**Intellectual Property and National Health Systems:
Case Studies of BRCA Testing in the United Kingdom**
Shobita Parthasarathy, Ph.D.

DR. EVANS: Great, Richard. Can you hear me?

DR. GOLD: I can, indeed.

DR. EVANS: That was fantastic. That's exactly what we needed.

In the next section, we're going to look at two case study perspectives regarding testing. Now, Richard, would it be okay with you if the other speaker went first and then we came back to you?

DR. GOLD: Either way is fine.

DR. EVANS: That would be great.

So Shobita Parthasarathy is an assistant professor of public policy at the Gerald R. Ford School of Public Policy at the University of Michigan. Dr. Parthasarathy conducts research on the politics of science and technology both in the U.S. and abroad. She's authored a very good book recently. It's titled "Building Genetic Medicine: Breast Cancer, Technology, and the Comparative Politics of Health Care." It was released earlier this spring.

And I'll turn things over to you, Dr. Parthasarathy.

DR. PARTHASARATHY: Thanks a lot and thank you very much for the invitation to speak to you today.

The title of my talk reflects conversations that I had with people at SACGHS about what you were interested in learning about vis-à-vis the Myriad case specifically with regard to, as Jim said, my recent book that's a comparative study of the U.S. and U.K. But I'm actually now doing some more work more generally on the comparative politics of biotech patenting broadly in the U.S. and Europe. So I'll bring in, I hope, some of those insights as well and hopefully link them to some of the comments this morning, as well as to Richard's comments earlier.

A couple of things before I begin, though. As Richard said too, please feel free to interrupt me if something is not clear or if I'm moving too fast trying to cover a lot. As you can imagine, when you've written a book on this stuff, you could go on forever, but I'll do my best to restrict my comments to just a few minutes.

In that vein, though, assuming that you guys will be interrupting me, I want to start out by at least hitting the main points of what I'm going to be talking about today. The first is that, of course, policy is important but the commercial and scientific and health care cultures that Richard alluded to just now are also extremely important in terms of how genetic testing is being built in different countries. And this is true certainly in the U.S. and Britain which I'll be focusing on today but also more broadly in Europe, which I'll also be talking about a little bit.

So you'll see, I think, in my analysis I'm going to be focusing very much on the gene patent and gene patent policy stories with regard to the development of genetic testing for breast cancer in the U.S. and Britain, but by no means are those gene patent policies the only thing that mattered in terms of the development of this technology very differently in the U.S. and Britain. And I

want to sort of make that caveat clear because if it seems like I'm creating sort of an A to B story too simply, I want to assure you that that's not actually the case, but I'm just highlighting that for the purposes of the discussion today.

Furthermore, I also want to make another point, which is that we often focus, when we think about technology, on the fact that perhaps the costs might be different. Certainly we can see that that might be the case between the U.S. and other European countries that have public health care systems or that access might be different, and you'll certainly see that that is the case when we talk about the U.S. and Britain.

But I will also talk a little bit today -- and it's also in much more detail in the book -- about how, in fact, the tests themselves are different. And this goes back actually to some of the conversation that was taking place this morning that Marc was talking about in terms of what is a genetic test and the fact that the technological design and the varying importance of the lab and the clinic are different actually, I would argue, in the U.S. and in Britain, as well as the management options that come out of the different ideas of what testing is. So that's sort of one major point that I'd like to hit today.

The second is obviously that patents and patent policies play an important role in the story, but I'd also like to highlight the importance of the opposition mechanism that's come up. Richard was talking about it a little bit, and Judge Newman also talked about the possibility that in the U.S. Patent Reform Act, there will be an inclusion of an opposition type mechanism. She was talking about this as the first window for public participation, and this actually was a very important part of the Myriad case in Europe. So I want to highlight that a little bit as well and, in addition, highlight again what Richard was saying more broadly about the role that health departments can play both in terms of gene patenting and licensing practices in particular countries.

Before I go into the comparison, though, I want to review a little bit the history of the BRCA genes and the BRCA gene patents. This is probably old hat to many of you, but I think it's worth just going over just in case.

So as many of you know, the first breast cancer gene, or BRCA1, was found by Myriad Genetics in September of 1994. Many researchers thought that there was at least one other gene linked to breast and ovarian cancer and continued to look. There continued to be what many referred to as an international race to find the breast cancer genes.

And in December of 1995, a group in London announced that they had found BRCA2. Something that's important to note -- and this comes up later again -- is that Myriad disputed this priority. So Myriad also filed for a patent on BRCA2. There has been work in terms of the scientific community, who believes who actually found the gene, and that work has suggested that in terms of citations, who cites whom, in terms of who had priority. There most people believe that it was the British group that found the gene. But this goes back to the issue of when you have many groups involved in this kind of thing, you're going to get this kind of priority dispute.

As, of course, one would imagine both Myriad and the U.K. group applied for multiple patents both in the U.S. at the U.S. Patent and Trademark Office and also at the European Patent Office, or EPO. The U.K. group, which was a group that was funded by the Cancer Research Campaign filed for what they have referred to as a defensive patent, and they explicitly said, in conversations with me, that when they applied for the patent, they really wanted to make sure that

groups like Myriad would not have a monopoly over what happened to the fate of the breast cancer gene patent and also the genetic test.

The British group then licensed that patent to an American company by the name of Oncormed who had also applied for patents on the BRCA1, a different consensus sequence of the BRCA1 gene, but as part of that licensing agreement, they had some very interesting provisions. And this goes back to the control that patent holders can have in terms of the licensing terms and also the licensees can have.

When they licensed that patent to Oncormed, the conditions included that the British NHS receive free access so that it would not impinge on the development of the NHS' testing systems. They also required that the patent be sublicensed, again to avoid a monopoly, and they also had a list of requirements for how individuals should be counseled. So they said you have to make sure that everyone who gets this test has to go through these particular counseling requirements. So they got really detailed into the nitty-gritty, and I haven't really seen that kind of example anywhere else in terms of really trying to influence how this genetic testing system was built both in the U.S. and, of course, in Britain where they were based.

Now, in terms of the U.S., of course, the Myriad story is a fairly familiar story probably to many of you who are involved and interested in genetic testing and patenting, but often some of the early history of the development of BRCA testing in the U.S. is lost and I think it's worth resurrecting, particularly when it comes to the gene patent story.

There are a number of providers that initially emerged. At least four were sort of major providers that were offering tests looking at the full gene sequences of both the BRCA1 and 2 genes. Some offered just simply mutation testing for the Ashkenazi Jewish panel. There are still some places that do that now, but there were basically four places that did this kind of testing early on. This is really 1996 to about 1997-1998. There were these four major providers.

I've sort of summarized them here just to give you the sense that there were actually quite different approaches to what genetic testing for breast and ovarian cancer meant in each of these groups. There were different approaches to DNA analysis but, perhaps even more importantly, different approaches to counseling in terms of whether or not you had to see a genetic counselor first, whether or not you could simply go through any primary care physician, whether or not you had to be at a certain level of high risk according to your family history. All of these kinds of things were variables in terms of the development of these different systems in the United States.

However, as many of you probably know, Myriad used its legal position, its intellectual property rights, as well as -- it would be incorrect to say it was just the intellectual property rights. It was also the fact that they had a very strong economic position, and they used that to shut down the other testing services.

The Genetics and IVF Institute closed its service fairly early along. They sued and countersued one another, but Oncormed then folded quickly afterwards. The University of Pennsylvania stuck it out for a little bit of time, in particular making the argument that what they were doing was in fact research and not health care. This got debated out basically, and Myriad eventually sort of adopted a pretty, broad expansive view of what a clinical service was and narrowed this definition of research. And of course, when Penn shut down their service and Myriad adopted this broad view, it also influenced the way in which we're defining research and health care, certainly when it comes to gene patenting and testing in the U.S.

So the Myriad testing system, again, I think it's worth reviewing. When I talk about the British system, it's an important comparative point I think. One of the things that's interesting about the Myriad system -- and I think Richard is going to talk about this as well a little bit -- is really what they're doing is involved in a pretty straightforward commercialization of their patented technologies. So it's really a laboratory service that they're offering as a state-of-the-art laboratory service. In their promotional materials and educational materials, they talk about the fact that they're offering a state-of-the-art laboratory service and that is their major concern.

So they're less concerned about the clinical dimensions of the test. They're very much focused on what they can offer and what they're involved in, and what they control is the laboratory dimensions of their test. So they don't require specialized genetic counseling. The test can be offered through any physician. It's marketed fairly widely to a number of primary care physicians, for example.

And the management options, when they talk about management options, are often defined by mutation status, and they integrate into their materials the idea -- and this is something I'm not going to talk about too much, but it's important in comparative perspective that tamoxifen adds a potential management option for women who have tested positive, was quickly accepted by Myriad as a potential management option available for women, which of course, sort of going back to the questions about clinical utility, it sort of demonstrates clinical utility when you have a drug available that could potentially ameliorate these risk issues.

Their service is costly. It ranges, however, but the full sequence analysis of both breast cancer genes is approximately $3,000. This varies a little bit. It's reimbursed, but many people still choose to pay out of pocket, worried about discrimination. This may, of course, change with the new legislation.

So when we're talking about what this system looks like, we're talking about a client who sort of can demand access to the genetic testing system. They can go through a variety of physicians. The health care professional facilitates access. They're not sort of a gatekeeper, which you'll see more of in the British system. They're really involved in a facilitating role, again when you think about it in comparative perspective.

So now I want to turn to the British system, and then I'll talk a little bit more about the European situation and spend a little bit more time on that.

Just to give you a sense of the context -- obviously, the American context is probably more familiar to all of you. So it's worth reviewing where genetics sits in Britain. In particular, the genetics care and genetics testing has evolved through the National Health Service in Britain. In fact, while there is private insurance available in Britain, there are no private genetics clinics yet. So really all genetic testing is being offered through the National Health Service.

And from early on -- again, in the U.S. early on as well -- genetic testing was offered as a combined sort of laboratory and clinical service often in hospitals. Now that's started to split apart with private companies offering testing that's laboratory testing. So it splits it a little bit, whereas in the NHS, these two things, the clinical dimensions and the laboratory dimensions of testing, have really remained coupled. And the NHS has de facto control over the activities of both the clinic and the laboratory because, of course, they're funding these services.
Basically the way that it works is that there are a number of NHS regions. They're cut up across the country, and each region has a genetics clinic. These regions have considerable control over what services they provide, although most of them do provide services in particular for BRCA

testing. And they get money from the national administration and they often have a lot of agency to disburse that money, although this is sort of a tension. The extent to which the national NHS administration and the regional administrations control health policy and access often differs according to the service, and it certainly became a tension in the BRCA case and I'll come back to that in a second.

I also want to add back in the sort of patent dimension of this and sort of remind you of that strain of the story, of course, since that's the focus of the orientation of my talk today. And that is that on the books there are a lot of similarities between U.K. patent policy and European patent policy and American patent policy when it comes to these kinds of issues, as Richard was talking about before. There are some differences in terms of first-to-file/first-to-invent issues, but in terms of the books, there aren't that many differences.

However, there is an important caveat to this which shapes the way that BRCA testing was built in the U.K. and also how people in the U.K. and people in Europe responded to the Myriad patents, and that is the EU Biotech Patent Directive which, as Richard referred to, was introduced initially in 1988, but the real fever and the public controversy and discussion was in the mid to late 1990s which is, of course, exactly the same time that the Myriad patents started to become an issue, that BRCA testing was being built. So there was considerable public discussion. So these two things fed upon one another.

So the Myriad case became a major issue in the discussions around the EU Biotech Patent Directive and the general controversies around patenting biotechnology fit then also into even national debates within the U.K. over how to deal with BRCA testing and patents and gene patents and, as I'll demonstrate later, Myriad's patents, which they had to deal with eventually.

Of course, in the early days when the British were trying to develop their BRCA testing service, the patent holders weren't involved. So Myriad was not in Britain. The U.K. Cancer Research Campaign group, as I said, had wanted to stay out of it, and to the extent that they had licensed their patent to Oncormed, they had agreed with Oncormed that Oncormed would stay out of it. So the patent holders were not at all involved in the way that testing was built in Britain.

The testing first emerged in these regional genetics clinics. So different clinics had been involved in the research in varying ways. The ways in which they had been involved and been doing testing sort of then led naturally to the ways in which they offered testing initially to patients in their region.

But fairly quickly there was an attempt to create a national system. Worried that because BRCA testing was the first major genetic test for a common disease, that it would probably end up being a model or a test case, if you will, for other genetic tests that were going to be coming down the pike, there was a lot of worry and concern about making sure that they got this right.

So they wanted to develop -- a group of health care professionals, patient advocates, and scientists, as well as government officials got together and developed a national system, a national risk assessment and triage system, to dictate how genetic testing for breast cancer would be offered throughout the country. Basically what they decided to do was to create a risk stratification based on family history information.

So individuals do see their primary or secondary care physicians. A family history is taken, and then based on that family history information, they're classified into three categories: low, moderate, and high risk. The low risk individuals are deemed not to be likely to have a gene

mutation, so they're reassured and turned away. Individuals at moderate and high risk are offered access to the tertiary care center. That's the regional genetics clinic. So they can have access to genetics counseling. But only individuals deemed to be high risk are offered access to testing.

However, those individuals who are deemed to be moderate risk are thought to be at increased risk of breast cancer. They're just not sure that testing is actually going to be useful for them. So they say, okay, you can have access to increased surveillance, in particular, a yearly mammographic screening. So those classified at moderate risk don't have access to DNA testing, but they do have access to increased management options, that is, increased surveillance.

DR. EVANS: Did they put a numerical figure on their risk assessments?

DR. PARTHASARATHY: So they don't put a numerical figure in terms of using the Gail model or something like that. What they do is they classified it according to the number of family members that you have and their ages and their types of cancers.

But interestingly, the initial sort of draft of this system, which was the public health genetics unit that was based in Cambridge -- they had a pretty severe threshold. It was four or more family members over age 50 for breast cancer in particular. Since then, that has been relaxed. The National Institutes of Clinical Excellence have relaxed that to three. And furthermore, one of the reasons that they've been able to get national uptake is to basically say, listen, this is a little bit flexible. In order to buy into the system, you don't have to necessarily buy into the exact criteria. So that's the basics.

So the other important thing to keep in mind in this system is that they will only test someone who has been affected by breast or ovarian cancer first. So they don't want to just do a full sequence analysis. They will only test your family if they can test someone who has been affected first so that they can link the mutation to disease incidence in the family and track it that way.

And they want to do that in order to enhance the clinical utility of the test and also to deal with some of the issues that come up often with the Myriad test, that is, the variance of uncertain significance that they're not entirely sure what the mutation means. That's one way that they try to deal with that.

But one of the things that I would argue is that this is also about the fact for them the DNA testing itself is actually not the focus of this system. The focus of the system is identifying and managing people who are at increased risk of breast cancer, which is a different kind of focus and leads to different kinds of decisions about how they'll put the technology together.

So, obviously, the focus here is on standardizing clinical care and all of this is paid through the National Health Service. So, obviously, that's a significant difference from the American system.

So then we think about this system in terms of the implications for users. The first thing I think that you see is that there is, as I said, a different kind of focus. This is about identifying and managing all of those individuals who are at risk according to family history. They want to treat those who are moderate and high risk whether or not they have a BRCA mutation. So it's sort of this kind of broad public health approach.
The testing is integrated into broader risk assessment services. It's part of this triage system where they have primary, secondary, and tertiary levels of care.

The methods of DNA analysis often vary between regions. One of the interesting things that I found in my study is that in the U.S. -- in Myriad's system, in particular -- there's a real focus on the state-of-the-art laboratory technology. Right? In Britain, what's interesting is that in this national risk assessment and triage system, the real focus was on standardizing the activities of the clinic. Much less attention was paid to standardizing the activities of the laboratory. And these are all high sensitivity methods. Whichever methods you use, the real issue is about standardizing clinical care. So the DNA analysis then I think within that kind of approach becomes an additional tool rather than the focus of the system, which I've already said.

One other thing that I want to mention. I mentioned briefly the tamoxifen approach, and I think that this is an interesting comparative point that, again, I'm not going to go into in too much detail unless you want me to. Tamoxifen is not approved in the U.K. or in the rest of Europe for that matter for treating women who have BRCA mutations. Basically the argument is that it's unproven, that it's deemed to be of increased risk and provides equivocal benefit. But there, of course, I would argue that what happens is that there there's a focus on the fact that these national health care services have to deal with providing tamoxifen over the long term. The long-term effects of tamoxifen -- those are things that they have to worry about too in making decisions about whether or not it's useful for dealing with BRCA risk.

So I think what you see here, in terms of the pure comparison between the U.S. and Britain, is two very different systems, both in terms of the design of the two systems but also in terms of the implications for the users of these systems.

So in Britain, of course, unlike the U.S., you have a system where the client is really what we would consider a traditional patient. The doctors and the National Health Service make decisions about what kinds of services the patient has access to. They have limited ability to demand access to services, although I should also say that if somebody wants, they can pay and get access to Myriad's service in the U.S. or there are now satellite laboratories at least in Germany and I think a couple of other places are developing them as well. The health care professional seems to take on, again, a more traditional role.

But the other part that's important to keep in mind is that here too the health care consumer is not really a consumer. It's a citizen who has certain rights as being a citizen of Britain and access to the National Health Service, free access to genetic testing, provided that they qualify for it, and certainly free access to care in general.

This, however, isn't the end of the story, although I suppose there's a lot that happened in between, although this stark contrast is sort of where we end up in 2007. There's an important piece of the story that I think is very relevant to the work of this task force that happens in between, and that is that Myriad in the late 1990s and early 2000s, anticipating that their European Patent Office patents would be issued, started out in Britain and wanted to enforce the patent rights. In particular, they wanted to shut down British services or ask the National Health Service to pay royalties to the company, again anticipating their EPO patents.

However, a vigorous opposition erupted among a variety of groups, so among patient advocates, among scientists, health care professionals. And they questioned a wide variety of things. They questioned all of the differences, the accuracy of the test, their focus on clinical care, the doctor/patient relationship that was envisioned by Myriad's test, but they also questioned the legitimacy of Myriad's patent rights. And as I said, some of this opposition had already been mobilized in response to the EU directive, and this is where a lot was feeding off of one another.

The opposition sort of came together. So the British Society for Human Genetics, for example, would write a press release for the directive, but also be writing in opposition to Myriad.

What I argue in the book is that there's a real clash here of different cultures of science, of health care, and of commerce that were all bound up in this Myriad opposition. And this went on for a little while, and then there was sort of a temporary resolution.

I should say that the National Health Service in Britain played a very important role in pushing back against Myriad and saying, listen, we can litigate this if you want, but we're not going to shut down the services that we have. This was, as I said, buoyed by the scientific and health care and patient communities in Britain.

They came to a resolution. Myriad initially opened a U.K. satellite laboratory by the name of Rosgen, and this satellite laboratory would offer access to Myriad's services, but still provide the NHS with free access. So it wouldn't actually affect the NHS service at all, but it would just be an add-on for people who were interested. But one of the things that was very interesting was that in the course of this conversation, Rosgen itself agreed that they would only allow access to their test if people got counseling, specialized genetic counseling, first. So here you saw even a departure from the approach that Myriad, in particular, had taken in the United States.

Now, this didn't last for very long. Rosgen eventually liquidated for reasons unrelated to the Myriad deal, but it's an interesting sort of moment in the story because it shows that there was, again, some opportunity to come to a middle ground, particularly when it came to the licensing of the BRCA patents.

Now, as this was going on, a number of scientists, health care professionals, governments, patients around Europe were watching what was going on in the U.K. but also getting involved in an opposition of their own, and they took advantage of the opposition mechanism at the European Patent Office. This was a pan-European coalition of groups, 28 opponents in all. There were 11 human genetics societies from around Europe. The Institute Curie, which is a scientific organization in Paris, took the lead, but there were a number of groups. There were four clinical genetics centers involved, three government health ministries, the European Parliament, three patient groups, one Swiss political party, and also Greenpeace. So it was a real wide variety of groups who opposed Myriad's patent at the European Patent Office.

And before I get into that in a little bit more detail, I just want to sort of explain what this opposition mechanism is because it was also mentioned this morning, and it is in the U.S. Patent Reform Act. So I think it's worth talking about a little bit, in particular how it works in Europe.

Basically the opposition mechanism is an opportunity within nine months of a patent's issue for any third party to challenge a patent. That is something that's different from the reexamination. In the American reexamination, as it currently stands, the people who can actually challenge is a very limited list, whereas here in this case, anyone can challenge a patent. The grounds are on the grounds of patentability. There's also a clause in the European Patent Convention that says that inventions that are contrary to public order or morality should not be patentable, and while this has strictly only been invoked in a couple of cases and actually been used in the OncoMouse and stem cell cases, I would argue that this sort of shapes the approach more generally in terms of whether and how third parties feel like they can get involved. This, coupled with the controversy over the EU Biotech Patent Directive, means that there's a lot of public scrutiny, and increasingly this opposition mechanism has been used by groups to shape and influence the patent process. And the Myriad case is one of them.

But in the work I've been now, I've been looking at this in a variety of different cases, and what's interesting is that while a lot of groups don't necessarily go in and use that public order or morality clause, they're often arguing about novelty or inventive step or industrial applicability, for example. In their public statements, they're almost always about public order or morality. So that's clearly what's guiding these groups, but it becomes a very technical argumentation in the opposition proceeding itself.

The opposition proceeding is an important part of the patent process in Europe because not only -- many people who are involved who are sort of dealing with this new crop of opposition from governments and civil society groups and health care professionals and scientists who may not be the traditional competitors who are used to litigating patents, what it does do is it often narrows overly broad patents because that's one of the issues that a lot of these groups are dealing with. And, of course, that's one of the issues that has come up repeatedly in terms of the patent situation in the U.S. So when there's increased scrutiny and increased public accountability, regardless of the reason, often these patents get narrowed, and that certainly happened in the Myriad case.

The Myriad opponents, as I said, in their public statements were talking about the European approach to public health and the questions about public order and morality, but when it came down to the opposition hearing room, there were very technical arguments. And they ended up being pretty successful. They were able to get a couple of the patents revoked entirely and one narrowed significantly so that now Myriad holds a patent on one BRCA2 mutation. So it's unclear how it will influence the public health services since it's only a patent on one BRCA2 mutation.

But this decision is currently under appeal. So it's not clear what will happen, but certainly in the interim these public groups have been successful in being able to narrow these patents.

So I think the opposition mechanism can provide then a couple of things that are relevant to, I think, the charge of this committee. The first is that, obviously, it's explicit public oversight, and it allows for accountability and scrutiny. It can also allow for the narrowing of broad patents.

In fact, in Europe now there are these groups who literally sit in Munich where the EPO is based and review patents, and that's part of what they do on a daily basis, is they decide which patents they're going to oppose. I should say these are all groups that are focused on biotech patents in particular. Really these are the only kinds of patents that have been opposed by civil society groups at the EPO so far, which is also I think an interesting part of this saga as well.

So then just in conclusion, to go back over the things that I have discussed today, there are, obviously, a number of differences between the U.S. and the U.K. in particular, but also the U.S. and Europe when we think about new health care technologies. There are, obviously, health care systems, different traditions of patient advocacy. But one of those important things is different approaches to patents and patent policy both in terms of the cultural approaches -- so whether it's the legacy of the Bayh-Dole Act in the U.S. or a general sort of discomfort with gene patenting among the university science community in the U.K. and in Europe, those kinds of things end up having significant implications both for the way that these new technologies are being built -- obviously, my case focuses on BRCA testing, but I argue that it's broader than that -- but there's also these controversies that are going on in Europe generally around biotechnology. I would say that it's become a bigger topic of debate in Europe. This is in the context of debates over genetically modified organisms that are much greater in Europe than in the United States.

But the patenting debate has occupied a large space in these discussions throughout Europe and continues to do so. The European Patent Directive, although it was accepted in 1998, took a number of years for all of the European countries to get on board with it because there was considerable hesitancy on the part of governments, and there continues to be, as I said, now at the civil society level. Now they're sort of going through opposition patent by patent.

One of the other things that's important is that health departments are taking an active role, whether it's the U.K. NHS stepping into the Myriad controversy and drawing a line or the other health departments that were opponents to Myriad's patents at the European Patent Office. They have played an important role in shaping the way that these patents are being addressed in Europe as well.

While I would say that in comparative perspective there's more public controversy and over a longer period of time in Europe than there has been in the United States, I would argue that over the last few months, I've been surprised to see the number of editorials in the New York Times, for example, that addressed these kinds of questions. Michael Crichton's new book talks about this kind of stuff. So it seems like this is becoming an issue of public controversy, perhaps raising again -- this seems to ebb and flow here. Whether or not that may influence, for example, the way the opposition mechanism might get used if the patent offices performed in that way is worth considering as well.

So I will just leave it there, and if you have any questions --

DR. EVANS: Great, and let's hold off on specific questions until after Richard's second presentation.

Richard, are you there?