

Subject: Accreditation of paternity testing facilities

BACKGROUND

David T. C. Davies MP asked 16 questions about the Accreditation of paternity testing facilities for answer 24-26 Oct.

Original Mail on Sunday articles

- The Mail on Sunday ran stories on 2, 16 and 23 October about David Blunkett's relationship with estate agent, Miss Anderson. They claimed that Mr Blunkett and Miss Anderson were introduced by businessman Tariq Siddiqi, whose wife is a Director of a company called DNA Bioscience. It appears that Mr Blunkett took up a directorship of DNA Bioscience this year but resigned after just over a month, when he re-joined the Cabinet.
- The article raised questions about DNA Bioscience, for example that it has never filed published accounts.
- The Mail on Sunday made claims that DCA has fast-tracked DNA Bioscience onto the list of paternity testers accredited by the Department to carry out court-ordered paternity tests; that DNA Bioscience has no laboratories and operates out of a rented office near the Old Bailey; that complaints were made about this but DCA felt that they did not disclose sufficient reason to remove DNA Bioscience from the list. The Mail on Sunday has followed up with a number of further questions.

There has been further coverage in the national press mainly focused on alleged breaches of the ministerial code. BBC's Newsnight, 31 Oct, raised concerns about whether DNA Bioscience should be on the accredited list raised by competitors. UKAS, the accreditation body said that they never accredited the company.

Issues raised

- The issues raised in these questions go wider than the DNA Bioscience application and are currently being investigated as a matter of urgency.

TOP LINE TO TAKE

The Department for Constitutional Affairs is carrying out an urgent investigation into the accredited list maintained by the department. The investigation will be a thorough review, and will also include attendant processes and procedures. Any organisation that ought not to be included in the list will be removed. Until the review is concluded, it would be wrong to speculate on its outcome.

DCA STATEMENT TO THE SUNDAY TIMES

There has been no communication, conversation, or correspondence between either DCA ministers or officials with David Blunkett about DNA Bioscience.

The Department for Constitutional Affairs (DCA) is responsible for maintaining a list of accredited bodies able to carry out court-directed parentage tests. The DCA is committed to the proper maintenance of this accredited list, and is carrying out an urgent investigation into the list. It will be a thorough review, and will include attendant processes and procedures. Any organisation that ought not to be included

in the list will be removed. Until the review is concluded, it would be wrong to speculate on its outcome.

With regard to monitoring, the proper standards are those of the International Standards Organisation (ISO). The accreditation bodies for these standards are the experts in carrying out the ISO accreditations. In order to be added to the DCA accredited list, organisations should produce evidence of a valid and current ISO/IEC/17025 certificate, and undertake to comply with the Department of Health's Code of Practice and Guidance on Genetic Paternity Testing Services. DNA Bioscience, which acts as an agent for DNA Diagnostics, has no ISO certificate because it is a referral agency rather than a laboratory.

While this investigation is in progress, all courts dealing with civil proceedings (including family proceedings) have been told about our review and have been informed of the bodies to which referrals should be made until the review of the list is completed. These are Cellmark Diagnostics, Crucial Genetics, LGC Diagnostics Department and the Forensic Science Laboratory in Wetherby. These four laboratories have produced satisfactory up-to-date evidence that they still meet all the criteria for DCA accreditation. We have done this as a precautionary measure while investigations continue.

DCA STATEMENT TO THE MAIL ON SUNDAY

The Department for Constitutional Affairs maintains a list of accredited companies to carry out DNA testing. The DCA is committed to the proper maintenance of this accredited list. The Mail on Sunday has raised a number of questions about the list. The DCA is carrying out an investigation into the accredited list. In advance of the conclusions of the investigation, though, the DCA can say that there has been no correspondence on this matter with David Blunkett or Lucy Siddiqi and Tariq Siddiqi. With regard to monitoring, the proper standards are those of the International Standards Organisation (ISO). The accreditation bodies for these standards are the experts in carrying out the ISO accreditation's. DNA Bioscience, which acts as an agent for DNA Diagnostics, has no ISO certificate because it is a referral agency rather than a laboratory. The DCA investigation will be a thorough and detailed review of the list and attendant processes and procedures.

Q&A

Q1: Why are we carrying out this review?

A: Issues have been raised by *The Mail on Sunday* and Parliamentary Questions have been asked.

Q2: What action are we taking?

A: The department is currently carrying out an urgent investigation into the status of the bodies on the accredited list of bodies that may carry out court directed scientific tests to determine parentage. If there are bodies on the list which should not be there, they will be removed.

Q3. Does the Department's accredited list apply for all paternity tests?

A. No. The Department is only responsible for accrediting bodies which can carry out parentage tests for court directed tests.

Q4. How does the court choose an organisation from the accredited list?

A. We do not influence the choice at all. The court will give a direction, which will include the name of the body that is to carry out the test. In practice, the Clerk of the

Court will show the parties the accredited list. If the parties agree on a particular testing body, it will be that body's name that is put on the direction. If the parties do not agree on a testing body, then the judge will pick one from the accredited list.

Q5: How does an organisation get on to DCA's accredited list?

A: To order to be added to the DCA accredited list, organisations should:

- Produce evidence of a valid and current ISO/IEC/17025 certificate; and
- Undertake to comply with the Department of Health's Code of Practice and Guidance on Genetic Paternity Testing Services, which can be accessed via <http://www.dh.gov.uk/assetRoot/04/07/82/96/04078296.pdf>

It's now our practice to send out a standard letter in response to enquirers who ask what they would have to do to be added to the accredited list. This sets out the criteria above, explains that they have to apply in writing and submit originals or certified copies of certificates. The Department has to check that the accreditation body is compliant with ISO Guide 58 (UKAS is an accreditation body in the UK which is ISO Guide 58 compliant).

Q6. What does being on the accredited test mean? Does it mean a company can then apply for government work? Does it mean that the results are recognised by the court?

A: The DCA is responsible for accrediting bodies which may carry out court-directed scientific tests for parentage, in accordance with a direction made by a court pursuant to section 20 of the Family Law Reform Act 1969.

Being on the accredited list simply means that a court may request that body carries out a court-directed parentage test. The tester's report will be received as evidence. The parties to the case can still challenge that evidence and cross-examine the tester. The fact that a body is on the section 20 accredited list does not give it any "rights" to apply for Government work.

Q7. When was DNA Bioscience accredited by the DCA?

A. DCA agreed that DNA Diagnostics Center, the laboratory used by DNA Bioscience for court directed tests, could be added to DCA's accredited list in October 2003. DNA Diagnostics Center is a US body with ISO 17025 accreditation, accredited by the Forensic Quality Services-International Division of The National Forensic Science Centre.

DNA Bioscience (which is not a testing facility, so does not have ISO 17025 accreditation), acts as an intermediary for DNA Diagnostics and was added to the list as part of the entry for DNA Diagnostics Center. Its details were added as a referral route.

Q8. Why is DNA Diagnostics Center shown with a UK address when you know that DNA Diagnostics Center is in Ohio, USA?

A. We were aware at the time of the application that DNA Bioscience used a laboratory based in the USA and DNA Bioscience's contact details were shown as a referral route to the laboratory.

Q9. Why have other DNA firms been told, in response to Freedom of Information Requests that there is no record of the application?

A: On 22 August 2005, DNA Diagnostics requested "a copy of the registration form submitted by DNA Diagnostics Centre and DNA Bioscience to register on the List of Accredited DNA Testers as prescribed by the DCA".

The Department responded on 20 September 2005 saying that it did not hold the information requested, as registration forms for the DCA accredited list have never existed.

Instead, in order to obtain accreditation to carry out court ordered tests, a laboratory must comply with the following:

1. *Make a written application for accreditation*
2. *Have a current and valid ISO 17025 Certificate. You need to send in the original certificate or a certified copy with your application. All original documents will be returned.*
3. *Undertake to comply with the Code of Practice and Guidance on Genetic Paternity Testing Services. The link to this is below:*

<http://www.dh.gov.uk/assetRoot/04/07/82/96/04078296.pdf>

The requestor was informed that DNA Diagnostics Center is a US company accredited by the Forensic Quality Services-International Division of The National Forensic Science Centre and has produced a ISO/IEC 17025 certificate..

It was agreed that details of DNA Bioscience could be included in the list of accredited testing facilities as part of the entry."

Q10. What correspondence if any is there with David Blunkett in relation to DNA Bioscience?

A: There has been no correspondence between this Department and David Blunkett in relation to DNA Bioscience.

Q11: Have organisations been taken of the list?

A: No, the Department is carrying out an investigation now. It is not yet complete, so the Department is not yet able to form a final view as to the status of bodies on the list. It would be wrong to speculate until the investigation is completed.

Q12: Why have we told courts not to refer some organisations?

A: The Department should soon be in a position to have a confirmed list of accredited bodies. But in the meantime, all courts dealing with civil proceedings (including family proceedings) have been told about the review and have been informed of the bodies to which referrals should be made until the review of the list is completed. These are:

- Cellmark Diagnostics,
- Crucial Genetics,
- LGC Diagnostics Department, and
- The Forensic Science Laboratory in Wetherby.

On the basis of investigations so far, these four laboratories have produced satisfactory up-to-date evidence that they still meet all the criteria for DCA accreditation. We have done this as a precautionary measure whilst investigations continue.

Q13: Is DNA Bioscience one of the organisations we have told the courts not to refer to?

A: I want to make it clear no one has been removed from the list yet. But DNA Bioscience is not among the bodies referred to above.

Q14: How long will the review take?

A: It should be completed in a matter of weeks.

Q15: Who is doing it?

A: It is being led by a senior member of the Department's staff.

Q16: Will there be a report?

A: The immediate review is into the status of the bodies on the list. After that there will be a review of the procedures and processes of accreditation. It is not expected that there will be a report. A confirmed list of accredited bodies will be published on the Department's website, along with the criteria and process for accreditation when the work is complete.

Q17: What are the implications for those who have undertaken tests?

A: As far as we are aware, all the organisations on the list were in a position to ensure reliable evidence was produced for the courts. The Department is not aware of anything to suggest that any of the organisations failed to do so in any particular case.

Q18: How many are likely to be affected?

A: (As I have said) the Department is not aware of anything to suggest that any of the organisations have failed to ensure reliable evidence got to the courts.

Q19: Why did unaccredited people get on the list?

A: I cannot comment as the investigation is not complete.

Q20: Has any body/individual been less than honest?

A: There is no evidence that any organisation/individual has been dishonest in their representations to the DCA.

Q21: What action do we plan to take against anyone in this position?

A: (As I have said) if we find that there are bodies on the list that should not be there we will take them off. But there is no evidence that anyone or any organisation has misrepresented himself or itself to us.

BACKGROUND – COURT DIRECTED PARENTAGE TESTS

Department for Constitutional Affairs is responsible for accrediting bodies which may carry out court directed scientific tests for parentage in accordance with a direction made by a court pursuant to section 20 of the Family Law Reform Act 1969.

The Blood Tests (Evidence of Paternity) Regulations 1971, as amended

It is a legal requirement for eligibility for accreditation by the Department, that a body must be accredited to ISO/IEC/17025. It is also a legal requirement that the accreditation to the ISO standard must be carried out by an accreditation body which complies with the requirements of ISO Guide 58. The details of the statutory regime are set out in the Blood Tests (Evidence of Paternity) Regulations 1971 (SI 1971/1861) as amended. Amending regulations in relation to accreditation were made by SI 2001/773, in the light of changes to primary legislation made in the Child Support, Pensions and Social Security Act 2000.

Laboratory Standards

Officials from the Department do not inspect the laboratories that wish to be added to the Department's accredited list. This is because ISO/IEC/17025 accreditations are a specialised business, and ISO Guide 58 compliant bodies, such as UKAS are the proper bodies to carry these out.

Department of Health Code of Practice

As a matter of policy, the DCA has also determined that bodies accredited by it must comply with the Department of Health's voluntary Code of Practice and Guidance. This sets out best practice and clear standards for organisations seeking to deliver genetic paternity services to the public.

The process relating to court ordered parentage tests

- Where the court is considering an application for a parentage test in the course of other proceedings, it will give a direction, which will include the name of the body that is to carry out the test.
- The testing laboratory will provide a testing kit to the sampler (usually a GP). Once the sampler has received this the parties will need to bring two recent passport sized photographs with them when the sample is taken so that the sampler can authenticate that he or she has taken the sample from the person in the photograph. Once the sample has been taken it will be placed in a tamper proof bag and sent to the testing laboratory for the test to take place and the report to be made on the findings. The testing laboratory will make a declaration that their findings in the test were taken from the samples submitted.
- Once the findings have come back to the court the results will be entered into evidence.

GENERAL BACKGROUND ON PATERNITY TESTING

What is genetic paternity testing?

Paternity testing using DNA is a well-established scientific procedure which can identify relationships between people. DNA paternity testing has become cheaper and more widespread. It used to require blood samples, obtained by a registered medical practitioners, but now uses samples such as mouth swabs for this purpose.

Paternity testing is normally over 99% accurate. If the putative father is not related to the child it is possible to exclude paternity by testing only the child and the alleged father are tested. To prove that a child is related to the putative father samples must be tested from the mother, the child and the putative father.

How can you order a paternity test?

Most DNA paternity testing services supplied to the public are undertaken privately. Approximately half of the estimated 10,000 paternity tests in the UK were conducted privately.

A very small number of tests are performed within the NHS as they are not usually required for medical diagnosis or treatment. There may be exceptions in cases of a genetic disorder where paternity may help in tracing a family history or confirming a diagnosis, or where the genetic relationship between a parent and child is required by law to be established before there can be a live organ donation.

How are paternity testers regulated?

The Department of Health has published a voluntary Code of Practice which sets out the standards best practice expected of organisations that seek to deliver genetic paternity services to the public in the UK. A copy is available using the following web link:

http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4005905&chk=GtA9Yh

Hard Copies of the Code of Practice can be obtained from: Department of Health, Genetics Secretariat, 652C Skipton House, 80 London Road, Elephant & Castle, London, SE1 6LH.

The Code of Practice will be reviewed before the Human Tissue Act comes into force in 2006. The review will be taken forward by DH, the Human Genetics Commission, The Human Tissue Authority, DCA and other Government and public bodies.

The Code of Practice and Guidance does not amend or limit any existing law. Compliance is voluntary, but without compliance laboratories/testing facilities cannot be accredited by the Department for Constitutional Affairs for use by the Courts to carry out court ordered paternity tests. The Department of Health advises members of the public only to use organisations who abide by the Code.