

**DR. SIMON FISHEL, MANAGING DIRECTOR OF CARE FERTILITY = HFEA
ANNUAL CONFERENCE 2008 = SESSION 1: MAKING BETTER
REGULATION HAPPEN**

Speaker	Transcript
S1	<p>So our next speaker is Dr. Simon Fishel, Managing Director of Care Fertility, and he's going to talk about what clinics want from regulation and suggesting quite some dramatically, as I have seen, some improvements the HFEA could make. Simon is an internationally acclaimed IVF scientist, and his work in the field of assistive reproduction for almost 30 years, and in fact was part of the original pioneering IVF team with Steptoe and Edwards. So, who better to challenge us, and who better to tell us what we could do better.</p>
S2	<p>Thanks very much. When I was given this title of course, I looked at it in full, why not? But then, actually, I went out and asked colleagues up and down the country about some of the feelings that they had apart from the ones that we've got and I realise 15 minutes won't do all the wingers and whinings a lot of justice. So, I'll do the best I can in a brief overview obviously with some examples. But I obviously feel a little bit like Daniel in the lion's den, except Daniel had the support of God, and we ask these questions don't we all the time; who and what is this Regulation for. I mean, obviously it's here because its a parliamentary requirement and maybe that was the case especially when Dame Mary Warnock was looking at this issue 25 years ago. Is it the same today with regards to patient protection, harm, patient's best interest, etcetera. I think these are interesting areas that continued to be debated as we evolve and what as some would argue today, routine medical practice, in text books, what children were taught and now taught in schools, and yet of course 25 years ago it was completely new and most of us are pilloried on what we are doing with ethical outrage, times moved on. Again, society at large, we heard some very oratorial words this morning especially with regards to some of the stuff that Baroness Deech was talking about 25 years ago, moral outrage, moral codes, indignation, but do they still exist today? Or are they largely gone away? Again, issues that are really up for debate; and we've had different eras with the HFEA haven't we? I think that from the very early days those we're really involved with them between probably 1991 and her first two years they were, incredibly prescriptive about what we did, both with regard to the scientific and medical aspects, I don't think It's the same today. Ethical principles was another era that was developed a lot with the Authority and it moved on a lot from the first</p>

eras I called it, and then we got in the period of some social policy from the Zeitgeist, and some would argue that we're experimenting, not we, but the regulators are actually experimenting with our social policy and our social structure with regards to IVF and reproduction. I'm going to give you an example, with the early 80's, when we did the first known donation in this country and I was down here in London, and we got absolutely pilloried, we were in real trouble, who were we to think, that you could bring about unknown donation, all the problems that would exist with unknown donation, and what resulted from that? It was outlawed. We could no longer do known donation, and we could only do autonomous donation, and where are we today? Exactly the reverse. And yet is the policy that exist today giving us the consequential outcome that the regulators want, and then again, we could at least a 15-minute debate on that particular issue, and I think we are in another era of enhanced regulation on paper assessment, possibly a good thing, I think there are arguments certainly that causes a lot of concern. There are some kind of issues that we face, inspection, yes, they can be modify, they evolve, and good thing to because we've had issues with them early on, but now I think they have improved, and there are always be issues, I think there will always be issues with regulation that will never go away, question is, is it right? Is it good? Is it best? The database, the issues we've had with the database, when we will be able to get the appropriate queries and a response from the database that we hope to get, and is it, anyway, is it always going to be reliable? Is going to be a scientific tool? Results, publishing of the results, are they really informative? Do they really tell us about the case mixed at clinics? Do they really, I mean, from example natural cycle. What do we know about natural cycle? I know a quite about natural cycle from two elements, we did hundreds and hundreds of cycles back in the very early 80's, and I wondered whether it's really changed since. So I asked the HFEA for the data that they have at the moment on natural cycle, its quite revealing, but do we have that data yet? Is it published? Women are going through natural cycle? Training of the HFEA staff, I think it is difficult for them, this is not a criticism, but when you have turnover staff in a regulatory field like this, clearly problems arise and I'll give you some examples of those as we go through. So the changes themselves, the constant, the frustrating, and many of us would argue they divert the professionals from their professional focus. Of course as the wings of the HFEA charged the official league tables, and I think the big thing I'd like to mention briefly now is the inconsistency, the problems that we have with regards to consistency. Let's look at that. There are just three examples, three examples, one is in the clinical domain, OHSS, I know one PR in a unit who was reprimanded from not reporting to the OHSS as an incident, so another PR dutifully reported one and got the response from the lead inspector for that unit, and who

couldn't understand why, the inspector couldn't understand why the incident was being reported, and a quote here, "I'll file a report in a box in case it come useful in future" that was what that PR was told. The green Donor form is an HFEA directive, and again questions were asked about what information can be revealed from the pen portrait on those forms, and completely opposite information was given to two separate units about what they should be revealing, and thirdly some of it came from the code of the practice. As an example, with regards to the standards "this morning A.10.19" this is definitive guidance on frequency in types of monitoring in laboratories, and when we asked colleagues around the country about what they felt this meant, again there was no guidance that was distinctive in terms of inspectors advising about the use of say, particle counts or settled plates; and we know that the microbiologists don't rely settled plates anymore, and a comment from one of a colleague was here, "It would be good to have some collaboration with the HFEA on their desires and recommendations." Sounds like, you know, like a gripe and it's very petty, but these are the issues, as I say, three examples of which rise in large volumes up and down the country for the clinics. So consistency is important, we've had bulk importing of donor gametes, it was allowed, it was inhibited, and then very few people have realised that it's now allowed again, apparently. Being prescriptive versus self-assessment, again those are the big changes that have come along the HFEA, and I think self-assessment, is something that we really do support, I think it's a far better option for clinics, and that has to be matured into good practice, and I'll mention something about that shortly, but the constant different messages to different clinics is an issue, I think for the various PRs. I'll give you one of the bottom which is really important here, even in terms of a potential license breach, my understanding is that there are enormous variations in certain issues, and one here is whether to use fresh or quarantined sperm for surrogacy. It's a very clear license breach, and yet clinics, some are allowed to perform it, because some PRs have to put up a **=9:22= consequence argument**, why fresh sperm should be used? Fair, but where's the consistency? Again some of the things that clinics struggle with. It's the idea of who's doing the PA review? Who's the expert that is being relied upon? I'll give you an example here which made us chuckle, and that was, many of you may know the arguments that have been held over, well the PGS (Preimplantation Genetics Screening), that's where we test for seven or nine chromosomes in an embryo to see whether or not there is a chromosome problem. Well fine, definite debate about whether it's effective or it's not effective. So, some of us has been working at alternatives. One of the arguments why it wasn't effective was simply because it tested seven or nine chromosomes, and in fact there are 23 pairs of chromosomes, so you will need to look at all of them before you start ruling out this

technology. An application was made to the HFEA with the development of this technology, it's got to a point where it could be used, and the license application came back saying, "great!" You've now got license what we call CGH technology, but you can only use it for the chromosomes that you're actually licensed to use it for. So, those who understand the science behind that, it was a complete oxymoron, it was a complete nonsense because you don't develop a technology that tells you information on all 23 chromosomes, but then have to decide to only use the data based on the 7 to 9 chromosomes that you are actually licensed for technology that is no longer perceived good enough, do you see what I mean? The same with PGD and this is a constant problem when one has experts from all over the world supporting different types of PGD cases, and they have constantly been rebirth or questioned as one has gone through in UK. Its local experts, having said that PGD has done a lot better and I don't want to criticise that too much, but these are the issues and the frustrations that arise, and yet some would say, what is the biggest issue facing patients and clinics in this country? And it's actually standards it's in certainly in terms of outcome results, why should there be no minimum standard to achieve in a clinic these days when ones understanding taking IVF which actually is really cook-book practice, you should have a minimum standard of outcome results. Many, and this is a lot of other stuff that I've got back when I questioned people, many said that, one of the problems the HFEA don't feel is tucked in all these years. It's actually why there should be still clinic able to practice at the very, very low end, and have what is probably an acceptable excuse for very low live birth rates, and I know it's an issue for the HFEA. Some have said to me they feel when they have an appeal on a decision regarding HFEA decision that is. It's only reviewed by the HFEA, is that an appropriate way to deal with appeals? So, in terms of regulations itself some would say, I think we all agree we need regulation, let me first of all say that, I certainly do. I've seen IBF practice very badly in lots of places around the world, and one of the great problems with IBF, which is different, it is different to other routine medical procedures is that failure is the norm, and that's the problem, that's the big issue for us, you can get a doctor or a practitioner who hides behind the bad results by actually telling the patient, well you know, statistically you're not likely to get pregnant, when actually the regulators and others would know that clinic's base level of result is extremely poor, so I think there are issues with regard to the practice of the IBF and in terms of needing regulation at some level, but should be limited. Some would say the treatment to research to training aspects probably should come under the wings of the HFEA, but professional bodies. Some would say patchy HFEA should not introduce policy reviews which affect society, and just maybe a small minority in society, but who really suffer. But there are necessary administrative areas, and

these are the ones that I list here which are very important for the HFEA to be involved in, and you can see that list there. One small note, and that is like plea to the HFEA, that whenever we get an update in our license, which for us in the PGD is about, at least one in a fortnight, once a week, is it necessary to send a full 40-pages or whatever it is the bulk license every time and lots of other communication that way, if you can use EDI at a great sophisticated level, I'm sure we can get a lot of other stuff in e-mail. So, the other areas that clinic is concerned about, we've heard haven't we, all of us for the last, whatever it is 17 years or so, that the HFEA is the envy of the world. Well, that might be in some quarters, but for the colleagues I talked to around the world, in the medical science domain, they always asked the question, how come your country slipped so far behind other countries in developing a technology that you once introduced? And we could argue that a large part of that is the way we've been regulated and perhaps to the medical scientific practitioners in this country may be the type of regulation that they've had over the last 70 years isn't the envy of the world. Certainly when we had a case of vitrification 15 years ago, and that baby was born normal and healthy, and she is normal and healthy today, and when the HFEA at the time found about this new technology, they mutually banned it, because it was too new. So, for some of us 15 years of wasted potentially development but maybe it's very similar to technology today that did back 15 years ago on vitrification when now we applaud what people thought was the first introduction of vitrification. And so, we've got other things coming up and so new strategies are going to be devised, like for example the multiple birth minimization strategy, we all support that, but we need to be able to do things to help bring about that change, and maybe one of that is to look at our embryo quality, maybe the way to do that is to see that there are technology that we could select the single embryo that will be the viable embryo. For example, the argument on the PGS criteria, and I understand that the HFEA have had a debate, and maybe at that criteria should be removed, and PGS is going to evolve for example in to a CGH or something else, then maybe there ought to be no criteria, give all patients access, self-assess it , review it, see if it works, but maybe it's a technology that will help the multiple births minimization strategy, but if the HFEA has taken the view as I understand it has, why remove that criteria, then why as I understand it, the view is, let's wait and see till the next Codes of Practice October 2009, if it's good now, why can't it be released now? So that we can all start working on this technology in the hope that we can have a better strategy for single embryo transfer? Maybe I'm asking too much. Maybe you can't have simplicity and regulation. And I'm going to take a quote from Tony Blair, when he gave the politics and media speech on the 21st century back in June last year, and I'm going to change one word of this quote, where he used the word

media, and I've change it to "regulation". What Mr. Blair said at the time was, "Outside of the really major decisions, which for us, this is of course our patient and they hope for unborn child, is coping with regulation, its sheer scale, weight and constant hyperactivity. At point, it literally overwhelms." And I think I'm honest when I say that many of us do feel that, but what a negative talk! I'm going to try to finish on something positive, what a winge! What do clinics want? We want to be on the focus of on the job of procuring maximum pregnancy rates or live birth rates, professionally and safely. If the HFEA, the regulators say professionally it means, no multiple pregnancies, fine! But you know, we'll focus on that, and we want maximum patient-focused time. How many of our practitioners are spending a significant amount of time on regulatory issues instead of patient issues. This is what we want, simplicity, functionality, consistency, fairness – particularly for the patient, opportunity – to maintain UK at forefront of development, I have to say there are strides being made by the Authority in that direction. So what do we want? Particularly for our patients who are the most important group here. Do we want regulation? Which I call regulation evolution, and maybe that's half the problem, we have evolved when I started out this talk, with different areas of the HFEA trying to make changes, trying to listen, listen to all the constituents involved and you know, that has caused problems in itself, although we want develation, which is devolved regulation, as I've mentioned also in my talk, taking out some of the stuff that we know that is so routinely that should be dealt with professional bodies, I don't know the answers to the question, but I hope I have raised some of the points honestly and fairly in this audience, that the clinics feel up and down this country. Thank you very much. **(round of applause)**