

**SESSION 1 – PROFESSOR JULIA BLACK – PRINCIPLES BASED REGULATION**

Speaker	Transcript
S1	<p>So this session is considering what modern regulation looks like and what it means to the HFEA, to clinics, to patients. So there's a whole raft of new legal and regulatory requirement: The Hampton Review, the Legislative and Regulatory Reform Act, the Regulators Compliance Code, the Regulatory Enforcement and Sanctions Act that are all now in place to help regulators, not just the HFEA, but regulators in general to meet better regulation requirements. We are very conscious that to meet these obligations and to make the best use of the opportunities they offer, we have to understand what other sectors and regulators are doing, as well as we have to work even more closely with clinics and patients. So, I'm delighted to welcome our first speaker, Professor Julia Black from the School of Law, the London School of Economics. So, Julia is going to share with us her knowledge and experience of Principles Based Regulation approaches in other sectors and we in the Authority have been wrestling, I think it would be fair to say, with Principles Based Regulation as we move forward. Julia is Professor of Law at the LSE and Political Science, LSE, the school of a... I didn't even know it had Political Science at the end, did you? ...and Research Associate at the Centre for the Analysis of Risk and Regulation at LSE. Her work focuses on the design, operation and accountability, there it goes, of Regulatory Systems and she has published extensively on these issues. So let me welcome her to the podium.  <b>(Applause)</b></p>
S2	<p>Good morning everybody and thank you very much for inviting me along this morning. The talk that or the subject that we are moving on to is the pragmatic phases where the day-to-day phase of the HFEA's business. When Lisa is making those finely tuned judgments, which I am very glad it's her job to make and not mine, the day-to-day business of regulation continues and as Lisa has suggested, that regulation occurs within a bigger context. Government likes to regulate its regulators and is increasing the way that it does that quite considerably and there is a wide debate about how regulation should be delivered. What is better regulation? We do not de-regulate now, we just, we just do it better apparently when we are not obviously nationalising, just in case, when all else fails. And one of the, sort of, there are various, you know, kids on the block basically. Things which are currently fashionable, you'll see them go around the better regulations circuits if you happen to be in those circuits.</p>

	<p>And one of them is Risk Based Regulation and the other is Principles Based Regulation. And as Liza has suggested the HFEA amongst others have been wrestling with this idea of what does principles based regulation actually mean. It, it sounds lovely but how do we, how do we go forward and would we want it even if we knew what it was. And so, what I have been asked to do today is to, to talk about Principles Based Regulation in that sort of broader better regulation context. I'm just trying to make our slides work. Rest assured, they would go this way or that. Anyway, I will continue until somebody comes along and helps me make my slides work. No... Anyway I can talk cause I don't have any...</p>
S3	Oh look, a technical person.
S2	<p>OK, I will continue while some, while the next button is pressed. I am always kind of glad actually when they go and check the power, that it was already on, you know. I kind of feel less incompetent. Anyway, so what is Principles Based Regulation? What it is all about? What it is, both in the rule books and in operation. Why have it? That's marvelous. I do not know how we did it again. Perhaps I will just wave.</p>
S4	It was not our fault.
S2	<p>Oh, it was not our fault. Marvelous. So why have it? We're with Risk Based Regulators. We talk about risks and regulation. What are the risks of PBR and what do we need to make it work? We still cannot make the IT work even if we could make PBR work. Okay. The context is... I will just go on. I will just wave, be like an auction room. I could end up with anything really, couldn't I? You know, trailer park in Florida, half of Colorado, you know it could be mine. <b>(Laughter)</b> Knocked down price of not even 700 billion.</p> <p>So, we go to context. <b>(Waved finger to signal change of slide)</b> Are you there, next one, next slide? Yes, thank you. It is there. The broad context as we said before, better regulation debate. How to deliver effects of proportionate as Allan said, there are whole mentor of them, etc, etc targeted regulation without compromising the achievement of social and economic objectives, and it is that without compromising what it was that one wants to do in the first place which is meant to distinguish better regulation as it were from deregulation. Now I could talk for more time than you could really be interested in, which would probably be more than a few minutes on the issue of better regulation but the bit that I am focusing on is PBR and within the UK, PBR is running alongside, and PBR means Principles Based Regulation, is running alongside the implementation of these Hampton principles which all the regulators now are under a statutory duty to</p>

implement.

So next slide, there we are. We turn to what PBR is. We got two levels of Principles Based Regulation. You can have Principles Based Regulation in the rule books. In other words, you change your rules, say, you write some principles, and then you got Principles Based Regulation in practice. Now, principles based regulation in the rule books means that you change your rule books literally to incorporate principles which are those general broadly stated rules which set the standards by which regulated firms have to conduct themselves and which moreover expressed the fundamental obligations that all should observe. So principles can serve a number of functions in this way. They can express the aims of the Authority. They can express the purpose of the regulation. They can improve communication. They're drafted at a very high general level. Basically thou shalt be good with a few elaborations on what good means in various contexts but basically coming down to thou shalt be good and fair and reasonable in closer terms and a highly purposive. Now you can put principles into the rule book and regulators are starting to think about how to do that and how to achieve that, obviously constrained by their legislative requirements which are not necessarily couched in those general and purposive terms and so, a bit of translation has to go on. But then secondly you have obviously PBR and regulatory practices and this is I think where the debates about of what does PBR actually mean get more complicated because Principles Based Regulation means different things to different regulators and different things to different regulated firms and different things to different beneficiaries of the regulation. Now, to come to the level of the regulator, rule book as it were, PBR can be associated with a number of these different regulatory practices. And here I am looking at regulators both here and overseas particularly in Canada, who have tried to move towards a more outcomes orientated approach but have done so sometimes with principles in their rule books and sometimes without because they have not been able to have the legislative power to actually write those principles. So these regulations, these are changes in practice which are associated as it were with PBR even though you might not have the principles in place. An orientation to outcomes to looking at what the regulator does and is asking regulated firms to do and saying, "Why are we asking them to do this? And if they do not do this very particular thing or perform a procedure in a particular way or ask for the consent in a particular way, does that matter? Okay, it might breach our rule, but does it really matter? Does it really affect the outcome that we are seeking? Now of course the big challenge, if you have not changed your rules, is you have a widening gap between what your rules are saying and what your inspectors and compliance people on the ground

are saying as necessary and acceptable. And so there is a limit to the amount to which you can shift to an outcomes orientation without changing your rules, otherwise, your rules will run into problems of credibility but overall, an orientation to outcomes. Now, associated with it is a much more explicit and developed reliance on firms' own internal processes. If you remove a roughed of detailed rules and not all detailed rules go. I mean something like the FSA, probably not the best regulator to draw on right now, maintains it is moving on to a more principles based approach, but its handbook still runs to 5,000 pages. It is just that it is online so you do not see this massive great turn. You still have the detailed rules but you have much more reliance on firms or centres, licensed centres, to work out what is this principle means in any particular circumstance. What does informed consent mean in any particular context? The challenge for firms or licensed centres or the regulated. The challenge for the regulator is a revised approach to inspection and enforcement. In an outcomes orientated/PBR world, a tick-box approach is no longer adequate or perhaps can get in the way depending on what the boxes are that you are ticking. If you are moving to an approach that says Okay, what are the risks here? What are the consequences and what are the outcomes that we want, then it is a very different mode of supervision, it is a very different form of interaction with the people that you are regulating and ultimately, a reallocation as it were of responsibilities for working out just exactly what it is anyone has to do at any one time, okay and I call this a re-framing of the regulatory embarkment which I will come back to in a minute. Why embark on any of these? Why have any of these? Why have rule book PBR? As I have hinted before, if you move to a statement of concise principles as to what it is you are trying to achieve then you facilitate communication. You may facilitate effectiveness, these are the aims by the way, by focusing on the purpose and outcomes by saying hey, and this is what we are all about. Facilitate durability of the rules. You live and work in a world where scientific innovations are fast and rapid paced and rules only ever tell you, you can only ever regulate this point in time and usually and regulate actually yesterday rather than today and very rarely can they cope with tomorrow. So if you have the broadly based standards, then it gives you greater durability. The aim is that you can improve substantive compliance by blocking loopholes, so it is not so easy now to just navigate your way through the nooks and crannies of the rules because you have these back strap principles in place and that you can communicate to those who are regulating from a regulator point of view. What it is you are trying to achieve and try and get them on board. Okay. So let us look at a little bit more detail at some of the implications. If we move to the practices, the outcome orientation. The implications for firms are good in the sense that they have flexibility to decide what to do. The implications for regulators are they have

got to identify what it is they really want firms to be doing and develop methods to assess that. In terms of internal management, then you have a link here with the, as I suggested before, a risk based approach, another good Hampton principle. In the sense that you look for what risks you are trying to mitigate or to manage and you assess to what extent certain conducts, control systems, etc are performing that function. Now, implications for those being regulated are that you need to show that you are actually achieving those outcomes. Evaluation of your own conduct and evaluation of achievement of those outcomes become centre stage. Implications for regulators as I said before, is to facilitate the evaluation of those outcomes and exercise judgments, it is very challenging. For inspection and enforcement, just to elaborate on what I have mentioned before, you need a prioritisation of issues to regulate your attention. This is a very, very hard thing for regulators to do. The safest course for regulator is to do as much as it can. The riskiest of course is to say actually we are going to do nothing. Prioritising areas which show the highest risk to the regulator's objectives makes perfect sense and seems quite motherhood and apple pie until you realise that that means that actually regulators are not going to do things that they might otherwise have done before. Regulators have to decide what to give up. So that is the implications for regulators. For the firms themselves, then they will ask for different types of data, different types of information. Inspections will or should, under a risk based approach, it takes about three or four years for these things to trickle through, experience tells, have a different approach to inspections. Some firms or centres will find themselves being more inspected. Others will find themselves being less than. What does it mean for the relationship between the HFEA or any other regulator and those that it serves and those that it regulates? Well, with flexibility comes responsibility for both. The implication for regulators is that they have to give clear guidance and exercise judgments. License centres like that. The implication for firms or license centres is they too have to exercise judgment. And so you have this new regulatory embarkment which is a very difficult one to agree and those regulators which have been trying to adopt these types of approaches for the last four or five years are still in the throw trying to negotiate as if where, what this actually means. But these firms' requirements and public's requirements are contradictory. Firms, to have a light touch regulation yet to be told what to do. The terms of the bargain are endlessly contested. Regulators do not want to be unpaid consultants. License centres, regulator firms want clear guidance from the regulator. The regulator wants to ensure full compliance and does not want what it says now to come back to ease the course of enforcement action. The license centres do not want retrospective enforcement. It is a boundary which is endlessly, endlessly contested and it is probably right that it should be. It does not

make it any easier but if one is moving to these different types of approaches which is so easily bound up in the kind of rhetoric of better regulation, this is what ultimately becomes involved.

Okay, we talked about risks. What are the risks of doing any of this? Well, the risks for firms or license centres, and this is why they do not like PBR, is what I called interpretive risk. So in other words they do not interpret the principles in the same way the regulators interpret the principles, and as a result they are going to get clobbered. The risks to consumers and patients and why stakeholders sometimes do not like it is because they think it might lead to backsliding and we see that in the financial markets. Now, I cannot tell you the number of journalists who phone me up and say, "Is it all because of PBR? Are we in this mess because of PBR?" I will leave the answer to that some other time, to be frank. **(Laughter)** I will just go on and on. You do not need my rant on that right now. Moreover, the rules themselves will not keep the regulators in check. There are detailed rules that are good because they make the regulators keep on their toes and not just the firms themselves. So, you got backsliding risk and interpretive risk. So how can we address these? I rather probably be unfair if the regulator focus on how the regulation should focus on these. I will take my nice little space model, we do probability and impact assessments. OK, focusing on the probability side. Regulators have been trying to reduce the probability, yeah through enormous guidance, communications, etcetera, and you usually, actually see a displacement with people who move to PBR from everything, the detailed stuff that was in the rule-books just shifts to guidance notes now, which are actually still treated as rules, so nobody is really gone very far down the particular road. But because this could over concern as it where with or understandable concern with interpretive risk. Okay, they have always addressed probability; regulators could also address impact which I do not often think about through their enforcement approaches, through adopting a clear enforcement policy, grade A approach, etcetera, and some who have moved to neither. We'll show, you know show you reasonable endeavors, notions of due diligence, etcetera, to try and at least as it is reduced the impact of licensed centres get it wrong but at least they had a good and honest try. Often not this is relatively an articulated and unsystematised however. Okay, what about backsliding risks? Well, regulators can, to an extent focus on backsliding risks, if they really do focus on those issues that pose a high-risk to their objectives, and not on the easy wins, OK? So in other words, they go through their approaches and they prune out that things which is very obvious that are not really serving a particular function anymore, but then they move beyond that just to really focus on what it is they all trying to achieve, and very hard to do

building a culture of risk awareness and substantive compliance in firms and the culture which is in accordance with that of the regulators itself. Firms that are going to operate in the context of risk, they operate on the context of risk, risk awareness, risk management, etcetera, but it is the alignment of those understandings. Regulators can reduce the impact of backsliding risks by what have I said here, giving attention to those high-impact areas and something which is usually, actually forgotten by those regulators, and those regulators who have moved to approaches say, "You know we never really get a handle on what to do when the thing goes up or down as we have seen." So in other words, they're good at predicting risks, at anticipating them, at trying to prevent them, but then when they actually arise, you often find they got a much less thought out policy of what should actually happen and they just got the usual kind of enforcement response come in, and all that they have an unsatisfactory set of enforcement tools because the legislative has not got around to changing them and they are also an offer that were announced through the very people for various reasons, and paying attention to clean up, actually before the financial crisis, but the paying attention to clean up is obviously something which really nobody had paid attention to before or not enough. So, PBR, it looks lovely and it can, in those regulators which should have used it in conjunction with some of these other changes in practice, at least change the way the regulation is delivered, whether or not improves it, is obviously a new point because the evaluation of any regulatory technique particularly in certain areas is very hard to do, but if you are going to do that properly as a regulator, then it is far reaching for all concerned and it takes time, so even those who are focusing on risk-based regulatory systems, often in conjunction with PBR, say look, we have four or five years down the tract, we are on version almost 16 of our system and half of our organisation is still coming to terms to that, Okay? It is a slow process. But ultimately it all depends on trust, at least talk before the relationship between the authority or any agency and those to whom it deals and those to whom it serves, and the problem is or the paradox is the principle-based regulation in focusing on outcomes, in focusing on the joint team in all purpose can facilitate in the ideal world, the creation of that trust, but it can not created it itself. It has to be a pre-existing condition before any of these could work, and all of that is up to all of you, Okay? Thank you very much.

***(Applause)***