We also take into account Dr. Econ's admission that he does not know how much of the controlled drugs were put in the saline solution or exactly what concentration of controlled drugs were in the 2 vials seen by the CQC inspectors.

183. The Misuse of Drugs Regulations 2001 [2001 No.3998] ("the regulations") classifies Morphine and Fentanyl as controlled substances. Morphine comes under Schedule 2 and is thus subject to the requirements of regulations 14, 15, 16, 18, 19, 20, 21, 23, 26 & 27. Fentanyl also comes under Schedule 2. Morphine also comes under Schedule 5 and is thus also subject to the requirements of regulations 24 & 26.

184. We are therefore satisfied that the 2 vials contained controlled drugs subject to the requirements of the regulations.

185. It is clear to the panel that on the basis of the account given by Dr. Econs and Ms. Paxford the controlled drugs were supplied to the clinic in breach of the following regulations:

- a. Regulation 14 – requiring documents to be obtained by the supplier of controlled drugs. There is no audit trail of the required documentation.
- b. Regulation 15 & 16 – Requiring a specific form of prescriptions. There is no audit trail of the required prescriptions.
- c. Regulation 18 – Requiring the marking of bottles and other containers with specified information. This was not done
- d. Regulation 19 & 21 – The record-keeping requirements were not followed
- e. Regulation 20 – An appropriate register was not made and maintained.
- f. Regulation 23 & 24– The necessary registers, books and other documents were not preserved.

186. Moreover Dr. Econs and Ms. Paxford gave confused and contradictory evidence about how the substances were supplied to the clinic and the panel remains unclear as to how exactly these controlled drugs came to be on the premises. The panel is concerned with the unorthodox way in which they were supplied. In addition there is no dispute that the substances were not kept in a locked cupboard in a locked room as would be required.

187. The panel accepts the Respondent's submissions that because the clinic was non-compliant with the legislation regarding supply, recording and administration of controlled drugs this presented a serious risk to a person's life, health or well-being. It is also evidence of the chaotic nature of the way in which the clinic handled all drugs and medicines which the panel is satisfied was systemic. There were no records of when or whether the substances were given to the patient or in what dose or concentration. It is also concerning that the controlled drugs were requested before any clinical assessment was undertaken. In the opinion of the panel these were further examples of how the way in which the clinic delivered its services (and is likely to do so if allowed to operate in the future) put people at serious risk.

188. The panel was told by Dr. Econs that he intended to destroy the substances (although had not done so yet) and that he would never have controlled drugs in the clinic again. However the panel was concerned by his attitude and that of other members of staff about this episode. In particular, Dr Econs seemed blasé about the incident. When asked how the drugs were transported to his clinic he said, "I don't know I'm not cognisant of every detail." He later said that it might have been brought to the clinic by the patient "or a spouse. I can't remember." He also said that in his opinion "the CQC inspector's claim that this posed a serious risk to life, health and wellbeing of patients is grossly exaggerated" and the substances had no street value. He was also asked if the vaccination room was now always locked and he replied, "yes, to deal with the exaggerated concerns of the CQC." This shows he is again merely paying lip service to the concerns identified by the CQC and continues to misunderstand the nature of those concerns, thus exhibiting a failure to learn lessons.

189. The panel is also concerned by the attitude of Dr. Alisa Care who said that she found “nothing odd” about the explanation about the supply of the controlled drugs that she had heard Dr. Econs give in oral evidence. In light of these attitudes (and other evidence dealt with elsewhere) the panel concludes that there remains a serious risk to a person's life, health or well-being.

Potassium Chloride

190. The panel is satisfied that 6 vials of 20% potassium chloride were found in the kitchen not locked away and near to other dilutions and compounds.. The panel is also satisfied that Potassium Chloride is subject to a safety alert issued in 2002. In particular the compound should be restricted to pharmacy departments and to those critical care areas where the concentrated solutions are needed for urgent use. The panel is satisfied that the compound was in the clinic otherwise than in accordance with that instruction.

191. Moreover the alert specified that Potassium chloride concentrate solutions should be stored in a separate locked cupboard away from common diluting agents such as sodium chloride (normal saline) solution. The panel is satisfied that the compound was in the clinic otherwise than in accordance with that instruction.

192. The panel is also satisfied that the reasons for this alert are fully explained in the text of the alert, i.e. that the compound can be mistaken for normal saline solution, particularly in reconstituting a drug for injections and that accidental injections may result in fatal accidents. The panel is also satisfied that all staff at the clinic were ignorant of this safety alert.

193. The panel accepts the Respondent's submissions that because the clinic was non-compliant with the safety alert (and its staff were not kept informed of safety alerts in general) this presented a serious risk to a person's life, health or well-being. It is also additional evidence of the chaotic nature of the way in which the clinic handled all drugs, medicines and compounds which the panel is satisfied was systemic. The CQC Warning Notice specifically dealt with the presence of this compound but it was still there in the October inspection.

194. The panel concludes that there was no need to have the compound in the clinic in such dangerously concentrated form and in such high quantities as it could have been obtained already diluted. There were no records of when or whether the compound was given to the patient or in what dose or concentration. In the opinion of the panel these were further examples of how the way in which the clinic delivered its services (and is likely to do so if allowed to operate in the future) put people at serious risk.

195. In addition the panel was concerned by Dr. Econs' attitude and that of other members of staff about this episode. In particular Dr. Econs again seemed blasé and combative in cross examination about the incident. When it was put to him that storing the substance in this way could cause a problem he responded in a sarcastic way by asking counsel a rhetorical question: "explain to me how this can harm patients?" even though this was clearly set out in the Alert. It was put to him that an accidental injection could occur. He said, "I don't accept this could happen." He was asked whether he accepted that the relevant Patient Safety Alert applied to his clinic. He said, "yes but you can't confuse them unless you are blind." He later said that the accidental injection of the Potassium Chloride was "very unlikely" and there would only be a risk if "someone did it on purpose." He later said angrily, "I know damn well how to use Potassium Chloride."

196. In re-examination he said that "99.9% of alerts are irrelevant to my work and I was surprised that I was chastised that I was receiving them but not my registered manager." He explained that now the registered manager did receive them.

197. The panel is satisfied that this shows Dr. Econs is again merely paying lip service to the concerns identified by the CQC and continues to misunderstand the nature of those concerns, thus exhibiting a failure to learn lessons. The panel is also again concerned by the attitude of Dr. Alisa Care who said that, even though she now accepted that the alert applied to the clinic nonetheless she did not accept that the presence of Potassium Chloride posed a risk as it was contained in plastic vials whereas the saline used in the clinic was contained in large IV bags.

198. In light of these attitudes (and other evidence dealt with elsewhere) the panel concludes that there remains a serious risk to a person's life, health or well-being. The panel accepts the submissions of the respondent that this incident shows that the staff at the clinic still fail to understand that there was a risk of an accident involving the mistaken use of potassium chloride for saline and that this is evidence (along with other factors dealt with elsewhere) that the Appellant continues to lack insight and appreciation of risk.

Staff Training Staff Checks and Safeguarding and Insurance

199. Upon considering all of the evidence the panel is satisfied that as at the time of the October 2018 inspection there was still a lack of adequate evidence of proper staff training, staff checks and safeguarding procedures in place, despite these problems being specified in the Warning Notice issued in March 2018.

200. We are satisfied that staff (including the locum nurse) had not been subject to required checks before they were allowed to treat patients. We accept the professional opinion of the CQC inspectors that this constituted a serious risk to patients.

201. The panel was told by Dr. Econs that "Staff training has now all been refreshed" However the panel was again concerned by his attitude and that of other members of staff about this matter. In particular Dr. Econs again seemed blasé about the need for proper safeguarding procedures and did not understand the requirements for undertaking a mental capacity assessment. In cross examination when the lack of training for staff was put to him he said "It's ridiculous for the CQC inspector to tell me that my nurse is a danger to the public or is a child abuser. It is unacceptable for the CQC to say this just because she hadn't had training for 3 years." He also said that requirements of mandatory training was "all new to me" and "Its straight forward to comply with these gaps and we meet the standards." He also said that "my nurse, she didn't need particular training because vaccines are not dangerous." This shows he still misunderstands the need for training thus again exhibiting a failure to learn lessons.

202. He also said that "My safeguarding certificate had expired in August but that

didn't mean I was a danger to the public." When he was asked why no checks were done in relation to the locum nurse employed by the clinic. He said, "the field of our work is very specialised. I know the nurse very well. Yes for the sake of the inspections it was an omission on my part but we are splitting hairs." He added, "I knew the level of her skills and I trusted her. Your talking tick boxes." This shows he still misunderstands the need for safeguarding and thus again exhibiting a failure to learn lessons. It also shows that he is only paying lip service to the need to follow regulations.

203. The panel is also concerned by the attitude of Donna Paxford who when asked whether she thought it necessary to undertake DBS checks on the locum nurse, said, "No. It was Dr. Econs who took the lead. He knew her for a long time and I went on his judgement." It was put to her that it was her duty to check these things. She replied, "If Dr. Econs feels it's OK, I accept that. He knew her for years." She then added that checks were only necessary for "regular staff", in relation to locum staff "it's up to Dr. Econs." This indicates that she as the registered manager still does not understand the importance of such checks and therefore has not learned lessons. In addition it shows that she is unwilling to challenge Dr. Econs if he behaves in a way that breaches regulations. In light of these attitudes (and other evidence dealt with elsewhere) and the fact that Ms. Paxford admitted an ignorance of the CQC regulations and a lack of any management training, the panel concludes that there remains a serious risk to a person's life, health or well-being.

204. In addition the evidence is entirely unclear as to whether the clinic was ever insured to manufacture vaccines or would be in the future. Dr. Econs was unable to give a clear account of whether the clinic was insured or not. In cross examination he was asked why the clinic did not have insurance for manufacturing the vaccines. He replied, "It was low dose immunotherapy. I don't accept that insurance of that level was necessary. I don't accept that my indemnity did not cover the manufacture of vaccines because we were producing unlicensed medicines". The appellant has never produced documentary evidence of being insured. In the opinion of the panel such lack of comprehensive insurance puts patients at serious risk and is a further example

of how the way in which the clinic delivered its services (and is likely to do so if allowed to operate in the future) put people at serious risk.

Patient X and Capacity & Consent

205. The panel is satisfied that patient X was a vulnerable person with mental health problems. The panel is also satisfied that there is a lack of evidence that Dr. Econs (or any other staff at the clinic) undertook an adequate mental capacity assessment or obtained her informed consent for treatment.

206. Dr. Econs said that his notes on 26/09/18, in which it was recorded that patient X “sounded coherent with no delusional ideation” was an adequate mental capacity assessment. The panel has studied Dr. Econs’ notes and concludes that at no point did Dr. Econs carry out an adequate mental capacity assessment and consequently there is inadequate evidence that she ever gave informed consent.

207. In the opinion of the panel this constituted a serious risk to the well being of this patient. Her GP wrote to Dr. Econs warning that over-testing had been identified by the patient’s community mental health team as constituting a risk to her health but nonetheless DR Econs continued to undertake repeated testing for allergies.

208. Moreover Dr. Econs still does not consider that he behaved wrongly and has learned no lessons. The panel was again concerned by his attitude. In particular Dr. Econs again seemed blasé about the need for proper procedures and record keeping and did not understand the requirements for undertaking a mental capacity assessment.

209. In cross examination he defended his decision to continue treating patient X by saying, “she had the classic history of a psychiatrist not believing her” and she had been “fobbed off by the NHS” and “I don’t believe it was a figment of her imagination.” He therefore accepted what she had told him at face value even though he was later informed that she had not made full disclosure of her history. It was also concerning that he said that he did not need to have “permission” from the GP to continue treatment and “none of the treatment we offer would undermine her psychiatric treatment” even though he later said, “I am not a

psychiatrist.”

210. It is also concerning that when it was put to him that he never made a mental capacity assessment of patient X, he said that “it was sufficient in the circumstances” and later said that “if that’s failure to provide consent then this is totally misguided as my duty is to the patient.” The panel also found it concerning that in re-examination he said that he could see no risk in how he treated patient X and when he was asked whether the treatment was effective all he could say was “she said so.” There was no independent audit or documentary record or assessment of the outcome of her treatment.

211. In the opinion of the panel this all shows that Dr. Econs still misunderstands the need for undertaking adequate mental capacity assessments or obtaining informed consent for treatment. This constitutes a continuing serious risk to patients in the future if the clinic were allowed to re-open.

212. Moreover the way in which the clinic dealt with patient X and the two patients who requested treatment with dilutions of controlled drugs and potassium chloride also raises ongoing concerns for the safety of patients in the future. According to the testimony of the staff at the clinic, the controlled drugs and potassium chloride were only on the premises because patients wanted these substances for a particular purpose and it was thought by staff that patients were qualified to assess the risk to themselves. This is linked with Dr. Econ’s view that patient X was in the best position to decide her own treatment needs despite no adequate mental capacity assessment.

213. In light of the above, the panel concludes that the staff took the idea of patient centred medicine too far and agree with the professional opinion of the CQC inspector that it is incumbent on a clinic prescribing and administering substances to ensure they are safe and not for patients to decide what is safe for them. In the opinion of the panel these were further examples of how the way in which the clinic delivered its services (and is likely to do so if allowed to operate in the future) put people at serious risk.

214. The panel concludes that whilst some of the failings identified by the CQC

could be remedied and some were, the underlying systemic problems outlined above and the ethos and attitude of the staff at the clinic towards CQC regulation and patient safety (which we are satisfied put patients at serious risk and still does) has not been remedied.

The Burghwood Clinic

215. The panel read and took into account the Inspection Report on the Burghwood Clinic issued by the CQC relating to an inspection carried out on 14/11/18. The panel noted that this clinic is also owned by Dr. Econs and the report indicated that the clinic was providing safe, effective, caring and responsive services but that “this service was not providing well-led care in accordance with relevant regulations.”

216. The panel does not agree with the final written submissions put forward by the appellant’s counsel that because Dr Econs runs both clinics this demonstrates that “no serious risk pertains to either clinic.” This is a logical non sequitur as each clinic has different clinical staff, different nursing staff and different administrative staff. In addition each is a different legal entity.

217. Moreover, the panel accepts the evidence of Beverley Cole the CQC Head of Inspection, that in her long experience she has “seen many times when a provider has more than one location and the clinics are very different. Sometimes they fail to meet regulations on one location but can in others..... This is something we see on a regular basis. It all depends on staff and the registered manager.”

The CQC Decision Making Process

218. After considering all the evidence the panel is satisfied on the balance of probabilities that the CQC followed a lawful , fair and proportionate procedure in making the decision to apply before a Magistrate to make an order under Section 30 Health and Social Care Act 2008 cancelling A’s registration.

219. The panel accepts that the CQC witnesses who gave evidence before it were reliable and honest witnesses who acted in good faith and followed their own procedures. The panel was impressed by the oral evidence of David Ross and

Beverly Cole and accepted their rationale behind the decision taken to cancel the registration of the Clinic, rather than to impose conditions or to suspend. They fully explained the inspection methodology adopted by the CQC and its enforcement policy, supported by a “Decision Tree” which was “a 4 stage structured decision making process which drives consistency and proportionality when considering enforcement action against a provider”.

220. In light of all the evidence, including the seriousness and persistence of the breaches and the lack of engagement by the appellant, the panel is satisfied that the decision of the CQC was entirely reasonable and proportionate.

221. The panel does not agree with the written final submissions put forward by the appellant’s counsel that “it is therefore wholly inappropriate of the Commission to have leapfrogged and gone to Section 30” and that “the Management Review Meeting was no more than a rubber-stamping exercise of the Section 30 initial decision by Joanne Cansfield. There was a wholehearted failure to consider the graduated approach and hierarchy to enforce and procedural obligations [sic].”

Procedure before the Magistrate

222. The agreed evidence is that the CQC sent an email to the appellant via the registered manager as per protocol and in accordance with the request made by the appellant as to how it would be contacted. This email was sent on 18 October 2018 at 20:17 hours and stated “Following this review, the decision has been taken to apply to the Magistrates Court tomorrow to cancel your registration with the Care Quality Commission. This will also include an application to cancel yourself as a registered manager with the CQC. Please could you provide a contact number for Dr Econs, medical director, as I wish to contact him directly tomorrow (Friday 19 October).”

223. It is also agreed that on 19 October 2018 at 09:01 hours Donna Paxford emailed the CQC saying merely that “Dr Econs would be available to speak to you at 10.30 am today. Please ring the clinic on 01535 603966 and I will put you through to him.” It is agreed that the CQC spoke to Dr. Econs at 10.30am and sent him a confirmatory email.

224. It is also agreed that on 19 October 2018 at 12:48 hours the CQC emailed Dr Econs as follows: “As we informed you earlier today by telephone, following our

inspection of Airedale Allergy Centre on 16 October 2018 the Care Quality Commission has today applied to Leeds Magistrates Court for an order under section 30 of the Health and Social Care Act 2008 to urgently cancel Airedale Allergy Centre's CQC Registration. The hearing is listed at 2pm and parties have been asked to attend court at 1:50am. The hearing will be at Leeds Magistrates' Court and Family Court, Westgate, Leeds, LS1 3BY you can find directions to the building online using the following link: <https://protect-eu.mimecast.com/s/cotSCR6z5Cn5M0oSom2Pw?domain=courttribunalfinder.service.gov.uk>. We will provide you with copies of the relevant documents by email as soon as possible today. We will also bring additional hard copies of the bundle to the court for you to review.”

225. Instead of making arrangements to attend the hearing or asking for the hearing to be delayed so that he could attend, Dr. Econs waited until 13:08 hours before sending an email (set out in full at Appendix 1) taking issue with the actions of the CQC. He made it clear that he would not be attending and did not ask for the hearing to be delayed so that he could attend. He followed this up with a further email at 13:57 hours (also set out in full at Appendix 1) taking issue with the actions of the CQC in more detail and providing lengthy submissions on the case.

226. The panel accepts the reliability of the Attendance Note made by the CQC's Counsel of the hearing at the Magistrates Court on 19/10/18 (set out in full at Appendix 2). This indicates that the hearing was listed at 14.00 hours and the case was called on at 14.15 hours and Keiron Jones and Joanne Cansfield gave evidence before the Magistrate. It was also recorded that “Due to the [Appellant] not attending, I sought leave to confirm and amplify their evidence and invited the Court to clarify any relevant matters for completeness.” Thereafter the Magistrate made her decision which is the subject matter of this appeal.

227. In light of this foregoing evidence, the panel is satisfied on the balance of probabilities that the CQC followed a lawful, fair and proportionate procedure in bringing the matter before the Magistrate and made all reasonable efforts to inform the Appellant of the *inter partes* application.

228. The panel also concludes that the Magistrate made a lawful and fair and

proportionate decision on the basis of the evidence before her.

229. The panel does not agree with the written submissions put forward by the appellant's counsel that the Magistrate was misled by the CQC or that "the way in which the Appellant was communicated with for the court hearing was flawed and the magistrate not fully informed".

230. Moreover the panel do not agree with the submission that "The Appellant was disadvantaged and the application was akin to an *ex parte* one" or that "the Commission is itself responsible for frustrating his knowledge of the hearing and his ability to attend" and that "It beggars belief that an Appellant on the end of such a draconian application would be stalled in receiving such information. There was no procedural fairness". In addition there is no reason to suppose that "the Magistrate did not have adequate time to understand what the issues were."

231. Counsel for the Appellant placed great reliance on the case of **Jain & Jain v Nottingham Health Authority [1999/369/RHT]** which according to his written submissions "is a scathing rebuke against a public authority for pursuing Section 30 in what are analogous circumstances." He added, "It may be a first tier Tribunal decision but it quotes High Court Judges and is one of the few authorities on point. Is entirely relevant case and cannot be ignored."

232. The panel has read the case but finds it of limited assistance for the following reasons:

- a. The case is somewhat old and considers a different legislative procedure, i.e. Section 30 of the Registered Homes Act 1984, which is albeit similar to the legislation being considered by the panel.
- b. The inspectors in Jain were criticised for being ignorant about alternatives to cancellation. This is not the position in the case before us.
- c. Jain makes clear that cancellation should be used only after all other alternatives have been considered. The panel accepts that in the case before us the CQC did consider the alternatives.
- d. The application in Jain was made *ex-parte*. This is not the position in the case before us.
- e. The information before the magistrate in Jain was misleading and

inaccurate. This is not the position in the case before us.

Proportionality

233. After considering all the evidence in the round the panel concludes that the Respondent has satisfied us that the high threshold engaged in section 30 was (and is still) met. We conclude that there “will be a serious risk to a person's life, health or wellbeing” unless the registration is cancelled.

234. We have also considered the matter in accordance with the principle of proportionality and take into account the impact of cancellation on the clinic's patients and staff.

235. Applying proportionality principles, the panel was satisfied that the decisions taken by the CQC and the Magistrate were in accordance with the law and pursued the legitimate interest of the protection of the safety and well-being of service users and the maintenance and promotion of public confidence in the system of regulation.

236. In reaching our decision on the issue of proportionality, the panel also took into account the many genuine and heartfelt statements made by patients who believe that their lives will be seriously affected by closure. We also took into account the likely impact on the staff of the clinic.

237. However, the panel is satisfied that the imposition of conditions/restrictions or suspension would not have been (and would not now be) effective in seeking to address the serious risks involved. For reasons given above we are satisfied that there was, and remains, serious risk of harm to life, health or well-being.

238. We consider that the public interest outweighs the interests of the Appellant, the staff and the patients and that the decision to cancel registration was (and remains) reasonable, necessary and proportionate to the serious risk to life, health or well-being involved.

Decision

The appeal is dismissed.
The order made on 19th October 2018, at Leeds Magistrates' Court against the Appellant is confirmed.

Tribunal Judge Timothy Thorne
Care Standards
First-tier Tribunal (Health Education and Social Care)

Date Issued: 29 April 2019

APPENDIX 1

AGREED CHRONOLOGY OF EMAILS

Date	Communication Type	Content	Page
18 th October 2018 20:17 hours	Email: Joanne Cansfield to Airedale (Donna Paxford)	<p>Subject: Urgent: Airedale Allergy Centre</p> <p>Dear Donna</p> <p>RE: The inspection of Airedale Allergy Centre on the 16 October 2018.</p> <p>The Care Quality Commission has carried out an in-depth review of the outcome of the recent comprehensive inspection of Airedale Allergy Centre. Following this review, the decision has been taken to apply to the Magistrates Court tomorrow to cancel your registration with the Care Quality Commission.</p> <p>This will also include an application to cancel yourself as a registered manager with the CQC.</p> <p>Please could you provide a contact number for Dr Econs, medical director, as I wish to contact him directly tomorrow (Friday 19 October).</p> <p>Kind regards,</p> <p>Joanne Cansfield Inspector Care Quality Commission</p>	91B
19 th October 2018 09:01 hours	Email: Airedale (Donna Paxford) to David Ross and Joanne Cansfield	<p>Subject: Re: Urgent: Airedale Allergy Centre</p> <p>Hi Joanne,</p> <p>Dr Econs would be available to speak to you at 10.30 am today. Please ring the clinic on 01535 603966 and I will put you through to him.</p> <p>Kind regards,</p> <p>Donna</p>	91A
19 th October 2018 10:30/10.32 hours	Telephone: Joanne Cansfield to Dr Econs	<i>Please see email 19.10.18 below sent 10:43</i>	N/a
19 th October 2018 10:43 hours	Email: Joanne Cansfield to Dr Econs	<p>Subject: Airedale Allergy Clinic</p> <p>Dear Dr Econs,</p> <p>Re: telephone conversation at 10.32 am regarding the inspection of Airedale Allergy Centre on the 16 October 2018</p>	59 & 91D

		<p>I can confirm that the Care Quality Commission has carried out an in-depth review of the outcome of the recent comprehensive inspection of Airedale Allergy Centre. Following this review, the decision has been taken to apply to the Magistrates Court tomorrow to cancel your registration with the Care Quality Commission.</p> <p>This will also include an application to cancel Donna Joanne Paxford as a registered manager with the CQC.</p> <p>Kind regards,</p> <p>Joanne Cansfield Inspector Care Quality Commission</p>	
19 th October 2018 12:48 hours	Email: Joanne Cansfield to Dr Econs	<p>Subject: FW: Airedale Allergy Centre</p> <p>Dear Dr Econs,</p> <p>As we informed you earlier today by telephone, following our inspection of Airedale Allergy Centre on 16 October 2018 the Care Quality Commission has today applied to Leeds Magistrates Court for an order under section 30 of the Health and Social Care Act 2008 to urgently cancel Airedale Allergy Centre's CQC Registration. The hearing is listed at 2pm and parties have been asked to attend court at 1:50am. The hearing will be at Leeds Magistrates' Court and Family Court, Westgate, Leeds, LS1 3BY you can find directions to the building online using the following link: https://protect-eu.mimecast.com/s/cotSCR6z5Cn5M0oSom2Pw?domain=courttribunalfinder.service.gov.uk.</p> <p>We will provide you with copies of the relevant documents by email as soon as possible today. We will also bring additional hard copies of the bundle to the court for you to review.</p> <p>Kind regards,</p> <p>Amy Davis Associate Hill Dickinson LLP</p> <p>Kind regards,</p> <p>Joanne Cansfield Inspector Care Quality Commission</p> <p><i>(NB: Sent from Joanne Cansfield's address but including the signature of Amy Davis)</i></p>	91E
19 th October 2018 13:07 hours	Email: David Ross to Dr. Econs and Mrs. Paxford.	<p>Dear Dr Econs and Mrs Donna Joanne Paxford,</p> <p>Please find attached for your information a copy of the statement of reasons that is to be submitted to the court in support of our application to cancel the</p>	372M

		<p>registration of the provider and registered manager. Regards,</p> <p>David David Ross Inspection Manager – West Yorkshire Team</p>	
<p>19th October 2018 13:08 hours</p>	<p>Email: Dr. Econs to Joanne Cansfield</p>	<p>Subject: Magistrates Court Hearing</p> <p>Thank you for the notification of the magistrates hearing.</p> <p>This leaves with me with no scope to be prepared or to be present at the hearing, especially as I have been kept in the dark as to the reasons why this action is being taken.</p> <p>I would like to put on record, for the attention of your superiors, as this can only be described as a draconian measure, disproportionate of any findings of the inspection, which have been taken in the absence of any evidence of the detriment to the public or our patients.</p> <p>As a matter of fact, I am holding you personally responsible for the inconvenience and the impact this action will have on our patients who have used our services for decades.</p> <p>I expect that the commission will be hearing shortly from my lawyers.</p> <p>Regards,</p> <p>Dr Apelles Econs Medical Director</p>	<p>91C</p>
<p>19th October 2018 13:57 hours</p>	<p>Email: Dr. Econs to Leeds Magistrates Court (Copy to Dr Econs; David Ross, Joanne Cansfield).</p>	<p>Subject: Re: CQC Section 30 Application - Statement of Reasons – URGENT</p> <p><u>Leeds Magistrates Court hearing - Friday 19 October, 2.00pm</u></p> <p>I wish to respond to the statement of reasons cited by CQC to cancel my registration as I was not given any time to prepare or indeed to be present during the hearing.</p> <p>My grave concern is that the withdrawal of the registration is likely to have a much more serious impact on hundreds of our patients' health compared with the risks identified by the visiting team of inspectors.</p> <p>I wish that the court of magistrates would consider the following comments appertaining to the same numbers as presented in the CQCs response.</p> <p>6. Manufacturing processes do exist for vaccine production, explaining in detail how to manufacture the vaccines. Responsible staff have been trained in the preparation of these vaccines, which should be noted has, since its inception 45 years ago been a simple procedure. The method of procuring these low dose immunotherapy vaccines is currently the</p>	<p>372K, L, M</p>

		<p>subject of discussions with the Medicines and Healthcare Regulatory Authority, which is currently placed in the hands of a barrister for a more expert opinion. The vaccines pose no serious risk to life, health or wellbeing of patients because they contain highly diluted allergens actually incapable of causing any harm, which have been determined on the basis of initial, detailed medical assessment.</p> <p>7. The deficiencies found in quality control processes was the result of the inspectors being confused between concentrates, whose expiry dates are usually 20 years, secured by the presence of glycerine, to conserve their allergenicity and preservative to secure their integrity against contaminants. The inspectors didn't bother to ask for scientific justification, which was available during their inspection.</p> <p>8. Deficiencies in the management of controlled drugs. The inspector with pharmacist experience, pointed out "controlled drugs", 2 vials of dilutions of morphine and fentanyl, which contained 10 times weaker concentrations of the pharmacologically equivalent and subsequent dilutions used for a patient, who was desperate to get some help to tolerate her opiate analgesia and were overlooked. It is plainly ludicrous that as a provider I was unaware of the nature of these medicines. I stated categorically to the pharmacist that we don't deal with any controlled drugs.</p> <p>9. With regards to potassium chloride solutions, which, according to the pharmaceutical inspector, has been banned since 2002, it is not the same substance. We obtained ours according to our records in June 2014 and we use specifications clearly stated by manufacturing company B Braun a form of dilution in physiological saline. I wish to question the expertise of the inspector on the subject.</p> <p>10. The deficiencies in the provision of patients' care in the context of mental capacity. The patient in question had a history of depression because nobody believed her that she was severely chemically sensitive. The report failed to point out that according to Good Practice guidelines, I communicated with the patients GP, explained that the condition of multiple chemical sensitivity is an extremely frustrating condition which can lead to patients becoming reclusive and sometimes confused, which unfortunately, in the absence of any other valid treatments ends up being treated by psychiatrists with psychotropic medications, which fail to address the underlying problem, but instead add to the environmental load of the immune system. This situation is very similar to the diagnoses of severe asthma, cardiovascular disease and cancer, causing British cities 52,000 deaths every year (DEFRA), when the actual cause of the problem is from diesel particulates from busy roads.</p> <p>11. I object to this comment purely on the grounds that the doctors concerned are involved with</p>	
--	--	---	--

		<p>childcare and fully trained in child protection, children who consult us are always escorted by parents or guardians and after 45 years in medicine, I am very confident that these issues are usually assessed at the outset, including risks and verification of a child's identity.</p> <p>12. I was surprised that the issues raised during the inspection of 12 March 2018, were not even discussed during the inspection but I believe we have addressed them individually, e.g. contents of the emergency trolley; a few out of date butterflies and needles and medicines for emergency. Our oversight in not stating the regulated activity of investigation for diagnostic and screening procedures is a purely administrative matter which would easily have been rectified when the inspectors pointed it out. Again, I fail to see how this matter could remotely be seen as endangering of the public.</p> <p>13. I take the opportunity to respectfully appeal to the magistrates that the decision is deferred until these issues can be rectified because cessation of offering our services to hundreds of our patients is likely to have an immediate, serious detrimental impact on their health given that the majority of them have been unable to find a reasonable and safe solution for treatment currently available through their general practitioners, hospital and specialist services. Given the pressure and the unacceptable timeframe of this case, I wish that the court can be given due consideration to my defence because the apparently upholding of the regulations is really likely to be more harmful than the apparent breaches the inspection identified.</p> <p>Dr Apelles Econs Medical Director</p>	
<p>25th October 2018 14:53 hours</p>	<p>Email: Amy Davis on behalf of Hill Dickinson to yorshired@hotmail.com (Donna Paxford)</p>	<p>Subject: Re: Urgent order to cancel your Care Quality Commission registration under section 30 of the Health and Social Care Act 2008</p> <p>Dear Mrs Paxford,</p> <p>I write following the above mentioned hearing at 2pm in Leeds Magistrates Court on Friday 19 October. I attach a copy of the full bundle put before the Magistrate on Friday and her statement of reasons dated 19 October 2018.</p> <p>This may assist you should you decide to appeal the section 30 order under section 32 of the Health and Social Care Act 2008. You are entitled to appeal this order to the first-tier tribunal no later than 28 days after this notice has been served upon you. The right to appeal is set out in section 32 of the Health and Social Care Act 2008. The first-tier tribunal may either confirm the Magistrate's decision or direct that it ceases to have effect.</p> <p>If you have not done so already we suggest that you take legal advice regarding this matter.</p>	<p>393A</p>

		<p>Regards,</p> <p>Amy Davis Associate Hill Dickinson LLP</p>	
<p>25th October 2018 15:32 hours</p>	<p>Email: Donna Paxford to Amy Davis Solicitor at Hill Dickinson.</p>	<p>Subject: Re: Urgent order to cancel your Care Quality Commission registration under section 30 of the Health and Social Care Act 2008 Dear Ms Davis</p> <p>Thank you for your email.</p> <p>Please could you confirm if the email from Dr Econs, sent directly to the court just prior to the hearing, was received and taken into consideration.</p> <p>With kind regards,</p> <p>Donna Paxford</p>	<p>393A</p>
<p>29th October 2018 11:44 hours</p>	<p>Email: Amy Davis to yorkshired@hotmail.co m (copy to <a href="mailto:airedale@allergymedical
uk.com">airedale@allergymedical uk.com)</p>	<p>Dear Mrs Paxford</p> <p>By the time your email (sent only three minutes before the hearing was scheduled to start) was received by my client, our barrister was already engaged in the conduct of the hearing. We are not aware that your email was considered by the magistrate on the day of the hearing. However, it is of course your responsibility to ensure that any documents you wish to bring to the magistrate's attention are duly filed by you with the court service in good time. We suggest that if you wish to confirm if correspondence sent directly by you to the court was duly received and considered, you raise that with the court administration directly.</p> <p>I refer again to my original email below dated 25 October 2018 in which you have been advised of your rights to appeal against a decision of the magistrates and to seek legal advice.</p> <p>You may also wish to refer to the CQC's guidance on appeals at https://www.cqc.org.uk/file/4506.</p> <p>Regards, Amy Davis Associate Hill Dickinson LLP</p>	<p>393A</p>

Appendix 2

Counsel's Attendance Note

Counsel: Danielle Gilmour (New Park Court Chambers)	Solicitor: Eleanor Tunncliffe (Hill Dickinson)	Date of Hearing: 19th October 2018 Time of Hearing: 14.00
Leeds Magistrates Court	Single Justice	Court 9
Hearing: Section 30 Health and Social Care Act 2008		
Counsel for the Respondent: Unrepresented		
<ol style="list-style-type: none"> 1. I attended at Leeds Magistrates Court on behalf of the CQC on Fri 19th October 2018, to make an urgent application under section 30(2) HCSA to cancel the CQC Registration of the Provider Thames Allergy Services and it's Registered Manager Donna Paxford. 2. The Respondent was given notice of the hearing at 09.00 this morning; the Registered Manager took the phone call and advised that the Applicant call back at 10.30 to speak to Dr Appelles Econs (the nominated individual for the provider). He responded in writing to confirm that no-one was attending on behalf of the Respondent. 3. I met with the relevant inspectors and witnesses at 1.30pm having read their statements and prepared them to give evidence. The case was called on at 2.15pm and I called Keiron Jones and Joanne Cansfield to confirm their statements. Due to the Respondent not attending, I sought leave to confirm and amplify their evidence and invited the Court to clarify any relevant matters for completeness. 4. The application was granted; a copy of the Justice's reasons is enclosed with this note; and an undertaking was given to serve the Order on the Respondent as soon as possible, along with a notice of their right to appeal. 5. If those instructing have any further queries, please do not hesitate to contact me. 		