

HFEA Licence Committee D Meeting

4 June 2009

21 Bloomsbury Street, London, WC1B 3HF

In respect of:

**The Assisted Reproduction and Gynaecology Centre ("ARGC")
(Centre 0157)**

ORAL REPRESENTATIONS IN RELATION TO THE CONDITIONS ATTACHED THE ARGC'S LICENCE

Members of the Committee: Gemma Hobcraft, Lay Member (Chair) Mair Crouch, Lay Member (Vice-Chair) Debbie Barber, Clinical Member Lillian Neville, Lay Member	Committee Secretary: Jonathan Lewis, Henderson Chambers Legal Adviser: Martin Forde Q.C., One Crown Office Row
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Attendees Mohamed Taranissi ("MT") James Lawford-Davies ("JLD") Trish Davies ("TD") Michael Mylonas ("MM")	 (the Applicant) (the Applicant's Solicitor) (the Director of Compliance) (the Director of Compliance's counsel)
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*At 9.30, prior to the commencement of the meeting, the Committee met in private.
Further, the legal representatives and legal adviser met in private.*

Preliminary Issues and Discussions

1. In its decision of 2 June 2009, the Licence Committee decided that it was unnecessary to hear oral representations from the Executive of the Human Fertilisation and Embryology Authority (the "Executive") in relation to ARG C's challenge to the conditions to which its licence is subject.

2. Shortly before the commencement of this meeting, the Executive asked to be present during it and confirmed that it would not participate other than by pointing out factual errors if there were any. Whether the Executive's attendance was permissible turned upon whether such oral representation hearings were public or private. The Executive did not provide any previous guidance or authority to suggest that such meetings had previously been considered to be public.
3. The Executive's request to be present as observers at the meeting and its submission that the hearing is a public hearing was founded upon Article 6 of the European Convention on Human Rights.
4. MT made it clear that he had been excluded from meetings in past and was concerned that the Executive were receiving preferential treatment.
5. Both parties then requested that the oral representations being made in relation to Regulation 7 of the Human Fertilisation and Embryology Authority Licence Committee and Appeal Regulations 1991 (the "1991 Regulations") be heard in public.
6. The Committee noted that this a matter with a long and involved history. It was troubled by the fact that it had not been provided with written legal submissions to assist it in deciding the public-private issue. However, it was of the view that it was in the public interest for a determination to be made in relation to ARGC that day.
7. The Committee reasoned as follows. The HFEA is a public body established by statute exercising a public function and arguably determining via its licensing committee MT's civil rights and obligations. Schedule 1 of the Human Fertilisation and Embryology Act 1990 (the "1990 Act") and in particular paragraphs 2 and 9 give a wide discretion to the HFEA to regulate its proceedings and facilitate the discharge of its functions.
8. In the particular circumstances of this case the Committee determined that the hearing be a public hearing and allowed the Executive to attend as observers.

The meeting commenced at 12.05

Announcement of the decision in relation Private / Public

9. The Chair read out the Committee's decision in relation to this issue (set out in paragraphs 5 to 8 above). MT was concerned to know whether this was a decision in *principle* to be applied in the future or something *particular* to this matter. The Chair stressed that the decision had been made to ensure that proceedings got underway as soon as possible. JLD noted that he was keen for the meeting to start.
10. The Legal Adviser advised that any decision made this Licence Committee is not necessarily binding upon any other Licence Committee in the future, because it is clear from the Protocol and from the Schedule to the 1990 Act that the HFEA, who delegate their authority to the Licence Committee for these purposes, can exercise a very wide discretion, on a case-by-case and issue-by-issue basis, in relation to the regulation of their own proceedings and the arrangements that they make. He opined that a binding decision on the public-private issue would most likely have to be made by a Court.

Quorate

11. The Committee and attendees introduced themselves. The Chair declared the meeting to be quorate and confirmed that the Committee had all the documents required by Paragraph 8.2 of the Protocol. She also confirmed that there were two bundles (from the 14 April 2009 meeting), a bundle provided for this meeting and correspondence from Clifford Chance. There were also five sets of earlier submissions.

Conflicts of Interest

12. The Chair confirmed that none of the Committee had any conflicts of interests in addition to those previously raised (see the minutes of the 14 April 2009 meeting).

Guidance on the role of the media

13. The legal adviser read out his previous advice in relation to this issue:

The relationship between the Applicant and the HFEA has been the subject of much media comment and interest. It is imperative that the Committee reach its decisions unbiased and uninfluenced by such media comment and interest, much of which may be inaccurate, sensationalised and misleading. The

Committee should only consider the evidence presented to it and nothing else.

JLD's General Submissions

The First Condition

1. *Annual inspection, at a minimum, with the first inspection to take place in early August 2009; given 5 July 2009 is the cut off date for compliance with issues raised in the Inspectors Report of November 2008. Inspection to include, but not limited to, consideration of and compliance with:*
 - a) *all witnessing to be properly recorded;*
 - b) *the protocol for assessing air quality;*
 - c) *that all documentation has been carried out correctly;*
 - d) *all procedures are complied with;*
 - e) *A13.3 – that all fees have been paid within 28 days of the invoice.*

14. JLD noted that the 1990 Act is vague with regard to the types of conditions that are permissible. However, he submitted that it is implicit that any conditions should relate to the activities authorised by the licence to which they are attached, and should be achievable by that licensed centre and its Person Responsible. The conditions requiring there to be various inspections of ARGC was clearly beyond MT's control.

15. He argued that, in any event, the number and frequency of inspections imposed by the conditions was excessive. He pointed out that 1990 Act provides for inspections once every calendar year (s.9(8)) and, even then, only if necessary (s.9(9)).

16. Further, there was no reason to impose licence conditions which merely duplicate requirements of the 1990 Act. He noted that the period between inspections in the future is going to be extended to two years (the Human Fertilisation and Embryology Act 2008, schedule 3(g)(4)(1)). Further, the HFEA has recently considered a new approach called the "New Compliance Cycle" which allows for less frequent inspections.

The Second Condition

2.The PR of ARGC is to provide documentary evidence that the actions required in the Inspector's Report of November 2008 have been completed by 1 August 2009.

17. JLD noted that whilst every HFEA inspection report has a list of actions that are to be addressed and taken forward by the clinic, he couldn't find any instance of this leading to a condition such as the second condition. On this basis he suggested that ARGC is being treated differently from other clinics and that the second condition is neither appropriate nor proportionate.

JLD's Submissions in relation to the specifics of Condition 1

Witnessing

18. In relation to the Inspection Report of November 2008 (the "Report"), the Committee had attached great weight, in its decision of 14 April 2009 to the fact that in three sets of witnessing records the date or time was missing on the witness sheet and in two reports there a total of three signatures missing. It considered this to be serious non-compliance.
19. JLD highlighted the fact that the Executive had failed to identify which records these were. This was important because it deprived MT of the opportunity to challenge those findings. Further he pointed out that some of the information missing from the witnessing records would have been recorded elsewhere and that staff were trained to use pro-forma sheets.
20. He claimed that the Committee's response to this area of non-compliance was disproportionate given that only three flawed reports had been identified out of approximately 1,300 reports per annum.
21. JLD then compared the way the Executive had responded to ARGC's areas of non-compliance in respect of witnessing to its response to other clinics. He acknowledged that there might be further comparators which he had not found and stressed that he did not mean to criticise the clinics to which he would refer. Some of the clinics he referred to were as follows:
- Centre 109, Kings College Hospital. 2008 Report: two records missing signatures and a number of signatures in the wrong place. Licence renewed for five years with no conditions.
 - Centre 0254, the Agora. 2007 Report: several breaches in relation to witnessing. Licence renewed for three years with no conditions.
 - Centre 0102, Guy's Hospital. 2008 Report noted *inter alia* practice of having all unprocessed sperm samples in the work area at one time (also identified in 2007 report). Licence renewed the licence for five years with no conditions.

- Centre 0035, Oxford Fertility Unit. 2008 renewal report identified *inter alia* witnessing (in five records) as an area of non-compliance. Licence renewed for five years with no conditions.
22. JLD responded to a question from the Chair by stating that the reports he referred to also contained other serious concerns, in addition to witnessing non-compliance, and that they were available on the HFEA website.
23. MT noted that the Executive only checks whether a clinic has rectified areas of non-compliance at its next inspection, not between inspections. He noted that problems identified at Guy's Hospital in 2006 had not been rectified by the time of the 2007 report. DB responded that at her clinic there is regular dialogue between the clinic and HFEA between inspection reports.

Air Quality

24. In the Report, the Executive had made a recommendation that ARGC ensure that the frequency of air quality testing be sufficient to ensure that, by 30 April 2009, the guidance is complied. JLD noted that this was a recommendation and not a breach.
25. He stated that it was incorrect that ARGC was relying on lab assessments that were over 18 months old. Rather, assessments are carried out every six months. He noted that ARGC introduced air quality control in 1999, long before it became a HFEA requirement in 2007. ARGC also has special equipment to enhance the purity of the air. MT said that he thought that the last assessment was in December 2008 or January 2009. He was unsure as to why a report of this assessment had not been made available. He confirmed that he uses an outside contractor to test the air but couldn't remember the identity of the contractor.
26. He pointed to three clinics in which problems with air quality identified in 2008 had not resulted in any conditions being placed on their licences licence: Centre 0267, the Heart of England NHS Foundation Trust; Centre 0004, Ninewells in Dundee and Centre 0063, which is in Leeds.

All documentation has been carried out correctly

27. JLD explained that it is not clear what this condition is referring to and was thus difficult to make representations in relation to it. Similarly the comments in the Report were vague. MT claimed that on the day of the inspection one of the Executive's team members commented that ARGC's handling of

documents was exemplary but that this comment was not recorded in the report. He said that none of issues later raised in the report were discussed with him at the time of the inspection.

28. The Chair raised the following issues in relation to ARGC identified at the 14 April 2009 meeting: problems with the submission of certain forms; no formal documented competencies and performance indicators had been assessed but not formally recorded. In relation to staff competencies, MT stated that most of his staff have been with the clinic for a long time and the clinic has a very low staff turnover. MT stated that the Executive should have their CVs on file. He claimed that no-one had asked him for the CVs of specific staff.
29. In respect of the submission of registration forms, MT noted that patients often fail to provide some necessary information (like passport numbers); hence the prompt submission of forms is often beyond ARGC's control. The same sort of reasoning applies to pregnancy outcome forms. Further, he could not decline treatment simply because a patient failed to provide passport numbers etc.
30. MT made reference to Lister Hospital by Chelsea Bridge and explained that from the period 2006 to 2008 they had 200 cycles that were overdue for reporting by over a year. Their inspection report doesn't mention any delay.
31. JLD concluded that the Committee's response to these failings was unnecessary and disproportionate. Most inspection reports for other clinics raised problems with documentation without additional conditions being attached to their licences.

Compliance with all procedures

32. JLD explained that this condition is not sufficiently precise in its phrasing to enable him to provide make any meaningful response. MT identified Ellie Fincham as the person responsible for quality control and stated that she generally deals with the Executive.
33. JLD noted that ARGC is regulated in a dual sense by the Care Quality Commission and that Ms Fincham is responsible for quality control. The Commission's remit is defined by reference to the 1990 Act and they also carry out inspections. He stated that there has never been any criticism whatsoever of ARGC's document management, document control or quality control by the Health Care Commission or the Care Quality Commission.

Late payment of fees

34. JLD argued that the late payment of fees was a problem with many clinics and that the Executive had only taken issue with ARGC. Only to illustrate, and not to criticise, JLD referred to the average time to payment in the clinics:
- Centre 0143, the London Female and Male Infertility: 55 days (2008).
 - Centre 0100, Bourne Hall: 58 days (2009).
 - Centre 0188, Isis 60 days (2008)
 - Centre 0013, Coventry: 73 days (2007)
 - Centre 0080, the Hammersmith Andrology: 92 days (2008)
35. Despite these delays, each licence was allowed to continue without any conditions being imposed. JLD also referred to Centre 0030, the Herts and Essex Fertility Centre, whose Person Responsible had provided feedback detailing difficulties that Centre had had with the HFEA when trying to make payment. He also referred to the HFEA annual report which listed large sums owed by various clinics.
36. As far as JLD was aware, the HFEA had only instructed solicitors to recover fees from ARGC and not from other clinics. MT explained that in respect of those fees, he had sent a cheque two or three weeks before Morgan Cole's letter before action. MT explained that he got his accountant to fax through a copy of the cheque to Morgan Cole at a later stage. MT noted that the HFEA's claims for fees were made when it owed MT around a million pounds.
37. MT acknowledged that ARGC was late in paying fees but was concerned that other clinics were equally late and were not penalised for being so. He claimed that invoices are actually often received a week or so after the invoice date. MT explained that one reason why ARGC was late with fees was because it was put under great strain by the court proceedings etc.

Concluding Remarks

38. JLD noted the ARGC has been inspected and audited far more than any other clinic that is licensed by the HFEA. He said that that the proposed conditions would provide what would be viewed as a free pass for the Executive to inspect at will (contrary to current proposals that the HFEA generally inspect less frequently).

39. He noted that MT is concerned that the Executive's focus is entirely negative, failing to acknowledge positive attributes of ARGC. For example, in its submissions on 14 April 2009, the Executive did not make any reference to the meeting which took place between the HFEA Executive and the police on Thursday 2 April 2009. The police dropped the matter on the basis of a lack of evidence.
40. JLD stressed that MT would like to adopt a constructive approach with the Executive.
41. In response to suggestions that licence committees in the future might take a tougher stance than those in the past, MT expressed concern (as did JLD at a later stage) that there might be inconsistencies between committees and thought there should be general policies in place. The Chair responded by noting that there is the protocol which governs licensing committees which is relatively recent. Further committee, members have, as part of their training, observed other licensing committees.
42. The legal adviser made the following concluding remarks. Any conditions that the Committee is minded to impose must be workable and proportionate. The Committee clearly has the power to revoke or vary the conditions, which would include the imposition of conditions that are more onerous than the current ones as well as a discretion to relax the current conditions.

Decision

43. **The Committee was disappointed that the Applicant had failed to provide sufficient information prior to its meeting on 14 April 2009. If such information had been provided this hearing might not have been necessary. Further, the Applicant failed to provide all the documentation that would have assisted the Committee today. However, the Committee has been prepared to accept Mr Taranissi's oral evidence today.**
44. **The Committee trusts that all information will be provided on time in the future. This is to ensure that future Licence Committees will not be confronted with the void of information this Committee has faced. The Committee recommends that these minutes be put before any future Committee dealing with these matters.**
45. **The Committee notes that there is a transcript of today's hearing which records Mr Taranissi's representations that he has complied with a**

number of requirements of which there was little or no written confirmation.

46. The Committee suggests that, in future, if Mr Taranissi has any concerns about an inspection report, he should raise them with the Executive as soon as possible.
47. The Committee grants the application made on 3 May 2007 by the Person Responsible for ARGC to renew the licence for the period of three years for the purpose of treatment and storage pursuant to section 16(3) of the 1990 Act. This licence is not subject to any conditions.

Signed.. *G. Hobcraft* Date... *11/6/09*

Gemma Hobcraft (Chair)