

## Speech to the HFEA Conference

### **“Looking to the future”: shaping human fertilisation and embryology regulation for the 21<sup>st</sup> century**

Thank you, for that kind introduction. It's a pleasure to be here this morning.

It was the American physician Richard Cabot who once said that science and ethics 'needed to shake hands'.

Well even today, and perhaps especially today, that handshake isn't always forthcoming.

When it comes to the field of human fertilisation and embryology, it's the HFEA that has the unenviable task of brokering this strained relationship and translating it into practice.

This is a really tough job, so I want to start with a big thank you.

The Authority grapples with some of the most demanding questions any regulator has to deal with.

It's a challenge the HFEA is meeting with great expertise, great integrity and great courage.

The last 12 months have seen some massive wins for the sector.

Crowned – of course – by last week's stunning figures showing a record 10,000 couples received successful IVF treatment last year.

This shows how embedded, how common IVF is today.

And how advanced techniques have become – which is testament to the skills and dedication of the clinical and research community.

The landmark figures are a fitting prelude, of course, to the Human Fertilisation and Embryology Bill which is now very close to becoming law, and will usher in a new era for us all.

This is what I want to focus on this morning, talking about

- what the Bill is;
- why it's needed;
- how it will help enrich and improve the regulatory environment to offer new support for researchers, clinicians and patients themselves.

### **The significance of the HFE Bill**

As others have noted, there is a nice symmetry that this year is the 30<sup>th</sup> anniversary of the first test-tube baby.

A moment of triumph and vindication for scientists, who worked throughout the 70s, amidst a storm of

controversy, to perfect the techniques that now give hope to thousands every year.

But the birth of Louise Brown also marked a watershed in the regulation of what was – if you excuse the dreadful pun – an embryonic field of research and clinical practice.

The immediate aftermath was an inquiry chaired by Baroness Warnock to consider the profound questions raised by embryology.

In 1984, the report of her Committee of Inquiry into Human Fertilisation and Embryology was published.

This ultimately led to the Human Fertilisation and Embryology Act and the creation of the HFEA.

At the time of the 1990 Act, Baroness Warnock argued the law needed to protect society from “a rudderless voyage into unknown and threatening seas.”

It was a prescient remark, because her words ring every bit as true today.

Eighteen years on, we face the anomaly that 21<sup>st</sup> century practice is regulated by 20<sup>th</sup> century law.

That's not to disparage the 1990 legislation – which was an international landmark in setting out legal limits on the use of embryos, and ensuring proper licensing of IVF treatment and research.

But it is to say that science and society has moved on, and the law must keep pace if it is to provide that effective 'rudder'.

The Bill was always likely to provoke controversy, dealing as it does with questions like the meaning of life, the nature of existence and the character and purpose of families.

We've been challenged to consider delicate social conundrums and profound ethical dilemmas:

- Whether we should allow so-called 'saviour siblings
- Whether admixed embryos should be permitted in medical research.
- And whether the requirement to take into account a child's need for a father should be replaced by 'supportive parenting'.

It's been a long, and sometimes difficult, journey, but I believe we've found the right balance.

Robust measures, on the one hand, to defend core ethical principles in the face of 21<sup>st</sup> century challenges.

But also a proportionate and sensible approach to regulation, giving medical research the freedom to stretch its wings.

## **Good for science, good for society**

And before we talk about process and detail, let's remember the people who could, in the future, benefit:

- the 350,000 in this country currently living with Alzheimers;
- the five people dying every day from Motor Neurone Disease;
- the 200 children born to same sex couples every year, who can now have both parents recorded on their birth certificate.

Nothing is certain, of course.

But the Bill will give the research community the best chance of major breakthroughs in these areas, while also setting clear limits to ensure science never steps beyond the bounds of acceptability.

The potential benefits are considerable for all of us here today.

The Bill will clarify the scope for the HFEA to licence cytoplasmic hybrids, as well as other types of human admixed embryos.

Changed consent provisions should help to open new avenues of scientific enquiry – including important research into serious paediatric conditions like spinal muscular atrophy and Batten Disease.

The Bill also allows the possibility – in the future – for patients suffering from serious mitochondrial diseases to have assisted conception treatments so that they avoid passing their condition on.

This is just one example of how we're 'future-proofing' the Bill to respond to new procedures – a recognition of the important research already taking

place, under HFEA licence, to develop these techniques.

Another [example] is in the testing of embryos for purposes we're not aware of yet. It may eventually be possible to treat a sick child with cells other than cord blood or bone marrow.

It's important we take action now to make sure this can happen in future.

Finally, the Bill promises more flexibility for the HFEA to release information to researchers, which could help us improve the effectiveness and safety of different treatments.

In short, the Bill is right for science and right for society – controlling but not constraining medical research so that it can make a big impact within safe limits.

**A shared journey**

Now I said that getting to this point has been a long journey. I should have added, it's been a shared journey.

We wanted to make sure the Bill wasn't conceived in a Westminster bubble.

So prior to the Bill even reaching the House, there was a lengthy Parliamentary inquiry, a public consultation and detailed Parliamentary scrutiny of the draft Bill.

This dialogue and debate continued inside and outside the Chambers, with MPs and peers feeding in their expertise and insight too.

If I could just embarrass him for a moment, I'd particularly like to thank Phil Willis, who chaired the joint Committee of both Houses with great skill.

The result of all of this scrutiny is a much better Bill – with a number of important changes coming from listening and responding to your concerns.

One very important example is the decision not to go ahead with the proposed merger of the HFEA with the Human Tissue Authority.

As you probably know, we had originally proposed the creation of a new regulatory body – RATE.

But on hearing your views, it was clear that we needed to preserve the HFEA's autonomy as a specialist regulator in the field.

### **Better regulation**

This was the right decision, and it means that the HFEA will be at the heart of efforts to put the HFE Bill into practice.

And, in turn, I believe the legislation can help the HFEA achieve its ambitions of being a world-class regulator.

A progressive, modern force in a progressive, modern field.

For example, the Bill allows the Authority to contract out certain functions, where it would be more practical or cost effective to do so.

It will also be able to delegate some licensing decisions to its staff, which will speed up decisions on routine requests, without the need for a Licence Committee of members to be convened each time.

Streamlining process is one thing. But we need the HFEA to continue being robust and reliable – nowhere more so than in the information held on the register.

The opening of the register, which I'm pleased to see is going to be discussed later today, is really significant.

This was a fundamental part of what the HFEA was set up for, and although the information has been collected, it's only now that this will be tested.

We need to make sure the right processes are in place to build confidence and safeguard the best interests of patients.

I know a lot of work is already underway to improve HFEA working across the piece through the Programme 2010 project.

I'm strongly behind what the HFEA is doing, and I hope the passage of the HFE Bill will inspire further action.

**HFEA as a forward-looking regulator**

As much as the HFEA must adapt to the new legislation, it's also important it continues to be forward-looking.

International horizon-scanning is central to this. I know the HFEA does an awful lot of work to keep abreast with developments around the world, and I urge them to keep up the good work.

### **IVF and single embryo transfer**

And being forward-looking also means leading the debate sometimes.

Over the last 12 months, the HFEA and other groups have taken important steps to reduce the number of multiple births following infertility treatment.

I applaud their efforts, but I appreciate this issue can't be separated from NHS provision of IVF and

the full implementation of the NICE infertility guideline.

That's why we've set up an Expert Group of NHS Commissioners working with patient support group Infertility Network UK to help Primary Care Trusts implement the NICE guideline.

It's good to see progress already being made.

NHS East of England, for example, has blazed a trail – implementing the NICE guidance in all of its 14 Trusts, which means all eligible couples will be entitled to three cycles of IVF from next April.

This is encouraging and I hope many other NHS Trusts will follow their lead in the months ahead. It's really important we build on this momentum.

**Next steps for the Bill**

Perhaps I could end by talking about the next steps. Because although the Bill receiving Royal Assent ends one process, it also starts another – the task of implementing the Bill's many provisions.

Just as we developed the Bill in close partnership, I want to make sure you've got an equal chance of shaping how we put it into practice.

So before the Bill commences in October 2009, there will be consultations on several sets of regulations over this winter.

We particularly want to get your views on the release of information to researchers from the register; the process for licensing and appeals; and the regulations on the extension of storage of embryos and gametes.

These will commence shortly after the Bill is enacted, and I hope as many of you as possible will feed into this process.

## **Conclusion**

I said it earlier, but I want to repeat it: I'm immensely proud of our country's rich heritage in medical research.

We've pioneered fertility research, and we continue to lead the way in our groundbreaking research into Motor Neurone Disease and mitochondrial diseases.

It's really important we stay ahead of the game, and the HFE Bill will help us do just that.

It's a strong, thoroughly modern piece of legislation. And in the hands of an equally strong, equally modern regulator, it will create new opportunities for researchers and clinicians, and new hope for patients.

I want to thank you once again, for all you have done, and all you will do, to make this happen.

It's a delicate mission, but a critically important one for the millions that stand to benefit from medical research. Thank you very much.