UNITED STATES PATENT AND TRADEMARK OFFICE

ROUNDTABLE ON GENETIC DIAGNOSTIC TESTING

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PARTICIPANTS:

Welcoming Remarks:

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Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office

Overview of Genetic Diagnostic Testing Study:

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United States Patent and Trademark Office

Roundtable Logistics:

JANET GONGOLA
Patent Reform Coordinator United States Patent and Trademark Office

Roundtable Participants:

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MARK ROHRBAUGH
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Closing Remarks:

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STUART GRAHAM
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Expert Advisor

P R O C E E D I N G S

(1:15 p.m.)

MS. REA: Thank you so much. To those of you who are in attendance, I am so pleased that everybody here is talking to each other, engaged, and energetic, because we've got a lot of work to do this afternoon and we're eager to hear from each and every one of you.

So, I want to welcome everybody and say thank you for being here. I also want to say, Happy New Year, it's not too late, still relatively new in the year even though I know all of us have already accomplished a great deal and perhaps more than we imagined with everything going on right now.

But I wanted to tell you that as we continue to implement the provisions of the historic America Invents Act, we value more than ever the dialogue that we have with our user community, both for the sake of our commitment to transparency and also for the expert insights that each one of you provide.

So, many thanks to those of you who have come to offer guidance and to explore how we can balance the interests of accessing information about our health with the interests of patents and licensing rights, and thanks also to those watching these proceedings via webcast. Your participation is also vital to the success of the America Invents Act and our agency.

And I'd also like to commend our chief economist, Stu Graham, who was unable to be here today, and our AIA coordinator Janet Gongola, who sits two seats to my right. Hello, Janet. And I want to thank both Stu and Janet for their support in hosting today's roundtable. Great work as always.

And, of course, we're also incredibly grateful to our roundtable participants and I don't want to name each one of you because I'm bound to forget somebody and then to regret it, but you will all be identified, obviously, before you go up to the podium, and thank you once again for being here today.

I would like to say also, though, that U.S. Ingenuity and innovation development depend on a fundamentally American social contract, which holds that hard work, innovation, and creativity must be rewarded in the marketplace, and as a society, we acknowledge, encourage, and reward innovation and we do so in large part by our patent system.

Now, patents spur the discoveries and breakthroughs we share with the world, and in the process, change the world for the better. Every advance gives us new tools to shape our lives and nowhere is this more important or more true than in the fields of medicine and medical care.

To those of you in this room who know me you know that I've spent a considerable amount of my career delving into life science issues and I have been amazed time and again at the awe-inspiring power of medical advances to give a new lease on life to countless patients who desperately needed it.

The issues that we are wrestling with

here today sit at a vital intersection of scientific research and law that puts much on the line. There's a lot at stake here. Our conversation has, and will, provoke strong emotions, but it is a conversation that we must have.

It is our responsibility to ensure that the patent system keeps pace with our capabilities, and this is especially important in matters pertaining to the human genome because as medical treatments become increasingly personalized and tailored to our genetic makeup, it is critical that patients be able to consider as much information as possible to arrive at robustly informed treatment decisions.

The American Invents Act was an explicit acknowledgment that the innovations of tomorrow cannot take root in the patent infrastructure of the past. With this in mind, we are committed to modernizing our IP system while ensuring that regulations do not establish a false dichotomy between incentives to innovate, on one hand, and

adequate access to healthcare on the other.

As you know, Congress directed the U.S. Patent and Trademark Office to study effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist.

We are to examine the impact that independent, second opinion testing has on providing medical care to patients, the effect that providing independent, second opinion, genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test, the impact of current practices on testing results and performance, as well as the role of insurance coverage on the provision of genetic diagnostic tests.

Now, originally, the report on this study was scheduled for release on June 16, 2012. However, given the far-reaching impact of the issues under consideration, we believed that further review, discussion, and analysis were

required in order to produce the best study possible.

Now, this subject is too important to leave out any useful input, so for this report, as with the six other mandated by Congress under the America Invents Act, we have focused intently on your concerns, experiences, and expectations. And these will give us the guidance we need to measure the implications of exclusive licensing and patents in genetic testing in the practice of medicine.

Today's roundtable actually gives us a real opportunity to kick off a new era in the intersection of intellectual property rights and patients' rights. Your contributing insights will not only shape one of the critical public health considerations of our time, but it will also help affect change that reaches beyond the health and wellness of our patent system and into the health and wellness of our healthcare system.

As previous testimony has made clear, life-altering decisions about surgery and medical

treatments can be immensely difficult when only one test on the market exists for identifying a specific genetic mutation.

Now, given the scope of gene patents, the current inability to ascertain a second opinion that verifies the presence of a genetic predisposition to cancer or other ailments hinders both the ability of patients to seek the optional care and the market's ability to encourage and incentivize genetic testing.

By addressing key questions about how the status quo is affecting patient outcomes, we hope to learn how best to provide independent and confirmatory tests and ultimately remove barriers for patient access. And the evidence we collect today will help us develop the recommendations that Congress has mandated us to provide in our report.

Now, certainly, there will be a variety of factors to consider and different perspectives to iron out, but a thoughtful discussion today can assist us in doing just that.

Now, we have an important challenge ahead of us in guiding the implementation of the America Invents Act, and while we are making excellent headway, sharing your experiences and thoughts on second opinion genetic diagnostic testing will enable the USPTO to continue preparing the most accurate and well-informed report and it will empower us to continue building the most innovation-friendly patent architecture the world has ever seen. So, please be honest, don't hold anything back, and let's engage in a very active dialogue.

Thank you again, and now let me turn the program over to George Elliott, the deputy administrator for our Policy and External Affairs here at the U.S. Patent and Trademark Office. George, take it away.

DR. ELLIOTT: Thank you, Terry. Prior to hearing from today's speakers, I'd like to just offer a little background in history on Section 27 and briefly outline what Section 27 requires us to do.

During the legislative process that led to the enactment of AIA, the America Invents Act, an amendment was offered by Congresswoman Debbie Wasserman Schultz provisionally titled "Permitting Second Opinions in Certain Genetic Diagnostic Testing." This amendment would have created a safe harbor for confirmatory genetic testing exempting such activity from remedies for infringement.

Prior to passage of the Act, the Congresswoman withdrew the amendment and substituted Section 27, which provides a mechanism for collecting evidence and recommendations to aid legislators in their efforts to address this area of public concern.

Section 27 mandates that the USPTO report to Congress answers to four specific questions which address the following issues. One, the impact that the current lack of independent second opinion testing has had on the ability to provide the highest level of medical care to patients and recipients of genetic

diagnostic tests and on inhibiting innovation to existing tests and diagnoses.

Two, the effect that providing independent, second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test.

Three, the impact that current exclusive licensing and patents on genetic testing activity has on the practice of medicine including, but not limited to, the interpretation of testing results and performance of testing procedures.

And, four, the role that the cost and insurance coverage have on access to provision of genetic diagnostic tests.

Importantly, the legislation further directs the USPTO to provide recommendations for establishing the availability of such independent confirming genetic testing. In ongoing and useful conversations with Congress, it is clear to us that such recommendations include possible legislative responses.

Prior to today's roundtable,

considerable information on some of the issues has been gathered from two public hearings, one here and one in San Diego, California. Much has also been provided relating to the patent eligibility of genetic material and ongoing high profile litigation. The intent of this roundtable is to fill gaps in our information, particularly regarding insurance coverage and reimbursement, licensing practices, and the value of carrying out a confirmatory genetic test in different situations.

Therefore, we have encouraged each of the speakers today to focus their comments on these questions and have asked them to propose or otherwise comment on recommendations that would be useful to Congress. We have a very full agenda, so let's now move on to live comments from several members of the public and representatives of organizations who have expressed interest in these issues and a willingness to give testimony. And for that, I hand the program over to Janet Gongola, the USPTO's coordinator for AIA

implementation. Janet.

MS. GONGOLA: Thank you, Mr. Elliott, and as Deputy Director Rea indicated and Mr. Elliott indicated, thank you to all of you in our live and our webinar audiences for joining us today to discuss the important legal and scientific issues surrounding second opinion, genetic diagnostic testing.

Now, as you can see from the agenda that you received upon arrival, we have 19 guests who have pre- scheduled to give commentary. Our agenda is very full. When I call your name, I ask that you please proceed to the podium to share your remarks. And for those of you who will be providing commentary by telephone, when I call your name, please begin to speak.

And at this point, I'd like to check to see if our guests who will be speaking by telephone have joined us yet. Those guests are Charis Eng and Linda Bruzzone. Are either or both of you on the line at this time? Doesn't quite sound like they've joined us yet, so by the time

they are up on the agenda, they hopefully will be here.

Now, because our timeline is tight, each guest has been allotted either five or ten minutes to speak. When you approach the one-minute mark during your commentary, I'm going to raise this red card to indicate to you to please begin to wrap up your remarks so that we can stay on schedule as much as possible.

And then lastly, after our prescheduled testimony is complete, we will be opening the floor for those of you in our live audience or on our webinar audience who might like to share commentary. We will also have a discussion time, mindful though that we are approaching the end of the day.

Let's begin now with Mr. Henry Wixon on behalf of the National Institute of Standards and Technology. Please proceed to the podium.

MR. WIXON: Thank you very much, Janet. And on behalf of myself and the National Institute of Standards and Technology, I want to thank

Deputy Undersecretary Rea and our sister agency, the Department of Commerce, the United States Patent and Trademark Office, for providing this opportunity to comment on issues presented by Section 27 of the America Invents Act, as George has outlined for us.

I am particularly pleased that the PTO has encouraged speakers at today's roundtable to focus their remarks on proposals or comments on recommendations that might be useful to our Congressional leaders. As everyone in the room here today and those who are with us through the webcast will recognize, there are no easy answers to the questions presented by Section 27 regarding confirmatory genetic diagnostic testing.

There are many interrelated factors in play that are affected by and that affect any legislative approach that Congress might consider. So, I think it is important to keep in mind that we're not likely to fix on a silver bullet solution here. We need to step back and look at the broader picture. For diagnostics testing and

for medical diagnostics generally, that picture includes foundational research, which, while the United States government has been and continues to be a significant source of funding, is increasingly supported by non-federal funding and increasingly involves collaborative efforts that bring together the federal government, state and local governments, industry, and non-governmental entities.

An important practical consequence of these increasingly collaborative efforts is that the federal government alone is less often in a position to dictate the outcome of any particular course of research and its commercialization.

President Obama has recognized the importance of encouraging this kind of crosscutting collaboration issuing last fall a Presidential Memorandum on accelerating technology transfer and commercialization of federal research in support of high growth businesses. In that Presidential Memorandum, the President challenged agencies across the federal research enterprise to

take actions to establish goals and measure performance, streamline administrative processes, and facilitate local and regional partnerships in order to accelerate technology transfer and support private sector commercialization.

The President's Memorandum tasked the Inter Agency Workgroup on Technology Transfer, which is chaired by the National Institute of Standards and Technology, or NIST, to make recommendations on opportunities for improving technology transfer from federal laboratories. NIST and the Workgroup have been working hard with federal R&D agencies to develop plans for improvement and those plans will shortly be published.

One of the major challenges we've recognized in looking for ways to improve technology transfer is how to successfully translate promising scientific discoveries from the lab bench into practical application through commercial products.

Today federal agencies have precious few

tools available to help facilitate this critical transition. The cost of such transition is typically borne by start up companies that may not, in today's very challenging economic environment, have the financial resources to survive the so- called valley of death and get a product to market. This, then, is an area worth serious thought when we consider new initiatives.

The valley of death challenge is even more acute where the commercialization of a product is subject to federal regulation, and of course, clinical diagnostic tests fall within that category. The cost of gaining regulatory approval can be a significant hurdle to commercialization, particularly in the context of products such as a second opinion test where the potential market for such a test may not justify the private sector investment needed to get through the approval process.

It is almost impossible for government to create a market where none exists and equally fruitless to attempt to force the private sector,

through legislative fiat, to invest in commercializing a technology for which there is no or too little return on that investment. One needs, rather, to look for incentives.

For example, in other contexts, notably for orphan drugs, this problem of a lack of a market substantial enough to encourage private sector investment has been addressed, at least in part, through incentives that have successfully encouraged private sector investments necessary to develop and gain regulatory approval for drugs needed by a relatively small number of individual patients.

Similar incentive structures, if applied to second opinion diagnostic testing, could form the basis for a win-win outcome.

Now, on the topic of the inability of government to create a market by fiat where none exists, I want to briefly address the so-called march in right, which federal funding agencies have had for over three decades under the Bayh-Dole Act. NIST, through delegation from the

Secretary of Commerce, has responsibility for issuing regulations and establishing standard funding agreement provisions applicable to federal agencies implementing Bayh-Dole.

Those funding agreement provisions provide that the funding agency may march in on a patentee whose patent resulted from agency funding, and may compel licenses to third parties if the patentee is not taking effective steps to achieve practical application of the subject invention or if action is necessary to alleviate health or safety needs.

Now, no federal agency has ever marched in on a performing small business firm or nonprofit organization despite having the right to march in for over 30 years over the Bayh-Dole Act. Why is that? Well, a 2009 GAO study on the government's use of march in rights, found that the use of the march in authority could have a "chilling effect on federal research. If a march in occurred, investors would be less likely to provide the funds to commercialize federal

inventions for fear of losing their investments."

Agencies know that the counterproductive chilling effect that marching in would have across the entire federal research enterprise and on the willingness of investors to fund the commercialization of inventions arising through it.

More importantly, I think, for the purpose of today's roundtable, the act of marching in does not create a market where none exists, so at the end of the day, it would not solve a key element of the problem, which is how to encourage the necessary private sector investment. Rather, incentives should be considered, possibly including incentives along the lines mentioned.

Such incentives can do far more to fill the gaps in our technology transfer and translational ecosystem and to promote, long-term, our nation's health and safety objectives.

That concludes my remarks and I want to thank you and, again, Deputy Undersecretary Rea and the Department of Commerce's Patent and

Trademark Office, for the opportunity to speak to you today and I look forward to hearing the comments of my fellow speakers.

MS. GONGOLA: Thank you, Mr. Wixon. Our next speaker will be Mark Rohrbaugh of the National Institutes of Health.

MR. ROHRBAUGH: Thank you. On behalf of the Department of Health and Human Services and the National Institutes of Health, I want to thank you and the Patent and Trademark Office for the opportunity to discuss NIH practices and policies with regard to licensing its patent portfolio, particularly in the area of diagnostics.

The mission of the Office of Technology Transfer at the NIH is to manage inventions made by both NIH and FDA scientists, scientists who work in the intramural program, to provide incentives for private sector commercial development such that these new technologies lead to improvements in public health.

At the same time, we provide broad access to technologies, including research tools,

for internal research purposes to for-profit and nonprofit institutions.

We are also the lead office within the Department of Health and Human Services on technology transfer policies such as our own internal policies for intramural NIH and FDA patenting and licensing that I will describe in a moment, as well as general policies that apply both to internal and external extramural research like the Research Tools Policy and the Best Practices for the Licensing of Genomic Inventions.

We have been in this business for more than 20 years and in doing so have developed the largest public sector biomedical patenting and licensing portfolio with more than 3,000 pending and issued patents, royalties from 500 companies under 800 licenses last year, and to date, 26 FDA approved products and hundreds of others not requiring FDA approval.

We have, between the years 1984 and 2010, executed about 56 licenses that resulted in identifiable commercial in vitro diagnostic

products or services, and I'll talk in more detail about that. We are also the agency with the most experience in considering formal use of march in.

We recently conducted a study of NIH managed patents that include at least one nucleic acid claim. We found 56 licenses executed between the years 1984 and 2010 that resulted in a commercial in vitro diagnostic product or service that we could identify. I say "identify" because some of the early records are not complete. Of these, 34 licenses resulted in 94 protein based tests, products, and services, mostly immunodiagnostics, and 22 licenses resulted in 23 nucleic acid test products and services. These tests cover six gene mutations, five infectious diseases, one autoimmune disease, and one cancer associated antigen.

Only three of these licenses from the 1990s were at least in part exclusive. Two of these licenses remain active with products on the market. One patent family is exclusive to Myriad for the BRCA test. The final agreement was

not a negotiated license, but a legal settlement in 1995 of a dispute over NIH co-inventorship after the University of Utah had already filed the patent and licensed it exclusively to Myriad. A second license executed in 1991 is for an infectious disease test kit.

Many licenses to these patents did not result in products or had a field of use that only included internal research, vaccines, therapeutics, drug screening, or reagent sales. In contrast, we have patents without nucleic acid claims that have been licensed for many uses including diagnostics that are based on cellular, biochemical, or chromosomal assays or associated with a traditional device.

By law and policy, we limit the use of exclusive licensing to the scope needed as a reasonable incentive for commercializing a product. Exclusive licensing is based on the request of the applicant, its justification, the existing market, and the time and expense required to enter the market. Rarely is there more than

one party interested in licensing a technology, and many technologies remain unlicensed due to their early stage of development and the risk associated with developing them.

Depending on the scope of the patent and the public health needs, we reserve exclusive licenses for those technologies requiring greater risk and high levels of investment to develop them and therefore would not be developed under a non-exclusive license. Our policies and practices for licensing patents are key to ensuring that technologies are developed in a manner that best serves the public in providing market access to treatments and medicines.

NIH does not grant fully exclusive licenses in the traditional manner. We always reserve the right to grant research use licenses, and the license limits the commercial use to a particular field. For example, the same patent family might be licensed under separate exclusive licenses for FDA approved therapeutics, vaccines, or drugs, and non-exclusively for internal

research and reagent sales.

Even for a drug or a therapeutic, the license may be further limited to applications of the technology to a particular disease condition such as a chemotherapeutic for lung and liver cancers, but not for blood and pancreatic cancers.

Like our colleagues in university technology transfer offices, our practices have evolved over time as we have learned from our collective experience, the experience of patients, including the need for secondary testing, and the challenging commercial business models needed to develop early stage technology into products and services that will benefit everyone.

For example, beginning in the early 1990s, we started requiring specific due diligence commensurate with the company's business development plan rather than relying on general due diligence requirements that made it difficult to manage a licensee who might not be making reasonable progress or adequately addressing public health and safety needs. It has been

standard practice for many years to include aggressive performance milestones in licenses. As the licensor, we can then terminate a license or renegotiate the diligence terms if reasonable progress is not being met to develop the various applications.

In considering how to license diagnostic technologies, whether protein/antibody based or nucleic acid based, our strategy is informed by our Research Tools Policy, Best Practices for the Licensing of Genomic Inventions, public health concerns raised by patients, physicians, and professional organizations, and our years of experience. We reserve exclusive licensing to products such as Class III FDA devices and diagnostics, and Class II where clinical trials are necessary to obtain marketing approval.

In these cases, the exclusive field of use is limited to the FDA approved kit. Under our licenses, we have always reserved the right to grant nonexclusive research use licenses. We have licensed in vitro diagnostics on a nonexclusive basis for CLIA

regulated laboratory developed tests and reserve this right in our exclusive licenses for FDA approved kits.

In the last few years, we have begun to add language to exclusive diagnostic kit licenses requiring independent, third party confirmatory testing to be available to patients. These terms ensure that parties will be able to find alternative sourcing of testing if needed by using laboratory developed tests or having alternative parties run the test kit.

This approach still provides incentives for companies to invest in the development of more expensive FDA approved kits. Yet this is not without a cost, because a few companies have refused licenses under these terms, and those tests remain undeveloped and unavailable to the public.

Henry talked about the march in authority under the Bayh-Dole Act, and I would note that this authority applies to inventions that were developed in part with U.S. grant or contract funding. It does not apply to federal agency patenting and licensing where the agency can act unilaterally

and more directly.

March in is an administrative process that includes due process protections for the licensee or patent owner and may result in the agency forcing the grant of a license or granting a license itself to third parties to move the technology to practical application or to address unmet health and safety needs.

Based on over 30 years of experience, we find this march in authority to be most useful as a deterrent. Agencies may use this authority when the agency determines that it has sufficient information to invoke a march in procedure. The fact that it exists is an incentive for owners and licensees of federally owned technologies not to act in a matter that would lead an agency to invoke its use. I've been told by companies that they take this into account when licensing federally funded technologies.

In addition, the rare circumstance where there may be some resistance to develop a technology or meet health and safety needs,

discussions with the parties about the possibility of marching in often leads to compliance and avoids the need to use it.

NIH has considered more formally the use of march in on four occasions. When thinking about the theoretical possibility of marching in to address public health concerns involving diagnostics, one needs to consider whether one of the prongs of the march in statute can be invoked, and secondly, whether marching in would address that particular matter.

In the context of diagnostics, one needs to consider the scope of patents required to practice the diagnostic test and whether the public health concern could be solved through the use of the march in. For example, it is not unusual for in vitro diagnostic products to utilize patents funded by the U.S. government and those not funded by the government.

Key to the decision making process would then be whether the public health need could be addressed by granting a license to a third party

for only the U.S. government funded technologies, that is, would a license to other patented technologies be required in order to practice that technology?

I thank you for the opportunity to speak today about the way NIH manages its patenting and licensing portfolio with regard to diagnostic technologies to provide incentives for private sector development and use while ensuring that public health needs are met. Thank you.

MS. GONGOLA: Thank you, Mr. Rohrbaugh. Our next participant is Arti Rai on behalf of Duke University School of Law.

MS. RAI: Thank you very much to the USPTO and to Deputy Director Rea for inviting me. I should say at the outset that I do not speak on behalf of Duke University or its law school, I am speaking only on behalf of myself and I also don't speak on behalf of any of the agencies that fund my research.

So, in my brief time I want to focus on just two issues. Both of these issues, I think,

are relevant to the question on which we have been asked to focus, and that is what, if anything, Congress should do.

So, one issue I will not address is the complex question of whether gene patents are likely to create a patent thicket, for example, for whole genome sequencing. Obviously, that issue is centrally in play in the ACLU v. Myriad case and is affected, as well, by the ruling in Prometheus v. Mayo. That, I take it, is not within the remit of our discussions today.

What do I want to talk about? Well, first, I do want to talk about the policy relevance of the background federal involvement in a very significant percentage of the research that has led to patents on genetic diagnostic testing. Second, I want to comment briefly on possible legislation enunciating exemptions from infringement liability for certain types of diagnostic testing such as second opinion diagnostic testing.

So, first, and primarily I will focus on

the policy significance of background federal funding.

As many of you know, my colleague, Robert Cook-Deegan, who is here today as well, has led an analysis of a suite of very important case studies on patenting and licensing with respect to particular genetic diagnostic tests. I want to draw upon some of these case studies to identify with particularity the very important federal role.

We can, of course, start with the Myriad case itself. Here, NIH, as Mark Rohrbaugh has mentioned, is actually a co-owner of several relevant BRCA I patents. Now, ironically the government's leverage as co-owner in this case may not be as great as it is in some other cases that are of relevance for us today. For example, NIH appears to be a co-owner in only one of the patents that's remaining in the ACLU v. Myriad lawsuit, i.e. the 282 Patent.

Even so, the government use license in that patent may represent some leverage. I think

the background federal funding is perhaps even more significant for some of the other patents that Professor Cook-Deegan has studied. These include colon cancer, Alzheimer's, spinocerebellar ataxia, and long QT syndrome. There the government clearly funded at least part of the research that led to the relevant patents.

In general, as Professor Cook-Deegan and his co-author Shubha Chandrasekharan have shown, of 93 patents associated with tests done at Athena Diagnostics as of February 2010, government funding was specifically declared in 40 of those patents, 40 of the 93. This is, obviously, almost half and it represents two-thirds of all patents with a U.S. Assignee.

These are cases, I should note, where the federal funding was properly reported, as it should be under the Bayh- Dole statute, on the face of the patent. Unfortunately, as recent research I've done with Bhaven Sampat has confirmed, universities are not always as conscientious as they should be about reporting

the federal funding role in the patents that they seek. So there are additional patents that are used by Athena Diagnostics and owned by universities where one might imagine there might have been some federal funding role.

So, what does this funding role mean for the government? Well, we've already heard some mention of march in and Bayh-Dole. The reason that this even comes up as a question, I'm sorry to say as a professor at an academic institution, is because academic institutions, unlike NIH, have not engaged in best practices with respect to their licensing of gene patents.

The sorts of best practices that Mark Rohrbaugh has mentioned are exemplary. Universities have not always engaged in those practices. Those sorts of best practices where one does field of use licensing exclusively where there's a need for additional investment, and non-exclusively where there is not, are the best practices that universities claim they should engage in. Most universities have signed on to

principles that would essentially implement those practices.

However, the cases in which we're seeing problems are cases where universities have not followed those practices.

So, the question of whether the federal government has a role to play is before us in those cases. Obviously, as the speakers before me have mentioned, march in is a very controversial provision and in many cases, even cases involving genetic diagnostic testing, the U.S. government may not own all of the relevant patents.

Nonetheless, I don't believe this should be a showstopper with respect to thinking about march in in certain cases where additional investment is not necessary to attract interest in diagnostic testing. Presumably these are cases where physicians would be willing to do such diagnostic testing on their own in CLIA approved laboratories, for example, and therefore we would not need the additional investment that kits require.

March in can be, as Mark Rohrbaugh has indicated, a deterrent, but it could also be, perhaps, a nudge, a nudge to help universities and their licensees think better about what they should do, think, in other words, along the lines that NIH has thought for a while now.

I should also note, and this is based upon some work that Professor Rebecca Eisenberg and I have done, that some of the very cumbersome due process protections that are currently in Bayh-Dole regulations are, I don't think, required by the Bayh-Dole statutory language itself and so the delay that many have feared with respect to march in, I don't think is required by the language of the statute.

I think march-in could be a more expeditious procedure than the current regulations set it out to be.

March in has the virtue, when used as a nudge, to be surgically calibrated to the specifics of a particular situation. In that way it is different from anything Congress could do.

Congress can only legislate in relatively broad strokes whereas march in, at least as a nudge, even if not as an actual procedure, can be calibrated to what is necessary in a particular context.

So, if the valley of death is a problem in a particular context, obviously one would not use march in. If it were not a problem because you had physicians who were begging to do the tests, presumably march in would be a relevant nudge.

Now, just briefly with respect to potential Congressional legislation, I do think that given the federal government's reluctance to use march in even as a nudge, there is probably some reason to think about legislation, exempting infringement, what would otherwise be infringement in certain circumstances.

I think this legislation should be relatively narrow, although perhaps not as narrow as that originally proposed by Representative

Wasserman Schultz in 2011. That language was criticized as perhaps being overly narrow with respect to research uses.

I do think that if Congress were to draft legislation codifying an exemption from infringement, it would be prudent to have additional language urging, even in a hortatory way, federal agencies to use their nudging power under march in and perhaps also to revise the currently very cumbersome march in regulations that I don't believe are required by the language of Bayh-Dole.

I very much appreciate the opportunity to speak here today and I am happy to answer any questions in subsequent discussion. Thank you.

MS. GONGOLA: Thank you, Ms. Rai. Our next participant is Hathaway Russell on behalf of the Coalition for 21st Century Medicine.

MS. RUSSELL: Thanks to our hosts for the opportunity to continue this important discussion regarding the role and impact of patent

protection in the field of personalized medicine. My name is Hathaway Russell and I'm a partner in the IP Group at Foley Hoag in Boston, Massachusetts. I represent universities and companies in obtaining patent protection primarily in the areas of diagnostics, therapeutics, and personalized medicine technologies.

I also work with the Coalition for 21st Century Medicine, which is composed of 25 companies committed to improving the quality of healthcare by encouraging research, development, and commercialization of innovative diagnostic technologies. Our members include Genomic Health, Kleiner Perkins, XDX, Veracyte, Genetic Alliance, and many others doing important work in this space.

In addition, I'm a cofounder of Diagnostics Insights, a nonprofit organization whose mission is to educate healthcare stakeholders on the power and value of diagnostics and their impact on improving patient outcomes and reducing costs.

My comments today represent my views on this issue, which are not necessarily those of any of the foregoing organizations and clients, but I mention them because working with these groups has helped shape my own opinions.

It is my believe that a legislative mandate requiring companies to license their patented technology to other commercial interests for the purpose of allowing confirmatory tests, will seriously weaken the patent system, a key driver of innovation in the United States, and thereby harm the prospects for personalized medicine to reach its potential with negative consequences for the health of the American people and our economy. Weakening patent protection will cripple the field of advanced diagnostics and personalized medicine before it can really hit its strive.

The vision for advanced diagnostics is that they will guide and optimize every phase of a patient's interaction with the healthcare system. Their utility begins, even before disease is

present, to assess which individuals are at risk for a disease, so that resources can be appropriately focused for effective prevention.

Increasingly, advanced diagnostics are used to make the diagnosis of disease, to stage the disease, as in cancer, to find identifiable subtypes of disease that may have different responses to treatment, to identify which therapy, among several options, is the best for the particular subtype of disease, and to provide prognostic information.

Once the therapy has begun, advanced diagnostics can be used to dose more effectively, monitor effectiveness of treatment, and determine when a change in strategy is warranted. Finally, they can be used for surveillance and in early diagnostics and early diagnosis of relapse.

The point is, diagnostics are absolutely at the core of medicine, critical to every stage of the prevention, diagnosis, and management of disease. Consequently, improvements in diagnostics have just as much potential as new

treatments to revolutionize healthcare. In addition to the improvements in outcome, each of those contributions of diagnostics has the potential to save money by focusing resources on individuals at risk, allowing appropriate surveillance, and earlier diagnosis, which may reduce morbidity, targeting therapy more precisely, avoiding the use of expensive therapies that are unlikely to work, and getting patients back to health more quickly.

This potential for cost savings is especially important as rising healthcare costs have become a fundamental threat to our fiscal solvency as a nation. But it's still early days for advanced diagnostics and personalized medicine, and many of these potential benefits will not be realized if companies are not able to obtain the capital they need for research and development and can't have a reasonable expectation for a return on investment.

Patents exist to promote the progress in the sciences and useful arts. Inventors are given

a period of exclusivity precisely to allow them to recoup their investment in research and development with the goal of encouraging them to continue to innovate and bring their innovations to market. That's what our Constitution provides. And the system has worked, making the United States of America a global driver of innovation in medical science.

However, if we weaken the protection that patents provide and force companies to give up their exclusive rights to practice the invention, the risk associated with investing in the development of a new test will be greatly increased. Over the past decades we've witnessed enormous developments in the biotechnology industry, which occurred because of the support of the patent system and our patent office.

There are a few points I'd like to emphasize. First, technology transfer for universities under the Bayh- Dole Act is a hugely important driver of innovation and economic activity in the biotechnology sector. Without a

doubt, most diagnostics tests would not have been developed without basic research performed in academic settings that sets the stage for the development of new diagnostics.

However, without the potential for exclusivity that patents provide, the risk to companies in developing these diagnostics and therapies would be prohibitively increased. The need for patent protection to realize a return of the investment that our country makes in federally funded research was explicitly recognized by the Bayh-Dole Act. Limiting patent protection would hobble the technology transfer process, allowing many discoveries to fall into a widening chasm between academia and commercialization, and crippling one of the great drivers of innovation in this country.

Second, there is investment in the products of academic research once they've been licensed by industry and in basic research developed within industry because of the availability of patent protection. A great deal

of research and development goes into these tests after the initial discoveries make them possible, work that is absolutely necessary, not only for regulatory approval, but also for adoption by physicians and successful insurance coverage determinations. The patentee and licensee must take on significant financial risk to develop and validate a test as reliably detecting a genetic marker of clinical significance for a diagnosis.

If Congress were to change the ability to protect these sorts of inventions, you would most certainly see a significant change in investment behavior.

Third, duplication of tests is not cost effective. More than one laboratory performing the exact same tests is not cost effective and does not address the uncertainty of an inconclusive measurement, as well as performing a fundamentally different test. Patents and competitive pressure give companies incentive to design different tests, to design around patents. This is actually beneficial for patients because

the more dissimilar a second test is, the less likely a false result is to be repeated by the confirmatory test.

It would be far more beneficial for patients for companies to invest their time and resources in developing new, non-infringing tests for the same condition. Forcing companies to license their tests would encourage competitors to produce "me too" tests, but not to innovate and produce novel and potentially superior results in tests.

Finally, the devaluing of diagnostics runs counter to an important thrust of healthcare reform. It is widely acknowledged that one of the weaknesses of our healthcare system is the undervaluing of diagnostic and cognitive work and the overvaluing of procedures. Reimbursements are not very good for the work of figuring out what patients have by talking through history, performing a careful exam, or for optimizing a care plan to prevent the development of disease, but are much better for performing a surgery or

administering a treatment once the disease has developed and has been diagnosed.

The economic incentives in this system have led to a great deal of wasted healthcare spending that doesn't improve the health of our citizens. Healthcare reform has tried to address this by increasing the funding for primary and preventative care and supporting comparative effectiveness research. The proposal to weaken patent protection on diagnostics but not on therapeutics, which can be protected by composition of matter claims, runs counter to the direction of healthcare reform by undervaluing diagnostics versus therapy in a new way.

Investment in finding out what the patient really has and which treatment are really best for them is being shortchanged while there's an assault on the patent protection for therapies, which may be wastefully misapplied without the new information that novel diagnostic tests could supply.

I'm concerned that the push to force

licensing for confirmatory tests, which singles out diagnostics as an area, would result in weakening our patent system in an effort to resolve issues that are not caused by the patent system.

Patients may doubt the accuracy of a specific genetic test, the performance of the test by the test lab, or the doctor's opinion about how to manage care in light of the result, but that's not the fault of the patent system, nor will it be solved by changing the patent system.

Limiting IP rights to address those concerns does not make sense and has the potential to dramatically reduce the development of new tests. If we want the field to grow, to develop new tests and better tests, then we can't cut it off at the knees. We need to incentivize universities and companies to make truly new discoveries and develop new technologies.

We need to encourage universities to license the technologies to entities who have the resources to invest in the research and

development that's required to bring an accurate and reliable test to market. We need to make companies that develop and bring these tests to market attractive to investors so that patients will have access to them.

The current level of protection that patents provide has accomplished and is continuing to accomplish these goals. As the flowering of advanced diagnostics in the last decade has shown, if patent protection is weakened and companies stop developing tests, there will be fewer tests available. The entire issue of second genetic testing will be moot. And proponents of weakening patent protection by forcing licensing for second tests will have won the battle, but lost the war.

Thank you.

MS. GONGOLA: Thank you, Ms. Russell. Our next participant is Sapna Kumar from the University of Houston Law Center.

MS. KUMAR: Hello. I'd first like to thank the PTO for inviting me here today. I'd also like to note that I am talking on behalf of

myself and that my views do not reflect those of the University of Houston.

Our previous speaker discussed the Constitution's protection for innovators and how to promote that. I'm here to discuss the Constitution's protection for individuals under the Fifth Amendment's due process clause, and in particular, why the PTO's issuance of gene patents currently violate the Fifth Amendment's protection of fundamental liberty interests.

There are two fundamental rights that are important with regard to gene patents: the right to knowledge and the right to make healthcare decisions. With respect to knowledge, three courts of appeals have found a fundamental right to medical information with regard to being able to refuse medical treatment. Also the Supreme Court has tacitly acknowledged a right to information in the context of medical decision-making.

Second, there exists a fundamental right of bodily integrity and physical autonomy, so

individuals have the right to make healthcare decisions so long as there is no moral type of conflict.

You may be asking yourself what this has to do with gene patents and the issues on the agenda today? Well, genetic information is knowledge and genetic information is an intrinsic part of our bodies. It is the key to being able to make an informed healthcare decision, and without that information we're essentially lost. Without knowing if we are a gene carrier for a particular disease, our doctors cannot make informed decisions on how to best treat us.

Thus, when the PTO issues gene patents that have the capability of blocking or limiting individual access to genetic information, this is an as-applied violation of the due process clause by compromising the autonomy of patients. Bob Cook-Deegan will give some examples, and Arti already has, with regard to Long QT syndrome where for a few years there was no

test available for the syndrome because the patent holder chose to not make one available.

Likewise, even for tests that currently have some availability, such as BRCA, there are limitations on that. For example, Asian women cannot get highly accurate testing done because of information that's currently missing.

So, what are the solutions to these problems? I see three of them. The first is to narrow the scope of Section 101, which would perhaps be the most difficult route to go, but there could be clarification that purified isolated genes are outside the subject material of 101.

The second is compulsory licensing to prevent gene tests from being withheld. Right now patent holders can hold our genes hostage. Any patent holder who owns the patent on a gene can choose to not offer the test at all and we are at their mercy. Compulsory licensing would provide a solution to this, and make up for the fact that march in rights have not been historically

exercised.

Third, having a research exemption formally placed into the Patent Act would allow researchers in nonprofit areas to continue to engage in important testing while the patent holder still receives protection.

Thank you very much for your time.

MS. GONGOLA: Thank you, Ms. Kumar. Our next participant is Robert Cook-Deegan for Duke Institute for Genomic Sciences and Policy.

DR. COOK-DEEGAN: So, thank you, and the first thing I can say is thank you for having us here and what I'm going to be talking about -- when we learned that this hearing was going to be held, this roundtable was going to be held, I and a bunch of other staff at Duke went kind of into scramble mode and just the most important thing I can do, probably, today is to indicate that we do have a website. If you do a search on Google for Section 27 + Duke, it will take you to there as the first click, and there's a written statement that's much longer than I'm going to go into in my

oral remarks, blessed to you, and also a bunch of background documents that are available and downloadable. And that's probably the most important thing that I can do today.

Second thing is to alert you to some other activities that are not yet out. There is an effort underway to actually look at the degree to which patent claims might get in the way of whole genome sequencing. This is a hot question that's looming over the debate right now, and we're actually going to try to do some empirical analysis of whether that's true, because there's a lot of debate about the degree to which it's true and even whether it's true. So, we're doing that as an empirical thing and there are a couple of other articles that are underway that are mentioned in our written statement.

But now turning to substance, a couple of points. I'm going to do two things. Basically I'm going to focus on two points of policymaking where there might be an opening for some progress -- not necessarily statutory, but I'll go into

that in a minute -- those are research use and diagnostic use.

The policy options that are on the table, of course, were elaborated in the Secretary's Advisory Committee report that came out in April of 2010. That analysis has already been done, those recommendations are controversial, but they do address creating safe harbors or research exemptions or diagnostic use exemptions under the statute that would address those two domains of use.

And if those two domains of use had been dealt with in policy terms, in fact, a lot of the controversy would disappear. Now, of course, the argument that you just heard from Hathaway is, so does the incentive value of patents, and that's the debate that we find ourselves in.

And I think a couple of things to say about policy options short of trying to create a statutory exemption, two things about the writing, I'm really glad that I don't have to write the report that you guys are trying to write because I

don't know what I would say that would command consensus. I'm not sure that it exists, so better you than me.

I do despair that any of the policy options listed in the Secretary's Advisory Committee report have enough consensus behind them to be turned into statutory language. So, is there anything we can do short of that? And I think there is and I think there are points of intervention at two levels that are quite possible, one is at the level of individual companies. If individual companies have stated explicit policies about verification use or research use and people can act on those policies, then that solves the problem one company at a time.

Now, the problem for trying to solve it at that level is each company then has to interact with competitors and they have business interests. That's not going to solve all the problems.

Are there collective options? Yes, there are. We could establish collective norms

and practices that set this is how we should do it as an industry, and when you deviate from that you need to answer for it. It's weak accountability. The enforcement mechanism is shaming mechanisms. But they work sometimes. And the very process of pulling the stakeholders together around a table can sometimes make progress when people realize, oh, my gosh, yes, you do have some interests here that I wasn't thinking about.

So, I think there is some possibility for collective action. I think the missing element on both verification testing and research use has been the lack of a process for trying to see if there's some common ground. Maybe there isn't, but maybe there is. And if there is, there are ways to get there. I don't think necessarily USPTO and this study is the way to get there directly, but this study could be a way of pointing the way to invoking something like a National Academy study. This is what they do, pull stakeholders around a table and say, can we find common ground, can we find consensus, can we

establish some norms and practices.

I'm going to now shift gears and make an observation about the verification part of your task, very specifically, because in my reading of the literature that's been surrounding this Section 27 study, I think there's been a tendency to narrow the question too much.

There are at least three levels of what has to happen in the real world of testing in order to do verification or second opinion or whatever. One is, have you got the diagnostic test right? Have you accurately assessed the mutation or lack of a mutation in a particular sample? That's actually the easiest problem to solve and almost all of the discussion has focused on that.

There are issues there and you'll see two examples of where patent rights have interacted with and people have asserted that because of patents even that verification process has not completely worked itself out. One example was from a diagnostic where a -- the way the lab,

Athena Diagnostics, was doing a particular test, happened to land right on top of a mutation so they didn't know that they were missing it. And this can happen. And no matter which protocol you're using, you're going to make errors if you're doing genetic testing.

So, it required other labs to say, hey, we've done this test, we got a different result, we found a mutation that you missed, going back to Athena. Athena then realized what was going on. And then the other one that's very famous that everybody in this room knows about was the 2006 controversy over rearrangement testing for BRCA. Myriad was aware of that, was already developing a test, but nonetheless, it's clear that nobody does a perfect test.

But that's the easy part. There are two other layers of verification where we haven't had very much discussion at all and where the patents are still mattering a lot. One is, and I'm going to give you an example of a case that came to our attention, this is a woman who was tested for a

BRCA mutation. She was tested at Myriad and was given the diagnostic that, yes, you have a high-risk deleterious mutation.

This was in 2008, the testing was done. In 2009, she got both breasts and both ovaries removed. Six months later she got a letter -- her physician got a letter from Myriad saying, oh, we've reclassified your mutation from deleterious to unknown significance. Now, that's really good that that notification went out. She had already made her fateful choice. We were contacted about a year and a half later by her lawyer saying, what should we do, who should we go to, and here's where the verification and the complex interaction between the intellectual property and the system of interpreting a particular result -- there is no disagreement about the mutation. This has been tested multiple times. Everybody agrees, this is the mutation that is there.

But what we have is the lab that has done a million tests, has reclassified from high-risk to intermediate-risk, but all of the

public documents -- and I went to those data bases and I fanned out through our network of people, they looked at the databases, everything says this is a deleterious mutation in the public literature. Myriad's saying it isn't. And, look, Myriad has probably hit this mutation 50 or 60 times since 2004, the period when they stopped sharing data with the Breast Cancer Information Corps.

So, where are we in the real world? We have a bunch of labs who have actually gone ahead and done testing. They know they are incurring risk of infringement liability, which is why I'm not mentioning their names, and it's why we do all of our research under a certificate of confidentiality, so they can contact us freely, and if somebody subpoenas us, we show them the certificate and we presumably quash the subpoena.

So, we know that testing went on. There's no disagreement about mutation, but we actually do not have the data in the public databases to be able to interpret this. It's

quite possible that Myriad is right. It's also quite possible that it's a deleterious mutation. How do we solve that problem? We solve that problem by sharing data. Why can't we share those data? Because the labs that did the testing and the clinicians who know about that stuff can't possibly notify Myriad because they would then be laying down the trail for infringement liability absent an explicit policy that we won't do that.

So, there's a solution there, I actually think there is a solution there, where the parties can get together and say, here, here's a rule set that allows us to share data when we need to share data at the clinical level.

There is a third level of verification that can sometimes, not always, be needed, and that's when you have a mutation like this what you can do is you take the mutation, you either put it into model animals or fish or yeast or whatever, or you put it into knock out -- you knock out the BRCA gene and you put that mutation in and see if the function is rescued, which tells you it's not

a deleterious mutation. Now, that costs $3,000, takes six months, nobody does that in all the model organisms, you don't know which organism's going to work. You need a network of scientists who are going to do that kind of work. They are all doing work that under U.S. Law, not necessarily European law, but under U.S. law, infringes patent rights.

That's a research use that's quite clear and it's in everybody's best interest, including the patent holders, to have a system that allows that kind of information to be shared.

So, let me finish by saying, what are the action items? One is, I actually -- I think it's great that Congress is interested, but I think the main reason that I think it's great that Congress is interested is because of the power of oversight and holding the USPTO's feet to the fire. We've heard from NIH, from NIST and from USPTO that you all are already engaged in this. And, look, we've had controversies over ESTs, over utility and written description examination

guidelines, now verification testing. There have been controversies dating back 20 years. Hey, guys, this is going to happen over and over again. Let's have a system for thinking about that.

Executive Branch can do something to interact with the Legislative Branch and the Judicial Branch. You also had to do a process of deciding whether the Solicitor General was going to weigh in on AMP v. Myriad. That was not a love-fest. It didn't reach consensus, but it did reach a decision.

So, this is a domain where there's going to be activity going on for the foreseeable future. Maybe systematize that.

And at the level of concrete actions, I think it would be really nice for Congress to mandate a process for trying to move forward on verification testing and research use, the places where I think there is some promise for actual things to happen in the real world that wouldn't be statutory, wouldn't be inflexible, but would involve all the stakeholders having to get

together and setting up norms that can then be used as soft enforcement of practices.

So, thank you.

MS. GONGOLA: Thank you, Dr. Cook-Deegan. Our next participant is Debra Leonard on behalf of the College of American Pathologists.

DR. LEONARD: Good afternoon. I'm a board certified and practicing molecular genetic pathologist and currently vice-chair for laboratory medicine in the Department of Pathology at Weill Cornell Medical College. I am here today representing the College of American Pathologists, or CAP, the nation's largest association of board certified pathologist physicians.

The CAP is the world's largest association composed exclusively of board certified pathologist physicians and is the worldwide leader in laboratory quality assurance. The mission of the College is to represent the interests of patients, the public, and pathologists, by fostering excellence in the

practice of pathology and laboratory medicine worldwide.

Pathologists play an integral role in healthcare as physicians who obtain and interpret test results from assessments of tissues, blood, and other human specimens for patient care. Pathologists and the College have a keen interest in ensuring that gene patents that claim gene sequences and not testing methods, do not restrict the ability of physicians to provide high-quality genetic testing services for their patients.

Most discoveries of human or pathogen genes related to disease can be effectively translated into gene-based clinical tests without the incentives provided by patents, but instead driven by the goal of providing the best care for patients.

Gene patents pose a serious threat to medical advancement, medical education, and patient care. Gene patents, unlike patents on clinical testing methods, claim the very analyte, which is the target of a clinical genetic test.

Gene patents cannot be invented around, as Ms. Russell suggested, because use of the claimed and protected gene sequences is required for any genetic testing method, limiting a pathologist's ability to perform testing for the gene or the related disease.

Therefore, a gene patent, when exclusively enforced or licensed, does not produce the desired effect of promoting innovation and broad availability of testing. As a consequence, patient access to care is limited to one or a few laboratories, the quality of patient care is jeopardized by limiting inter-laboratory proficiency testing comparisons, broad clinical observations correlating test results with disease characteristics are compromised and new discoveries of limited, and training of healthcare providers across the United States is restricted.

The research, development, and practice of genetic testing in academic and other medical centers is essential to assure the high quality of personalized healthcare, the continued improvement

of medical care, and the training of physicians and other healthcare professionals.

The College believes patients should be empowered and able to obtain information about pathology results, including second opinions on genetic or other clinical tests and interpretations. Exclusive or restrictive patent enforcement or license agreements on disease-related gene sequences, have prevented broad and local performance of genetic tests. Patients suffer because genetic tests limited by patent or exclusive license enforcement are less affordable and accessible as reported by the Secretary's Advisory Committee on Genetics, Health, and Society in their April 2010 report entitled "Gene Patents and Licensing Practices, and Patient Access to Genetic Tests".

Unlike most independent second opinions for diagnostic tests that are rendered today, patients would have a difficult time obtaining an independent second opinion on a genetic test protected by a gene patent even if the law is

changed to allow second opinion testing. No laboratory can routinely develop and perform a genetic test solely for confirmatory testing purposes because the test volume would be too low to maintain test performance proficiency and quality and would be very costly.

The quality of clinical laboratory testing depends on the ability of laboratories to replicate each other's measurements and interpretations on a national basis, formally, through proficiency testing and accreditation programs, such as available through the College, and informally for individual patients through second opinions.

The quality of clinical laboratory testing also depends on maintaining the competency of the technical staff to perform a test and the pathologist's ability to properly interpret test results, which is difficult to maintain with a very low volume of testing.

In addition, as Bob Cook-Deegan pointed out, databases of observed mutations are essential

for proper interpretation of genetic results, but patent protected proprietary databases are not available for the second opinion test, making proper interpretation difficult, at best, or just wrong, at worst.

Finally, the cost of only performing the limited second opinion testing would be very high because pathologists and laboratories spend significant time and resources to develop and validate genetic tests, FDA approved or laboratory developed, which would not be warranted for the low volume of a second opinion test requests. Therefore, second opinion genetic testing will not be provided by clinical laboratories if routine primary testing also is not possible because of gene patents.

The trend of using patents to monopolize genetic testing services is a radical departure from historical precedent in pathology practice and works against the goal of making genetic tests widely accessible and affordable for the public. Especially troubling is the fact that under patent

protection, knowledge about the utility of a genetic test, as well as the underlying disease mechanisms driven by gene variations, also becomes proprietary thereby imposing a profound change in how the medical profession and the public acquire knowledge about this rapidly evolving area of genetic testing, the diseases diagnosed by these tests, and their clinical usefulness.

Beginning to sum up, the College believes that gene patents pose a serious threat to medical advancement, medical education, the quality of genetic testing services, and patient care. Peer-reviewed evidence is the basis for information that pathologists use to render primary diagnoses as well as second opinions.

Patent restrictions on the broad practice of genetic testing limit the generation of medically important, peer- reviewed evidence, which will diminish the quality of medical care.

To restrict a patient's ability to evaluate and understand their own genetic makeup is the ultimate de- personalization of medicine.

The CAP has had a policy opposing gene patents for over a decade. In response to the request for recommendations, the College has advocated in the past for extension to pathologist physicians the protection provided to non-pathologist physicians by the Frist Ganske Amendment, 35 USC, Section 287, which basically protects non-pathologist physicians from patent infringement lawsuits for use of patented medical information.

Extension of Ganske Frist to pathologists would ensure that genetic testing services, which are part of medical practice, can be performed for the benefit of patient care, medical training, and medical research without fear of patent or exclusive license enforcement.

The CAP encourages consideration of this protection option to allow broad access and affordability of genetic testing, both for primary diagnosis and for confirmatory purposes. Thank you for allowing the College to make comments today.

MS. GONGOLA: Thank you, Dr. Leonard. Our next participant is Charis Eng on behalf of the Cleveland Clinic Genomic Medicine Institute. And I believe that Charis has joined us on the telephone.

DR. ENG: Hi. Good afternoon. Thanks for inviting me. So, I'm Charis Eng and I'm chairwoman of the Cleveland Clinic Genomic Medicine Institute and also its clinical component, the Center for Personalized Genetic Healthcare. As well, I am the vice-chair of the Department of Genetics and Genome Sciences at Case Western Reserve University. I am formally trained in clinical cancer genetics.

So, I represent the clinical viewpoint today and you might not hear the word patent apart from what I just said.

To me, what is most important thing about genetic testing is, in fact, who has the proprietary oversight for ordering tests, and I believe -- I joined you rather late, just a few minutes ago, where you have rightly, because of

your represented expertise, focused on the testing and patent -- I said it once again -- and how it affects patient care and research in that setting.

So, I'm going to focus on the oversight and I would like to posit, and I know my clinical colleagues would agree that the oversight should be by individuals who understand the evidence base, as mentioned by two previous speakers, and the clinical genetics as well as the nuances of genes and mutations, and these are genetics professionals in the broader sense. They could be MD geneticists, and they definitely should be genetic counselors. I'll just give you an example. So, before 2010, our institution, we have a very -- comprehensive from prenatal to old age, but our institution did not restrict testing (inaudible) what institution did, and in a medical operations research we found that non-genetics professionals who are ordering tests willy-nilly, the wrong diagnosis was made, therefore the wrong test was ordered, and a mutation negative did not serve the patient well. Huge panels from Athena

were checked off wasting lots of money and getting the wrong diagnosis whereupon patients finally wound up, after a couple years, in genetics.

This was not uncommon. This is why healthcare money is being wasted.

After that came in the Cleveland Clinic, had a pilot of restricting certain tests, so, a cadre of testing was chosen and because we use an electronic medical record, it was quite easy to block the testing with the alert that says, please refer your patients to genetics and genetic counseling.

And in the short period, about a year and a bit, almost two, of this pilot, we found that, of course, the patients are better served, the right diagnoses were made very quickly, and healthcare dollars were saved.

Now, I'll move on a little bit to what I also heard briefly two speakers ago about interpretation and I have to say that interpretation based on evidence is of the utmost importance, and with the interpretation again

comes the plug that geneticists and genetic counselors are here to help the patient and in fact (inaudible) doctors interpret the test.

We also heard about do we need second opinions clinically and does research need to be done, and I think the answer is, yes and yes. We do, in fact, today -- I am in clinic today and before clinic we always have family review. And in our family review alone today, we had three cases where we questioned whether the -- there was an administrative error. So, in one case there were two different mutations in the family. Well, that could happen, one wonders, and so this is when one would want a rerun. Sometimes it's at the same lab, and because it's an administrative error, but because of (inaudible), for example, the PCR primer on a mutation, that's one example, or certain companies like Emery, who only use one method for the (inaudible) analysis, MLPA, where the single company MRC Holland changes their probes without telling anyone is not very good, so in that situation you would want to go to a

different company who would at least run a second test to validate the results obtained by the single test from a company that continues to keep changing probes without telling anybody.

So, finally, I was also asked whether there are concerns of false positives and negatives, and I think what I mentioned covers that, unless you have specific questions, and insurance reimbursement, I will also comment a bit. These days, many insurance companies, third party payers, do cover for the gene testing, but many do not cover for genetic counseling, which actually has a CPT code, 96040, which is new since 2007.

Without referring -- without covering for genetic counselors, many non-genetic professionals feel it's their duty to just perform the gene test requested by the patient, whether rightly or wrongly, and most common is BRC1 and 2, because a patient had breast cancer. I will tell you that there are 10 high (inaudible) genes predisposing to breast cancer, and so I would

posit that proper insurance coverage for the CPT 96040 code or similar genetic counseling code would right the wrong of ordering the right test or ordering any genetic testing at all for our patients.

Thank you.

MS. GONGOLA: Thank you, Dr. Eng. Our next participant is Bruce Quinn for the Coalition for 21st Century Medicine.

DR. QUINN: Thank you. My name is Bruce Quinn and I'm here on behalf of the Coalition for 21st Century Medicine, which is a client of the firm I work for, Foley Hoag. My goal is to discuss typical insurer policies on second opinion testing using the general published rules of the Medicare program as an example.

The U.S. healthcare system is in a fairly rapid state of transition with new entities, new contractual arrangements between doctors, between doctors and hospitals, between providers and insurance plans, but my presentation will focus on the basic published rules of the

traditional Medicare program, which is complicated enough.

I had the chance to review documentation on the PTO website from the February and March meetings last year. Section 27 of the Act provides four questions for the PTO to answer, and the 2012 agenda included a much more complex set of 14 questions, some with multiple parts.

Speaking as a professional writer/thinker/consultant, I would have found it very hard to organize all the data in the 14 questions into one report.

The agenda for today's meeting returns to the original four Section 27 questions, and my contribution fits within those boundaries.

Public statements last year which addressed insurance policies include Hans Sawyer of Bio, Kevin Noonan, and others. Prometheus Labs, a member of our coalition, presented data last year that it's apparent incidents of repeat measurements for genetic tests were 0.2 to 0.3 percent.

By way of background, I'm an MD PhD, I'm a board certified pathologist, and I was on the full time faculties of NYU and Northwestern in my first career. Since 2001, I've worked as a physician executive at a global consulting firm in biotechnology, as a regional Medicare medical examiner, and now as a policy expert inside of a law firm, Foley Hoag. I'm not an attorney.

Therefore, I have nine years, or about 18,000 hours of full time experience with Medicare policies, which you can now benefit from.

Medicare's published policies generally do not provide coverage for repeat testing of diagnostic tests. As some commenters stated last year and even today, health insurance distinguishes between a second opinion of a physician and a repeated test.

So let me give you some background and I'll provide citations. I'm also going to provide a written transcript within a short time.

Medicare is a defined benefit health plan and many of the benefits are very broad, like

hospital care or physician care or ambulance transport. One category is called X-rays and other diagnostic tests, Social Security Act 1883 S3. This category for X-rays and other diagnostic tests is 50 years old, but it's broad enough to include genetic tests.

The tests must be reasonable and necessary to diagnose disease, so historically screening tests like pap smears or mammography in healthy people were excluded from Medicare unless Congress specifically provided for such a test, as it did.

Now, Medicare has a benefit policy manual, which, in Chapter 15, Section 30, Paragraph D, says that you allow second opinions before major surgeries or procedures. Second opinions are defined as a second opinion of a physician. They even go on to say if those two opinions diverge, you can get a third opinion as a tiebreaker, and that's the A-to-Z of the second opinion of a physician.

All diagnostic tests fall under

Regulation 42 CFR 410.32 stating that each diagnostic test must be ordered by a treating physician and used in patient care. That doesn't necessarily allow or exclude that second test, but other policies do.

Medicare also has a published policy manual about the way it pays for clinical chemistry and other lab tests. This is found in the correct coding section of the Medicare website. Here you get to Chapter 10 of the National Correct Coding Initiative Policy Manual for Medicare Services, where it states in several different places that Medicare can only pay once for a given analyte.

For example, it says, "Even if an analyte can be measured by two different methods, it will pay for only one of them." Verbatim it says, in several places, here's one, "Medicare does not pay for duplicate testing. Multiple tests on the same analyte marker or infectious agents cannot be reported separately. For example, it would not be appropriate to report

both a direct probe and an amplified probe for the same agent."

There is an exception for measuring the same analyte in two materially different tissues, so you could have skin cancer on the left arm and skin cancer on the right arm and you might test both of them for something, but that would not apply to hereditary tests.

Then the correct coding website has something called MUE Edits, MUE. These are called, at various times, medically unbelievable or medically unlikely edits, and they block payment for a second test under the same CPT code. HIPAA law requires that providers communicate with insurers using a uniform national code set, that's been referred to today, called CPT codes, and Medicare national policy blocks those germline genetic codes from being paid more than once.

Another policy, called the data service rule, 42 CFR 414.510, sets the date of service as the date of specimen collection, so even if three labs ran the same test on day five then day ten

then day fifteen, Medicare would review it as being the same -- performed on the same day administratively.

So, in short, this Medicare policy says that ordering the same genetic test twice is "medically unbelievable" so it's not payable.

One final barrier, and some of your speakers last year referred to this -- I'm, I guess, providing footnotes to what they said -- one final barrier would a typical statement in insurance policies such as Medicare, Noridian Policy L24308 "a specific genetic test may only be performed once in the lifetime per beneficiary for inherited conditions."

You've heard that verbally, that's a quote from insurance.

Similarly, the largest U.S. private payer, AETNA, has a genetic testing policy, policy 01040, that states, "Genetic testing for inherited disease need only be conducted once per lifetime of the member." I found similar language in the insurer WellCare, Capital, BlueCross, BlueCross

Alabama, Humana, and so on, and this was also stated in a 1997 NIH report on genetic testing, they're only performed once in the lifetime of a beneficiary.

So, these citations support statements made last year that in general insurance companies state that they will cover germline genetic tests only once in their published policies on paper or on the web.

So, those were my prepared statements. I had a short comment based on some of the discussions of judging aforehand when licenses should be exclusive for commercial practical reasons. Working as a policy consultant part-time in the diagnostics industry, there are some very severe incentive gaps that can occur in developing diagnostic tests. Insurers frequently complain about the lack of enough evidence for diagnostic tests. There are now well over 100 codes for genetic tests, many of them generic genes, and I heard a Medicare medical director said we wouldn't pay for 90 percent of these because there's not

enough evidence.

So, that's a significant issue, getting enough evidence to be paid for.

I've written on this publicly in book chapters and some peer reviewed publications, and excellent papers by Richard Frank in "Journal of the American College of Radiology" 8:124 in 2011, and a paper a month ago in January by Eric Faulkner for the International Society for Pharmaco-Economics and Outcome Research in Value & Health, 15:1162 in 2012.

So, imagine a generic drug and generic genes that are regulated with metabolism. There's potentially huge value in knowing more about how to give generic drugs better, having more data on how to use the generic metabolic genes, and yet it's extremely difficult to have that data.

I've been on calls with investors and talked at board meetings of companies that are trying to do this, and it is very, very difficult. That would be an example where you have no FDA protection, no patent protection, no obvious other

IP protection, and it's very hard to dig your spade in the ground and put in $50 million and do it.

I'll give you another example from a different area just to be sure we've made the point clear. Another diagnostic test would be PET scans. There are three -- basically three brands of PET scanners, Siemens, Phillips, and GE. Any one of those companies could spend $100 million showing how accurate its PET scanner was in breast cancer, but once they'd invested that and published it, everybody would know that all the PET scanners would be exactly that accurate in breast cancer, because they all have the same performance characteristics.

So, it's an example, it's a little bit -- it's a valley of death problem. It's not so much the free rider problem after the fact, but the fact that you foresee that ex ante, as economists would know.

The other thing is, as alluded to it, is whether you're a sole company or a multi-source

test, it's hard to work on a national basis with insurers. There's one Medicare program, but there are dozens of sub-plans called Medicare Advantage Plans that are about 25 percent of patients. There are 50 Medicaid programs and in many states there are several HMOs inside of the Medicaid program that process their own claims.

BlueCross has 38 different plans, each of which processes lab claims separately now, that's been a new barrier to entry, and then there are dozens of large and small private insurers, so you literally potentially could get claims in from whether you're one big lab or whether you're St. Mary's Hospital in Evanston, you could potentially get claims in from hundreds of different insurers with their own policies, their own barriers to payment, and so on.

So, if you're looking administratively at what the potential barriers are, I think it would be easy to underestimate them without working in the industry. Thank you.

MS. GONGOLA: Thank you, Dr. Quinn. Our

next participant is Beth Peshkin from the National Society of Genetic Counselors.

MS. PESHKIN: Thank you very much for the opportunity to speak with you today. I am a board certified genetic counselor at Georgetown Lombardi Comprehensive Cancer Center and the Fisher Center for Familial Cancer Research.

Today, I am also privileged to represent the National Society of Genetic Counselors, NSGC, an organization consisting of over 2,700 professionals who are committed to integrating genetics and genomics to improve health for all individuals.

The timing of this roundtable is apropos as our nation examines our healthcare goals and strategies for the future. Without question, a key feature of the Affordable Care Act is access to healthcare, which is also a central theme in the dissemination of genetic medicine.

As the roundtable participants consider the current landscape of genetic testing, how it has been impacted by patents, and how it may be

leveraged to improve the health and well-being of individuals, I want to take a moment to underscore that it is genetic counselors who have been in the trenches for decades helping people to understand and adapt both medically and psychologically to, first, the risk of disease or diagnosis of a genetic condition, two, the need to make informed decisions about managing disease risks, and three, the challenges of navigating and assessing resources for clinical, research, community, and support services.

Genetic tests are clinically available for over 2,500 diseases. Within my area of expertise, hereditary breast and ovarian cancer, genetic testing for mutations in the two most commonly implicated genes, BRCA 1 and 2, it's probably the most frequently ordered test for an adult onset condition. In fact, a recent paper estimated that there are about 940,000 BRCA 1 or BRCA 2 mutation carriers in the United States and that only about 5 percent have been identified to date.

Even in this small 5 percent cohort we have witnessed in ways we could have never imagined how the granting and enforcement of patents for these two genes by Myriad Genetic Laboratories, have impeded access to these lifesaving tests.

What we have learned is that patents, when enforced to the letter of the law, can result in genetic tests that are cost prohibitive and incomplete. Patients can become unwitting donors of DNA and data to proprietary bio banks and a continuum of research from basic science to translational medicine can be stalled. Thus, these pitfalls have hampered, and in some cases, compromised, the delivery of high quality medical care.

However, the days of single gene testing are numbered. As the cost of analyzing dozens of genes simultaneously and eventually all of our genes at once with whole genome sequencing becomes more affordable, we are standing on the cusp of a major paradigm shift in medicine.

The scientific community is immersed in complexities and conundrums related to how to interpret and disclose the vast amounts of information that will be forthcoming from whole genome testing, what bio-informatics tools will be needed to analyze these data, and how to store and transmit the information.

In my field, the essence of our work is to tackle these new challenges by building on our past experiences. Make no mistake about it, although much attention has been paid to consumer genomics, the so-called spit and click model where individuals obtain genetic test results from their saliva samples over the Internet, genetic counselors will be at the forefront of determining appropriate test ordering, preparing clinicians to assimilate genomic information, and in translating results to consumers.

What is at stake with genetic testing? To name just a few possibilities, the life of a fetus, the health of a newborn baby, the avoidance of devastating side effects from a drug in an

adolescent cancer patient, the decision of a healthy woman to remove her breasts, the well being of a young man at risk for a fatal neurologic disease. The incentives for obtaining correct and complete genetic information are innumerable, but in order for the benefits of genetic information to be realized, access to genetic testing is critical.

Individuals must be able to have options for affordable, state-of-the-art testing and have confidence that the potentially life altering decisions they make based on that information is accurate and complete. Patenting creates a barrier to access that should not exist.

With a bright future for genomic medicine on the horizon, fears about the slippery slope of gene patenting have led NSGC to take the position that nucleic acid sequences should not be patented and do not meet the novelty criterion for patenting. This stance is, in essence, the basis for the federal court's 2010 ruling under Judge Sweet, in which the patents for BRCA 1 and 2 were

invalidated.

As you know, a final ruling about this issue has not been made yet. However, within the current system there is still an opportunity to learn from our experiences with BRCA patenting to improve access to research and clinical care to patients.

I encourage the USPTO to encourage what 20/20 hindsight has taught us and to move forward as we brace for new challenges in the delivery of genomic medicine. We now have the unprecedented opportunity to avoid these barriers as we prepare to implement the next generation of genetic testing.

Today I will share four goals that can guide policy around gene patenting as next generation genetic testing becomes today's reality.

First, individuals who pursue genetic tests should have access to the most comprehensive testing possible. Would anybody find it acceptable for a doctor to look at only 90 percent

of breast tissue on a mammogram because 10 percent of tissue was patented and couldn't legally be examined? It sounds absurd, but in fact for many years, the comprehensive testing that Myriad performed on the BRCA genes was comprehensive in name only. Entire sections of the genes were not analyzed, but tested individuals could not get a second opinion, could not get their DNA analyzed by a different lab using a different method to possibly detect a mutation.

Invariably, individuals with mutations were missed, cancers often ensued, women who would have pursued life saving measures to reduce their risk of breast and ovarian cancer were denied the tools they needed to make informed decisions. And like we always say about genetics, it's not just about the individual, it's about the family.

Unlike other medical errors, missing a critical mutation in a patient can affect the health of several other relatives and several generations.

When whole genome sequencing becomes

widely available, will we have to discard the term as a misnomer because certain sequences are off limits due to the fact that they are patented? Rather than undergo a single test using genomic sequencing through one laboratory, will consumers have to undergo multiple tests through multiple testing companies which will be expensive in terms of both time and money, resulting in increased healthcare costs?

If we have learned our lesson, the answer to these questions will be no.

Second, financial barriers associated with genetic testing need to be dismantled. The most important way to do this is to open up the market to competition. Put simply, exclusive licenses on genetic tests need to be prohibited.

Cost concerns extend to the clinic most often manifesting as patient refusal to undergo potentially lifesaving testing when insurance coverage is not available. This means entire segments of the population, the uninsured, and the underinsured go without important medical

information. A type of monopoly, genetic patenting allows us to continue as the patent holder sets their price and forces the market to comply.

In this scenario, serious concerns about access to healthcare arise and merit our full attention.

Third, researchers need to be able to perform genetic testing without prohibitive restrictions imposed by patents. Research will further the development of improved methods of mutation analysis and interpretation as well as clinical care, but the playing field has to be level. For clinically valid tests, such as BRCA 1 and 2, research participants must be able to have access to their results and to the authoritative interpretation of those results.

And, finally, information from genetic testing needs to be in the public domain. Successful interpretation of the thousands of variants identified from whole genome sequencing will depend on pulling data about functional

implications of various mutations as well as correlation with clinical outcomes.

A grassroots effort is underway to solicit the classification of BRCA 1 and 2 mutations from ordering providers, pursuant to Myriad's decision to stop reporting such information to a public database. Will dozens, perhaps hundreds, of mutations, some of which could potentially be disease causing, remain un-interpretable because the data needed to understand their significance are re-posited in a proprietary database held by a patent holder?

Again, if we avoid this consequence of patent law, collaborative science will proceed at a rapid and efficient pace.

I hope that I have made the case that genetics is a critical part of the future of medicine and genetic testing is obviously its lynchpin. Patenting genes may confer certain benefits to certain segments of society, however the net effect of genetic patenting is to stop the free flow of information. It loosens the lynchpin

and it puts progress itself at risk.

NSGC looks for a future in which the expertise of all who have labored in the field of genetic discovery will be leveraged and utilized, in which all the possible benefits of genetic medicine can be realized, and will accrue to society as a whole. Gene patenting is a tax on the future of health writ large, and one we, as a society, can ill afford. Thank you very much.

MS. GONGOLA: Thank you, Ms. Peshkin. Our next participant before our break is Linda Bruzzone on behalf of Lynch Syndrome International. She's joining us by telephone. Linda, are you there?

It does not appear that she has joined us by telephone at this point, so let's take our break and return in 15 minutes. We'll take a 15-minute break and in the meantime, we'll work to get Ms. Bruzzone on the telephone. So, please return to your seat in 15 minutes at 3:15 p.m. Thank you.

(Recess)

MS. GONGOLA: Thank you, everyone. Before we took our break, we were looking forward to the testimony from Linda Bruzzone on behalf of the Lynch Syndrome International. She's joining us by telephone. Linda, are you on the telephone?

MS. BRUZZONE: Yes, I am.

MS. GONGOLA: Very good. Please proceed with your remarks.

MS. BRUZZONE: Thank you. I can't begin to tell you how grateful we are to the USPTO for the opportunity of being able to share our experiences. My comments represent experiences with confirmatory tests and insurance policies with genetic testing from the perspective of the end user. I'm here speaking in respect to experiences with Lynch Syndrome International, our interaction with over 4,000 families within an all volunteer, global education and advocacy organization, which also provides support for families at high risk for Lynch Syndrome cancers as well as supports research endeavors.

As volunteers, our primary motivation is

simply the continued existence of our families. In mine, every single person from my grandfather through our generation today have all contracted multiple Lynch cancers caused by a defective gene by the age of 58.

As a result of genetic testing and annual cancer screenings and diagnostics, our current generation is living longer than generations before us. Hope increases with each one. My daughter is diagnosed with Lynch Syndrome and hopefully she will never experience a full-blown cancer as a result of genetic testing and those screenings. For that, we are so very grateful. We depend upon lifelong diagnostic tests for our very existence.

Our genetic condition is due to a defective mismatch repair gene. Its role is to repair errors in DNA duplication, and as a result, errors stack upon errors, tumors form, and we're faced with a very high lifetime risk to many cancers --

82 percent colorectal, 65 percent

endometrial, 19 percent gastric tract, 11 percent ovarian, and a higher than average risk for all organs below the belt -- the skin, the brain, the thyroid, as well as sarcomas.

Certain subsets of breast cancer have recently been found presenting an approximate fourfold the risk above that of the average woman. It affects primarily the young, can metastasize in two to three years in compared to eight to ten years for sporadic cancers. And our kids have a 50 percent risk of contracting the defective gene.

Each year we have an accumulated 3 percent risk of acquiring another cancer. So, for us, it's not an issue of whether we get cancer, it's more of an issue of when we get cancer, where it occurs, and how early it can be detected.

In the U.S. alone, there are 600,000 to a million people projected to have Lynch Syndrome, of which less than 5 percent are currently diagnosed through genetic testing. This is amazing, despite the fact it has been openly available through many different companies for us since

1993.

Over the past 20 years, multiple patents exist. There is no “ownership” of the testing of the mutation. As a result, our families are not getting diagnosed and are dying. We don't have the luxuries afforded those with hereditary breast cancer of diagnosis, public health assistance, public awareness, legislative intervention, and medical education to help professionals, including gateway diagnostic specialists such as OB/GYNs, gastro docs, pathologists, dermatologists, general and family practitioners, and oncologists.

Due to the small base, there's a misconception LS is a “rare disease.” Being “rare,” public health departments often don't focus upon it. In fact, one public health official stated it wasn't worth even taking family histories due to the expense. “We have to sacrifice some to save the masses” she said.

We have a newsflash. Lynch Syndrome is not rare, but it is severely under diagnosed. We

don't get the attention of those with breast cancer, nor the resources or services. We don't get the legislation. Often we feel like the redheaded stepchildren of hereditary cancers who sit in the shadows of those with hereditary breast cancer.

In regard to genetic testing, of over 4,000 affected individuals with whom we've been in contact, we know of nobody who has requested a second opinion for a positive test. All testing companies run a second blind test to ensure that there is no error when a positive is discovered.

However, in the event of a negative test, many companies are willing to confirm a test. However, the consumer needs to be aware, because each testing company is different and it's difficult to determine the capabilities of the company and whether they are lesser or better than the original testing company. None are equal. Each offers different services based upon their capabilities and limitations. Some are better, some are worse, some offer more variants, some

offer less, some may not get a valid confirmation. Some don't offer large rearrangements. In our case, for some of the more unusual variants, such as the EPCAM deletion, the use of multiple testing companies is often used as very few companies have the technology to test for it.

It complicates matters and increases the cost of diagnosis. Last year we assisted two patients with mutation testing, single mutation testing, choosing a lesser expensive company to perform the test. Unfortunately, they couldn't confirm the variant as it wasn't within their database. They requested thousands of dollars more for full sequencing and we determined, no, we're going to have them test at the original company. One was positive, the other was negative. It was a long, emotional ordeal taking months.

Within our scenario, we can envision the cost of genetic testing would possibly double with confirmatory testing due to the existing circumstances and multiple patents and licensees.

Our experience with open licensing is, even with competition, the cost of genetic testing has been primarily unaffected without great reductions. The same problems exist for us as for those with hereditary breast cancer. We have to utilize resources for paying co-pays. For those without insurance, we refer individuals to Myriad Laboratories which provides the test at little or no cost if they qualify.

Thankfully, both Ambry and Myriad provide a payment plan for those families with an ability to pay and it helps us with our underserved populations.

Major changes in technology of genetic testing have occurred. However, this has confused physicians, requiring more services of genetic counselors, as the testing process has become too complicated. Many insurance companies are mandating genetic counseling as a prerequisite to obtaining genetic testing.

There are delays from three weeks up to six months in obtaining appointments for some genetic

counselors which affects decision making for patients pending surgeries for cancer treatment. Genetic counseling is ordinarily paid for by insurance and fears of discrimination from insurance companies are a major barrier deterring individuals from testing, especially in light of reporting health conditions to a nationwide insurance database, which can also be accessed by the life insurance industry.

Advocacy efforts are greatly hampered. The donor base is so small it's difficult to get money and to operate without funding, even for an all-volunteer operation such as ours with low operational cost. We recently learned from experience even the thought of possibly needing confirmatory tests creates confusion, anxiety, uncertainty, and fear for those affected by Lynch Syndrome.

Complicated procedures require genetic counseling. We are advocates of genetic

counseling. We think that genetic counselors are great, but they don't need to be used in every procedure and in every circumstance. Mandated genetic counseling creates a barrier for individuals, especially men, in addition to additional cost.

Genetic counseling should be a choice, not a requirement. It adds a form of discrimination and it has negative connotations, as the only other required counseling most people think about is ordinarily court appointed.

Most insurance companies provide coverage of genetic testing. Federal standards for insurance coverage for Social Security, Medicare, Tricare, the VA, and insurances which follow their underwriting guidelines, don't provide for genetic testing for those who do not have a cancer.

We see the same problem within most public health departments not providing genetic testing. Many are now just simply providing FIT Tests, which tests for cancer through the feces.

Government health organizations don't support genetic testing in the manner they should, and as a result, our families are dying. The majority of funding, legislation, awareness, and resources, have gone into hereditary breast cancer. We haven't been provided the federal legislative protections of those with breast cancer.

The recent healthcare act recently defined preventative and diagnostic test cost, increasing the cost for survivors and providers with required co-pays for annual screening tests. And our biggest fear is that a gene therapy or a treatment may be discovered, since we have neither, and without a patent, it won't become available to our families, they may not learn about it, as what is occurring with genetic testing at this time. Our biggest fear is there will be no significant research without a patent as corporations will step back and move into different health areas.

With the HCA, we fear there will be

reductions in screening tests and accessibilities to genetic testing, as what exists with the federal insurances today.

So, we urge the PTO to think very cautiously of the affects upon the public and to focus on only those issues which jeopardize lives. We believe this may create another barrier toward genetic testing and insurers may not cover it due to the increased cost.

The state of genetics evolves with rapid technology. Legislation can become antiquated in a day, a week, or a month, with the rapid changes, and what currently occurs with us, will occur with others.

The key to survival is to not get oneself into something one can't get out of, and we fear this may happen with this type of legislation, which affects so many different conditions and not simply hereditary cancers. We urge the PTO to explore the views of those with other genetic conditions and exercise caution with all new technology. The government should be

prudent in respect to testing for genetic conditions and support it, making certain all interests are represented, not just those of one particular cancer community. And we believe Congress needs to invest in genetic testing, as it is the future.

Many of us with Lynch Syndrome wish there had been a patent in place for us. It would have protected us and perhaps protected the lives of our loved ones. Thank you.

MS. GONGOLA: Thank you, Ms. Bruzzone. Our next participant is Karen Canady on behalf of the American Intellectual Property Law Association.

DR. CANADY: Good afternoon. My name is Karen Canady and I am pleased to be here today as a member of the American Intellectual Property Law Association, or AIPLA.

I'm also a patent attorney in private practice in California with my own practice, Canady and Lortz. I have a PhD in neuroscience and I represent clients before the Patent Office.

Most of my clients are universities or start up companies so I see firsthand how critical patent protection is to move biomedical technology forward.

I'm a past chair of AIPLA's biotechnology committee and I'm currently co-chair of its subcommittee on diagnostic and gene patents. AIPLA appreciates this opportunity to participate in today's roundtable and its membership shares the underlying concern about facilitating development and availability of confirmatory genetic tests.

I would like to begin by acknowledging that all of us, regardless of our views on gene patents, we all share the goal of ensuring patient access to genetic tests and we all want to facilitate the development and availability of these tests. While the goal is a shared one, we realize that the opinions differ widely on how best to achieve that goal.

We appreciate Congresswoman Wasserman Schultz's willingness to share her decisions from

her own personal story that exemplifies the difficulties an individual faces when making crucial medical decisions that depend on a patented genetic test.

AIPLA is as concerned as you are and we are willing and eager to work together with you and everyone here to arrive at an effective solution that addresses any need for increased access to confirmatory tests without interfering with the incentives for innovation and commercialization in genetic diagnostic medicine.

A substantial amount of study data and anecdotal evidence has already been presented in both oral testimony and written comments, so we're not going to repeat that now, but we refer to the citations and summary and information that's been provided in the written comments that were submitted in March of 2012.

The data indicate that, for the most part, patents do not impede scientific research, nor do they harm access to genetic tests. In fact, the promise of a temporary period of

exclusivity that patents provide has played a pivotal role in enabling the investment in development and commercialization of new diagnostic tests. More clear from the evidence, gene patents do not block, for example, whole genome sequencing or at least it appears to be the case as more evidence comes in, contrary to what many had previously claimed in public discourse on the topic.

AIPLA, however, recognizes and understands the sensitivity and importance of the testimony presenting examples of a few situations in which researchers and pathologists have felt hindered by patents, as well as examples of patients who have been frustrated by a lack of access to confirmatory testing, either in a first instance or for confirmation of initial results.

While much of these problems can be attributed to issues that arise independent of the patent system, at least some of the problem appears to arise from misinformation and misconceptions about patents including how the

patent system works, what acts constitute infringement, how to analyze the scope of a patent claim, and the difference between patent claims that merely recite DNA sequences and what we really mean when we're talking about gene patents.

I think what I'd like to do, though, is instead of going over these problems, let's get right to addressing the question that we've been asked to address, which is, what actions Congress can and should take to increase the availability of confirmatory genetic diagnostic tests while protecting the incentives for innovation and commercialization in genetic diagnostic medicine.

After reviewing all the studies and reports on this topic, AIPLA has not found evidence that patents pose a significant problem for access to genetic tests, nor does AIPLA find any practical solutions achieved through changes to the patent rights in such tests.

But to the extent that considerations are being given to actions that Congress might take to address these things, I'd like to clarify

that it appears there are two types of concerns, one is about research and the ability of research to continue in these areas where there might be patents involved, and the second being, patient access to confirmatory tests.

With regard to the first concern, AIPLA is willing to work with others on developing a clarified experimental use exception to patent infringement. Regarding patient access or whether anything needs to be done to ensure access to confirmatory tests, in the written comments that were submitted in March 2012, near the end, there are eight points that we presented that lay out the concerns that we think are very important that have to be take in into account if any action is taken so that we can ensure that we don't interfere with the system of innovation and the incentives for commercialization and development of these tests.

AIPLA believes the patent system is working well, doing its job. Let's work together to make sure that whatever changes are made, do

not impede the incentives that keep biomedical technology moving forward so that we all have access to the future generations of genetic tests. Thank you.

MS. GONGOLA: Thank you, Dr. Canady. Our next participant is Lori Pressman on behalf of the Association of University Technology Managers.

MS. PRESSMAN: AUTM thanks the USPTO for the opportunity to speak at this roundtable.

AUTM members want first opinion, better opinion, and different opinion diagnostic tests available to as many people as possible as soon as possible. We believe skilled licensing aligns interest and fulfills the promise of personalized medicine. AUTM's view on this matter is described in detail in point nine of the Association's nine points.

These objectives, AUTM believes, are all possible now under the Bayh-Dole Act, which provides universities needed flexibility to license technologies on terms that encourage prompt commercialization making federally funded

inventions available to protect public health and welfare.

Rushing to enact additional legislation can do more harm than good, particularly if it is designed to solve a poorly defined problem. It would also be a serious mistake to pressure agencies to invoke march in rights provisions against companies who have fully complied with the terms of their licenses. Such change in the rules at the end of the game would undermine industry confidence in universities and federal laboratories as reliable research partners. The resulting damage to our economy would far outweigh any short- term benefits.

Before focusing on possible legislative remedies, we should first understand the issue at hand, patient access. The terms nucleic acid, gene patent, and diagnostic patent, are misleading. Patents simply don't map particularly well to diagnostic tests. Some biomarkers are completely unrelated to nucleic acids and some are not even biochemical. Thus, rules and policies

directed to this ill-defined object, the diagnostic patent, will be blunt, confusing, costly, and ineffective.

The data in appendix two of the SACGHS report and the March 2012 BNA study show that the field of use of the license is a far superior predictor of the type of product a patent will cover than is the patent itself.

Very recent scientific advances, the June 2012 Human Microbiome Project publication and the September 2012 revelations on the importance of Dark DNA illustrate the remarkable and plentiful design around and design better opportunities for innovators in personalized medicine. The future is happily, predictably unforeseeable and the best diagnostics are yet to be.

AUTM notes that the sole alternative to patents is not open source, it is also proprietary forever databases unrelated to patents. Some companies, such as the crowd- funded µbiome and bioinformatic 23andMe, collect tissue samples

and other personal information and create proprietary forever biomarker databases, - forever in that there is no requirement for the company to share the collected information.

In contrast, patents incentivize disclosure by granting time-limited monopolies to innovators. Robust application of the written description and enablement requirements serve the public interest via a requirement to disclose and describe the invention. Licenses can also incentivize disclosure in the public interest. License diligence can include a contractual requirement to publish data or to permit confirmatory laboratory testing by a provider other than the licensee.

This type of diligence requirement, however, is typically present only in licenses with exclusivity.

On insurance, we previously noted that the sales of OncotypeDx appeared to increase following favorable insurance reimbursement decisions. We suggest that Figure 6B and Table 2

in the BNA paper also reflect the influence of insurance companies and their willingness to pay only for actionable diagnoses. This reminds us that patient benefit is a very important part of our conversation on patient access.

The importance of flexibility to grant patent licenses with exclusivity, particularly for innovators, has been well documented in the AUTM surveys, in the Better World report, in the 2006 Nature Biotech paper, Appendix 2 of the 2010 SACGHS Report, and most recently in the 2012 BNA paper.

The accumulated evidence on the incentives and benefits created by skilled licensing, including the flexibility to negotiate exclusivity and diligence of patented and thus expiring proprietary rights, supports broad patent eligibility, skillful patent examination, and skillful patent licensing as the best means of advancing patient access to diagnostic tests and personalized medicine. Thank you.

MS. GONGOLA: Thank you, Ms. Pressman.

Our next participant is Hans Sauer on behalf of Biotechnology Industry Organization.

DR. SAUER: Good afternoon. Thank you for having us here to testify again on the matter of the roundtable. We incorporated, if I'm allowed to use a patent law term, our previous testimony by reference, and so that allows us to not repeat ourselves, you know, that would be a bad thing in a setting like this.

When we first testified on this matter 11 months ago, we noted that, you know, there seemed to be at the time an insufficient empirical basis for recommending legislative action on the subject of confirmatory genetic testing where so-called gene patents and exclusive licensing exists.

Bio does understand, to be sure, right, Bio does understand that the America Invents Act directs the Office to provide legislative options to Congress, but today, as then, developing such options -- legislative options, in doing so, the Office owes it to the Congress to develop also a

solid empirical basis that clearly frames the problems that are to be addressed. Anything less, we think, would invite legislation on the basis of assumptions and unstated beliefs.

So, to be clear, I think, you know, then as now, Bio does not really believe that the problem has been sufficiently framed or to the extent it's been framed, it's sufficiently substantiated. Is Congress concerned about patients' rights? Is Congress concerned, perhaps, about test reliability? These are different questions and addressing them involves different considerations.

It appears, in public discourse, their calls for second opinion tests are most often couched in terms of patients' rights.

Bio was told quite consistently in consultations with clinical practitioners that patients, you know, at the provider/patient level, only very infrequently actually ask for such repeat tests. The result comes in and the patient spontaneously says, I don't trust this, I would

like to have this repeated.

But none the less, you know, however uncommon such requests may be today, if respect for patient autonomy is accepted as a fundamental principle for ethical medical decision making, then surely a patient's expressed and informed desire for a confirmatory test cannot simply be dismissed or ignored. It is important, however, that second opinion testing, if you want to call it such, be more than the bare exercise of it right. Ideally, it should be a patient benefit or at least not cause more harm than good.

So, when faced with such requests, it would therefore be the obligation of the clinical practitioner to manage unrealistic hopes and to inform the patient's decision. It would have to be understood, for example, that a retest will likely not be reimbursed -- we heard this today -- and that the result will almost certainly not change.

Prolonged anxiety and uncertainty, out-of-pocket expenses, and the risk that comes

from deferring treatment decisions likewise would have to be factored in as potential down sides.

Moreover, in our desire to do the right thing, we should also be mindful of potentially creating other dilemmas that follow down the road. So, for example, if second opinion tests are not reimbursed because they're not considered medically necessary, would we be comfortable leaving poor patients without that option because they cannot afford to pay for such tests so that it becomes the privilege of some and not all to seek such confirmation?

Moreover, would raising the option of second opinion testing with patients in itself create doubt where there was none before, an unwarranted suspicion in the minds of patients that genetic test results perhaps cannot be trusted?

Such considerations have not really been part of this debate. We're only beginning to hear them aired today in prior testimony. I think we should give much closer attention to such

considerations. To the extent Congress is concerned it's driven by doubts over the quality and reliability of genetic diagnostic testing services, it may actually be useful for the PTO to survey available data about the known analytic performance of different genetic diagnostic tests.

Known or extrapolated error rates of currently used tests may provide at least a ballpark idea of how often confirmatory testing would at least seem to be necessary from a quality standpoint. So, for example, the sensitivity and specificity of mutation testing for cystic fibrosis or hereditary hemochromatosis and some comparable tests is reported in proficiency testing studies as ranging from lows around 98 percent to well over 99 percent.

So, these are some tests. We don't have these data for all tests, of course, but nonetheless, you know, let's assume as a working hypothesis that laboratory performance is fairly high and that errors are infrequent when we look at analytic validity.

So, while this indicates high analytic performance, it's also known empirically that the majority of so-called laboratory errors actually don't occur in the laboratory. This has been extensively studied and is pretty well established. Reported estimates indicate that 60 to 70 percent of errors happen in the pre-analytic phase, that is, at the hospital or drawing station, or during shipment as a result of sampling error, mislabeling, sample preparation, degradation, or switching, and that another 10 to 15 percent of errors occur in the post-analytic phase, when the results come back out of the laboratory and when, then, there are errors in reporting, matching results to patients, and the like. Errors are unavoidable.

So, even if one assumes as a working hypothesis that the actual lab work is very accurate, mistakes will nonetheless occur and, you know, can't completely be eradicated because they happen at other parts of the system.

In the first instance, either way, it

must always fall to the clinical practitioner to identify the circumstances under which any given test result would need to be confirmed through retesting. Whether or not such retesting should actually be done at an independent third party laboratory, however, is a very different question. Only analytical errors would be detectable by sending a sample to a different lab. The sources of pre- and post-analytic errors remain the same. It's still the same hospital, it still has the same error sources, it's still shipment, sampling errors might happen, and the like.

So, in other words, if only 10 to 20 percent of all laboratory error is actually the laboratory's fault, insisting on independent confirmation testing at independent laboratories will actually only capture a minority of lab errors that we're worried about.

Because so little is gained from legislating in this area, and because so little of this has anything to do with patents at all, the offices legislative recommendations should follow

the do no harm principle. The risks for harm and unintended consequences are great as has been testified today and previously. Any legislative recommendation would have to be narrowly targeted to confirmatory diagnostic testing. Interference with existing contracts, with beneficial licensing practices, and with incentives for innovation and commercialization must be avoided. This is no simple task, but maybe the wheel does not really need to be reinvented. We had reference before to Congresswoman Wasserman-Schultz's predecessor provision to Section 27 of the America Invents Act. Congresswoman Wasserman-Schultz had developed a detailed, narrowly targeted provision that would have created a limitation on remedies for infringement in instances where a so-called gene patent would be infringed by a confirmatory test akin to that found at Section 287C of the current patent act relating to surgical method patents.

The basic preposition was, of that provision, that if a first test is indeed done by

a licensed provider or the patentee, then permitting an independent confirmation test of that result for that patient is unlikely to cause the patentee much harm. At the time, Mrs. Wasserman Schultz's proposal was widely circulated and it was detailed and it was obvious that a lot of thought had gone into it, and it could have, in our view, been developed for further productive discussion. Well, it's not part of the America Invents Act, but at least it's a proposal out there has undergone some form of vetting.

And I encourage the Patent Office to look back through the records of when the America Invents Act actually went to the House floor where that provision was included in Chairman Smith's Managers Amendment.

Contrasting proposals involving the creation of blanket exemptions from infringement, the issuance of compulsory licenses, mandatory non-exclusive licensing or changes to the Bayh-Dole Statute, on the other hand, would be highly problematic. They would be much more

likely to interfere with broader incentives for innovation and would be much less likely to achieve consensus. Thank you very much.

MS. GONGOLA: Thank you, Dr. Sauer. Our next participant is Roger Klein on behalf of the Association for Molecular Pathology.

DR. KLEIN: Hi. I'm Roger Klein. I'm a practicing molecular pathologist here on behalf of the Association for Molecular Pathology, often referred to affectionately by the acronym AMP.

So, we just wanted to make a few comments. First, gene patents cannot be used to prevent physicians from examining their patients' DNA sequences. In Mayo v. Prometheus, the Supreme Court remained true to prior precedents and reaffirmed the patent ineligibility of natural law, such as those claimed by the BRCA 1 and BRCA 2 gene patents. These patents have value to Myriad Genetics precisely because, in practice, they claim relationships between variants in these genes and their biological consequences.

Second, the sequence, and therefore,

informational content of a native DNA is not changed during genetic testing. If this fundamental property were altered, the DNA would lose its usefulness for medical testing.

Third, gene patents inhibit the acquisition of new knowledge and represent a barrier to the application of new molecular technologies. Others have mentioned the revolution in gene sequencing that is transpiring that will allow us soon to sequence virtually all of the patients, 20- to 30,000 genes simultaneously for $1,000.

As Judge Bryson recognized, patents on individual genes potentially represent a substantial impediment to the full realization of the promise of these astounding technologies. Further, gene patents have impeded systematic acquisition and publication of data regarding the medical meaning of individual genetic changes identified in patients. Others have brought this up. Gene patent holders and exclusive licensees have great incentives to keep these data

proprietary.

Robert Cook-Deegan was too modest to mention his paper published in The European Journal of Human Genetics this fall, but he demonstrates that Myriad does this to great effect.

Fourth, gene patents increase costs of and decrease access to genetic testing. My mother was afflicted with an inherited neurologic disorder. When I sought to obtain genetic testing on this patented gene, my choices were the hospital that had discovered the gene, but which had retained genetic testing rights, and a private company that had an exclusive license. The cost of obtaining the test from the hospital was slightly over $200. The cost of purchasing the test from the company was about $800. This substantial difference would have been multiplied several fold had other family members required testing.

I couldn't test myself without infringing the patent.

Fifth, insurance reform is unlikely to guaranty that all patients have access to genetic testing of patented genes. In the case of BRCA 1 and BRCA 2, a single provider of testing sets all the rules -- test construct, methods the mutation's detected and in which order, the price, and the insurance that is acceptable. The Affordable Care Act was enacted to ensure patient access to essential healthcare services, including diagnostic testing. Yet there is still no guaranty that all Americans will have access to BRCA 1, BRCA 2, and other genetic testing.

Six, gene patents are not necessary to incentivize the discovery of genetic relationships or to encourage the provision of genetic testing services. Most genes used, as mentioned previously, in genetic testing, have been discovered by academic physicians and scientists in the normal course of their work, the traditional academic currencies of publications and research grants, as well as scientific curiosity and, importantly, the dedication to the

welfare of our patients provide ample encouragement for these physicians and scientists.

Genetic testing can be performed using routine and justifiably patented molecular biologic tools and techniques. The cost of developing, validating, and providing genetic tests are modest, and well within the reach of the typical practitioner when reasonable test volumes and reimbursement can be assured.

Yet gene patents typically could cause multiple providers to discontinue or not offer these vital elements of patient care, and Dr. Leonard has published on this. Thus, gene patents violate the usual rule that patents advance discovery and provide greater options for consumers in society.

Finally, confirmatory genetic testing does not solve the problems posed by gene patents. In theory, statutorily guarantying confirmatory genetic testing on patented genes could restore the rights of BRCA 1 and BRCA 2 positive women undergoing surgical removal of their breasts

and/or ovaries to second opinion testing.

However, compulsory licensing is an impractical solution, and Dr. Leonard explained why. For BRCA 1 and BRCA 2 tests in which mutations were not detected, a provider would need to offer patients assays for which Myriad likely charges in the range of $3,000 with, as we've heard, little prospect for reimbursement.

Even if a small number of providers did choose to engage in confirmatory testing, patients would still be deprived of the right to have the pathologist or geneticist of their choice perform their DNA examination. We heard about differences in reporting of variants of unknown significance. The way I draft my reports, particularly when I'm not sure of the meaning of a particular variant, differs from others and it's considered in the light of the medical importance of the result. It does matter who does your testing.

Most important, the issue of confirmatory testing is a red herring that distracts from the multitude of other problems

gene patents cause for patients and providers. We are optimistic the Supreme Court will resolve the gene patent issue in favor of our patients. However, in light of the preceding, any recommendations by the USPTO for compulsory licensing should not be confined to second opinions. Rather, such recommendations should mandate compulsory licensing of gene patents at reasonable rates or reasonable fees for all genetic testing.

Thank you very much.

MS. GONGOLA: Thank you, Dr. Klein. Our next participant is Kristin Neumann on behalf of MPEG LA.

MS. NEUMANN: Hello and thank you to the U.S. Patent and Trademark Office for hosting this roundtable and to the efforts of the esteemed committee in organizing and facilitating it.

I am the executive director of Librassay, the patent licensing supermarket for molecular diagnostics. Librassay is owned and operated by MPEG LA, the world's leading

independent provider of alternative patent licensing solutions.

Librassay is unique in these proceedings because we are the only entity offering a private sector solution to the issues concerning patent licensing in the context of second opinion diagnostic test availability, and, indeed, all diagnostic test availability.

On one side, we have those who call for a ban on gene patents or legislative infringement exemptions or compulsory licensing, none of which exist in the law today, and in all likelihood, would unleash a raft of unintended consequences and produce more harm than good.

On the other side, we have those who justifiably make the case that the patent system is working as it should to protect and reward innovation and investment and that patents are not the culprit in the second opinion test problem, if there even is such a problem.

Librassay, however, occupies the middle ground by recognizing the indispensability of

patents to the development and commercialization of new healthcare innovations while at the same time addressing inefficiencies in bilateral patent licensing transactions that hold back the supply of new products and tests in the field of molecular diagnostics.

The good news is that Librassay is a reality, it is up and running right now, it is fully funded, and it leaves our government free to turn its attention to the many other issues facing our country for which no private sector solution is at hand.

So, here are the details of the Librassay patent licensing supermarket. It's a one-stop shop for the nonexclusive licensing of molecular diagnostic patent rights to any and all test providers and product developers who desire such a license on fair, reasonable, and cost-effective terms. Librassay balances the interests of test providers and product developers with the interests of patent holders and investors who rely heavily on patents as an inducement for

taking on investment risk necessary to fund development efforts, regulatory approvals where required, and marketplace acceptance and adoption.

In the absence of patent protection and its quid pro quo of public disclosure, at best innovations will become locked up in corporate vaults as trade secrets, which will choke off the rapid dissemination of innovations in this important field, and at worst, they will not be developed at all.

The Librassay patent licensing supermarket opened for business in September of this year with the support of eight anchoring institutions including preeminent research and healthcare institutions such as the National Institutes of Health, the Ludwig Institute for Cancer Research, Memorial Sloan-Kettering Cancer Center, and Partners Healthcare of Boston, and world class universities such as Johns Hopkins, Stanford, the University of Pennsylvania, and the University of California San Francisco. That is our anchoring group of institutions in the

Librassay patent license supermarket today with their patents available for nonexclusive licensing to everyone.

We presently have nearly 400 patents in the portfolio. They are all available on a nonexclusive basis to any and all medical practitioners, labs, and companies wishing to use them, and we expect to add many more institutions and patents to the program in the coming year.

Answering the call for unencumbered research in the field, Librassay provides a royalty-free license under all patents in the portfolio for basic research and educational purposes. The Librassay website provides an online storefront for searching, downloading, and viewing the patents available for licensing plus a summary of the key terms and conditions for the license and invite you all to visit the store at www.librassay.com.

We have plans to advance Librassay as fast as is humanly possible. In addition to growing the portfolio, we are hard at work

cultivating from the portfolio patents that lend themselves to being licensed in bundles that will assist companies and labs in their effort to obtain freedom to operate with respect to new test services and product offerings. And further, we are open to working with other entities having the common mission of further knowledge and technology dissemination in this field, such as the NIH's genetic test registry and ClinVar Resources.

So, the advantage of Librassay over any of the other solutions proposed in the course of these proceedings is that it fits squarely within our country's established leadership role in healthcare innovation and within our legal system as it exists right now. Librassay requires no legislative, regulatory or other measures having any unintended consequences.

In Librassay, patents retain their full stature and continue to perform the role envisioned by our Founding Fathers in the Constitution and we are confident that Librassay will work because a similar solution was put into

play by MPEG LA 15 years ago to solve the problem of blocking patent issues in the consumer electronics field, and it led to the tremendous success of the MPEG standard in digital video transmission and to the rise of that popular industry.

Thank you very much.

MS. GONGOLA: Thank you, Ms. Neumann. Our next participant is Leonard Svensson on behalf of BIOCOM.

MR. SVENSSON: Good afternoon. My name is Leonard Svensson. I'm a patent attorney with intellectual property law firm Birch Steward Kolasch & Birch in San Diego, but today I'm here on behalf of BIOCOM to provide some comments from the view of industry companies, many of which are patent owners in the diagnostic and biotechnology industries. All of these companies depend upon strong patent protection and value.

In previous testimony this past March in San Diego, I explained BIOCOM's concerns about the economic impact of weakening patent protection in

this field. Today my comments will focus on questions one and two raised in Section 27 of AIA, but first I'd like to give a few comments about BIOCOM and its members.

BIOCOM is a regional life science association representing more than 580 members in Southern California including bio pharmaceutical, medical device, diagnostic, and other life science companies, and patients groups, approximately 60 of which companies are developing gene based diagnostics.

Southern California is home to some 97,000 people who are directly employed in about 3,500 life science companies. The life science industry in Southern California indirectly generates a total of 248,000 jobs and pays over $17 billion in wages and produces a total of $57 billion of economic activity in the region.

Without robust patent protection or the ability to control licensing of innovations, most BIOCOM members and companies would never be able to financially recoup their upfront costs and this

would greatly inhibit their ability to attract vital investment money. This lack of capital will cause promising discoveries to go undeveloped into therapies and diagnostics legislation that undermines the patentability of innovations where the strength of the valid patents would no doubt result in the further diversion of investment capital away from biotechnology, the outcome of which would be detrimental to both the financial and public health of our nation.

It's our understanding that the underlying assumption behind the requirement in the AIA for the USPTO to provide a report on genetic diagnostic testing is a belief that patients need and are unable to obtain a second diagnostic opinion because of patents that are not being licensed to provide an alternative source for a given test. Now, concerning questions one and two raised in the AIA section, first of all, question one seeks input on the impact that the current lack of independent second opinion testing has had on the ability to provide the highest

level of medical care to patients.

Frankly, we're not aware of any objective or empirical studies that in any way establish that there really is any medical benefit, which would result from the repetition of genetic tests by a second entity distinct from that which performed the initial test. Genetic diagnostic companies perform rigorous quality control procedures on each sample tested to ensure that there are no technical deficiencies in their analysis and that their results are accurate.

We're not even aware of any significant testimony by patients or medical practitioners to establish that the quality of medical care would be improved by the repetition of a genetic test at a second facility or that patients or medical practitioners are actually unsuccessfully seeking such second opinion testing by a different laboratory.

Absent such evidence, there simply is no valid basis for weakening the value of the patents that our member companies depend upon to protect

their valuable innovations and products. So, we understand that the natural response may be a request for objective evidence in the other direction, namely evidence that there's no medical need for second opinion tests.

Some of our member companies have actually tried to obtain some actual evidence regarding the frequency of requests for repetition of a genetic test by physicians or patients, but obtaining testimony or evidence from medical practitioners has, frankly, been difficult, apparently in part because of medical privacy concerns. So, we appear to be in a situation where there's no objective evidence on either side of this issue, but we submit that before laws are changed or validly obtained patent property rights are weakened, the burden must be on those who propose such changes to provide some objective basis for the need for such changes.

A second important point raised to question one that we believe has not been addressed or recognized at all in this debate is

that the proposed solution to the perceived need for second opinion testing would not actually provide for good and valid testing and could do more harm than good. Simply providing with a second company or laboratory with a license or some other freedom under a genetic test patent would not give that company all the tools needed to perform a valid test.

Good quality tests and result interpretation require additional information from proprietary databases or other know-how, which may not be easily obtained by the second testing facility.

In addition, technical expertise gained by performance of many, many tests and high-level quality controls on measurements and interpretation, are also required. Without these additional features, tests run by a second opinion laboratory would actually be less reliable than those run by the patent owner or patent owner licensed laboratories.

Less reliable results would certainly

not be good for patients and could lead to negative attitudes about the test by medical personnel that could lead to patients actually receiving less quality medical care.

Question two of Section 27 of the AIA seeks comments on the effect that providing independent second opinion genetic testing would have on existing patent and license holders. In addition to any short-term effects, we believe the discussion needs to look beyond the current debate that seems to be largely focused on breast cancer testing and needs to consider what any proposed weakening of the patent protection right means to future innovations in medical care.

If life science and diagnostic companies cannot depend upon the value of their patent portfolio to protect their huge investments they need to make to develop new products or methods, then who will make the investments to discover and develop the next important products? Do we really want to encourage more and more investment money to go towards developing new video games and

entertainment products instead of new medical advances? Now, that's not simply hyperbole. That's the natural, predictable consequence of making it less possible for biotech and diagnostic companies to protect and recover their investments they need to make to continue to develop the life saving innovations that we all want to see.

Finally, we're aware that the USPTO is seeking some suggestions for specific recommendations regarding possible legislative action. BIOCOM's position is that any patent concerns so far raised in this debate or any patient concerns so far raised in this debate are not really patent related, but that require some sort of patent related solution. The concerns that we have heard are actually insurance coverage issues, so any proposed solutions should be focused on understanding and solving those problems.

We strongly urge you to carefully consider the broader implications of any proposals to place limitations or compulsory licensing

requirements related to the scientific advancements. BIOCOM and its members would be happy to work with you on ways to address the real concerns over the patenting of genetic-based diagnostics while also avoiding potential detrimental effects on the U.S. biotechnology industry, which relies on intellectual property protection and patents in order to fund the development and innovative life science diagnostic and therapies that we all want to see in the future.

Thank you for listening to our concerns.

MS. GONGOLA: Thank you, Mr. Svensson. Our next participant is Richard Marsh on behalf of Myriad Genetics.

MR. MARSH: Good afternoon. Myriad Genetics would like to thank the USPTO for this opportunity to come and participate in this roundtable discussion. I'm Richard Marsh. I'm the executive vice-president, general counsel, and secretary at Myriad Genetics.

As we're all aware, there has been much

discussion concerning this topic of confirmatory genetic diagnostic testing. We've heard a “myriad”, pun intended, of views on this matter. And I'd love to take the opportunity to address each and every one of them. Myriad is very proud of what it has been able to accomplish with respect to hereditary breast and ovarian cancer testing. Unfortunately, time would not permit that, and in that regard, I'd refer you back to Myriad's prior testimony back in San Diego where we shared Myriad's belief and our experience that the BRCA patents have incentivized research, have driven research and development of hereditary breast and ovarian cancer testing, has resulted in broad and accessible testing for women, has resulted in affordable testing through insurance reimbursement to the point that I don't think anyone would contest that today we in the United States are -- lead the world in hereditary cancer testing.

I think the patent system works. It is just as our Founding Fathers had envisioned in the Constitution. We've seen great promotion or

progress of the sciences as a result of the patent system.

Now, Myriad understands that today the USPTO is more interested in gathering some empirical evidence or data with respect to the questions being posed rather than a rehash of the issues that we've heard before, and so I'm going to limit my remarks to one specific area, and that's Myriad's experience with insurance reimbursement, particularly dealing with payers and the medical policies that they have, and to try and provide some further information to the USPTO.

Now, in that regard, Myriad has now tested approximately a million individuals for hereditary breast and ovarian cancer. We're reimbursed by all major insurance providers. We're reimbursed by Medicare and by most Medicaid state plans, and so we have a great breadth and scope of experience with respect to insurance reimbursement.

As genetic testing has now become

mainstream within the medical society, we have found that the insurance companies now will reimburse for genetic testing, but they will only do so when they make a determination that it is medically necessary, so they have drafted written policies or guidelines of when they will or when they will not reimburse for genetic testing.

We've provided a short list, a sampling, if you will, of some of those provider policies. We'll provide those with Internet links to the USPTO along with our written comments later. But we believe it's a representative sampling of the policies and the practice. It's not exhaustive, there are obviously many others, but it's indicative of the insurance payors' practice to not reimburse for a second confirmatory test. In our review, some of the policies even said -- Bruce Quinn referred to it earlier -- having once in a lifetime limitations in them.

But I won't take the time to go through them specifically. The policies speak for

themselves. You can review them in that regard.

But now let me speak a little bit more specific with respect to Myriad's experience, first with respect to BRCA analysis testing.

Now, candidly, Myriad may not be the best example or entity or company to look to with respect to confirmatory testing because we are the principle entity that does the testing in the first instance. Accordingly, I do not think that someone would seek out Myriad to do a second confirmatory test if they had done the first one at our facility.

So, having said that, though, we have not seen any measurable number of inquiries being made or requests being made to identify other labs where that testing could be done. By way of example, which kind of supports our belief that -- or the statement that the insurance companies don't reimburse is, some of the other policies that they have -- so, for example, with respect to negative test results and ensuing reflex testing, many times when an individual receives a negative test result

they'll be reflexed to broader testing to see if there are some other conditions that may be causative.

Let me give you the example of an individual who would have -- of an Ashkenazi Jewish background -- who tested negative for the triple site panel might be reflexed to a broader full BRCA panel.

Insurance companies, many times, will deny that second test for reimbursement because they'll see that the blood draw date is the same because it emanates from the original sample, and we'll have to go into the insurance company and tell them, no, this is for a much broader -- it's a different test, in which case they'll then reimburse, but it's indicative of the point that if they see a test being done again, for the same indication, they won't reimburse it.

The other area that we would -- that probably would be insightful is with respect to our Colaris testing or colorectal testing on our Colaris product. There we are not the only

provider of that testing. There are various others, both commercial and nonprofit, and so you would think that we'd be able to have a little bit more input (inaudible), if you will, with respect to that testing, but unfortunately, we haven't. Once again, unless a doctor specifically requests or reaches out to indicate the purpose of the testing, we don't know. Our test request form is not structured in a manner that we collect that. The doctor typically does not identify that information, and so once again we don't have much specific information or data that we've gathered other than to make the observation that with a rarity do we ever receive any inquiries with respect to where one may go to have a test done a second time.

Finally, I think the third major area is in the Medicare reimbursement area. Again, Bruce Quinn has spoken to that and I think rather than take the time, we would just echo our experience is the same in that regard on the Medicare reimbursement side of things.

So, in summary, it's been Myriad's experience that hereditary cancer testing is now widely available and is reimbursable by insurance companies, but that the insurers have decided on their own, through their own policymaking, that they will not reimburse for a second test. Myriad will continue to evaluate and gather as much data and information it can in this regard and we'll append to the written comments that we'll make hereafter. Thank you.

MS. GONGOLA: Thank you, Mr. Marsh. Our last participant on our prescheduled list is Lisa Schlager with Facing Our Risk Of Cancer Empowered.

MS. SCHLAGER: Thank you. Good afternoon. As she said, my name is Lisa Schlager and I'm the vice-president of community affairs and public policy for FORCE, which is an acronym for Facing Our Risk of Cancer Empowered. We're a national nonprofit that represents nearly a million people affected by hereditary breast and ovarian cancer. The majority of our constituents are BRCA positive, although we also

serve individuals who maybe test negative for a family mutation, but have a hereditary pattern that's recognized.

We appreciate the opportunity to speak on behalf of the high-risk community today.

In response to this committee's request for quantitative data, we've gathered quite a bit of information from sources including healthcare providers, high-risk patient community, respected institutions such as the Cancer Legal Resource Center, and the Michigan Department of Community Health.

Of the four key questions presented in Section 27 of the America Invents Act, we're best qualified to address the issues surrounding the role that cost and insurance play in access to genetic testing and the desire for confirmatory or second opinion testing in the patient community.

In 2005, the U.S. Preventative Services Taskforce, or USPSTF released a grade B recommendation statement entitled Genetic Risk Assessment and BRCA Mutation Testing for Breast

and Ovarian Cancer Susceptibility, and they indicated that fair evidence was found that the service improves health outcomes. So basically, something with a grade B recommendation is generally recommended-- the risks are not significant, and the benefits outweigh the harms.

They specifically stated that women whose family history is associated with an increased risk for a deleterious mutation in the BRCA 1 or BRCA 2 gene, should be referred for genetic counseling and testing.

The National Comprehensive Cancer Network has published guidelines for BRCA counseling and testing for men and women with a personal history of breast cancer, women with a personal history of ovarian cancer, and individuals with a relative with a known genetic mutation. It should also be noted that NCCN has guidelines for cancer risk management services for women who test positive for a BRCA mutation.

Unfortunately, based on the data from the Michigan Department of Community Health,

nearly half of the health insurers do not follow these testing guidelines, and our research indicates that two-thirds of the insurers have not adopted NCCN guidelines for risk management services.

My testimony to this committee in February 2012 noted that approximately nine million people did not have access to genetic testing or BRCA testing because Tricare had discontinued coverage of this test. Nine million people, they didn't have access to this critical genetic test for nearly nine months.

Tricare has reinstated coverage for BRCA testing as of August. This isn't always the case. Again, the Michigan Department of Community Health, which is a leader in the utilization of genetic information to provide statewide public health benefits, has a cancer genomics program that has done extensive work to increase the availability of cancer-related genetic information in order to decrease barriers to risk appropriate services.

After significant efforts to get insurers on board with the written policies, only 14 out of 25 major Michigan health plans have written policies that are aligned with the USPSTF recommendations. That's slightly more than half, and there are now only seven plans aligned with the NCCN recommendations for cancer risk management services for BRCA women. That's less than a third.

Despite some earlier comments that Medicare is a good place to look to, it is not a glowing example for patient-focused, personalized medicine. Medicare only covers BRCA testing for women who have had a cancer diagnosis. It doesn't cover BRCA testing for men, and it also doesn't cover BRCA testing for anyone who is unaffected or who has not had cancer themselves, so tens of thousands of high-risk people over age 65 cannot get BRCA testing through Medicare, and many can't afford to pay out-of-pocket. This has a significant impact on these individuals and their

families who are trying to determine if there is a genetic mutation in the family, and what side of the family it may come from.

Cost and insurance coverage, or lack thereof, place a significant financial burden on the patient population. In the Michigan Department study conducted between 2007 and 2011, of almost 2,000 patients who had genetic counseling and did not receive BRCA testing, nearly 15 percent cited inadequate insurance coverage as the reason for not receiving genetic testing. This data demonstrates the importance of inadequate insurance coverage as a barrier for many patients who might benefit from such testing.

In an effort to confirm this number and collect data on some of the other questions, FORCE developed an online survey--I believe you all have received handouts--which was promoted widely to the patient and healthcare professional communities. We gathered over 500 responses to the survey over three days.

Of the 38 individuals who responded that

they did not undergo genetic testing -- and we recognize this is a small number -- but of those 38 individuals, 26 percent indicated that health insurance had denied coverage and that was why they didn't get testing, because they couldn't pay out-of-pocket.

Five percent stated that they were uninsured and unable to pay out-of-pocket as the reason they didn't undergo testing.

Of those who did have genetic testing, 7 percent indicated that insurance initially denied and they had to appeal, and approximately 7 percent experienced denial of coverage by their health plan but they paid out-of-pocket, and then 1.5 percent didn't have health insurance but they were able to pay out-of-pocket.

Given the cost of some genetic tests, this is a significant burden on the patient community.

We also queried the healthcare community about their experiences with the impact of cost

and health insurance on the patients who meet nationally published guidelines on BRCA testing. A summary of that information is included in your handouts and we're happy to make more detailed information available to the committee at a later time, but of the 115 healthcare providers who answered a particular question, 22 percent indicated that their patients often experience difficulty in getting health insurance to pay for genetic testing, and 64 percent said occasionally.

Over half of the healthcare providers indicated that at least 80 percent of their uninsured or underinsured patients are unable to access genetic testing through other means, such as participation in research or via financial aid.

On the topic of lack of independent second opinion testing, Medicare, in at least 11 states, currently mandates coverage of some form of second medical opinions. The majority of these laws allow for patients to visit a second physician. While they don't explicitly mention genetic test results, it's important to

acknowledge that there's a trend and a value to second opinions as a cost saving measure for insurance companies, and a right for patients before making life changing medical decisions.

On the question of demand for second opinion testing, the FORCE survey indicated 60 percent of healthcare professionals and 34 percent of patients who tested positive for a gene mutation would like the option of a second opinion or a verification test.

Comprehensive information on the impact of insurance and cost on access to genetic counseling and testing, as well as other information, is provided in the surveys that we have handed out and we've also provided some personal accounts on the impact of these issues on the overburdened patient community, as well as the healthcare providers that serve them.

In closing, I want to emphasize again that cost and health insurance coverage are often key factors in patient access to genetic counseling, testing, and preventive services. I

also want to bring attention to the fact that as has been stated, Myriad's "comprehensive panel" has been shown to be less than comprehensive. The Bart rearrangement panel is evidence of this and even Bart misses sum arrangements. In fact, research presented at the San Antonio Breast Cancer Symposium in December suggested that the BRCA testing currently being done is not inclusive of all BRCA mutations. Thus, it's difficult to claim that they have comprehensive testing. It's a misleading statement.

Thank you for your time.

MS. GONGOLA: Thank you, Ms. Schlager. I want to encourage you, when you submit your written remarks to follow up, to please give us more information about the survey that you've handed out. We'd like to know more about the methodology so we can understand the data a little bit better, so if you could please include that with the written remarks.

Now, I know we have one member of our audience who would like to share commentary, so

I'll begin with him. We're going to also open the floor for other members who -- for anybody else who would like to share commentary, we'll invite you to come forward. So, would Mr. Jaydee Hanson, on behalf of the International Center for Technology Assessment, please come forward?

MR. HANSON: Thank you. Happy to be here today. One of the reasons I asked to -- or I was asked to speak is we submitted comments to the docket back in March. One example of how technology may not always work, the regulations.gov office said our comments were accepted and the Patent Office didn't get them. So, now the Patent Office does have them.

We also -- these comments are on behalf of both my organization, the International Center for Technology Assessment, and Friends of the Earth.

We also contacted the Patent Office suggesting that this roundtable be delayed until after the Supreme Court makes its determination. I do know that there was a deadline set by

Congress, but this won't be the first time a Congressionally mandated deadline has been missed, and I do seriously recommend that given that this assignment landed in your lap, mostly because of a kind of politics that doesn't always happen in Washington, DC, there were people in the Democratic side of the aisle that were of two minds on the Wasserman- Schultz issue and there are people on the Republican side of the aisle that were of two minds on the issue, and the way to avoid a debate that would have slowed the whole patent bill was to punt to the patent office to do this study.

Glad you have it. You helped a lot at the time that the Section 27 was given to you. Again, our recommendation is that you wait a bit longer for your report, so the Supreme Court may do half of your job for you, and there will still be issues that you'll have to address probably after the Supreme Court, but it -- your report will be more useful if you wait until after the Court says what happens.

That said, we do think that there are serious issues that need to be addressed by you and there will probably, as I say, some left. We believe that the access to independent second opinion diagnostic tests is limited by patents on human genes and on other naturally occurring DNA sequences. And those other naturally DNA sequences will become clearer the more we understand about the genetics of everything that is there, even Francis Collins is now calling things that aren't genes "non-coding genes", so we've -- we keep changing the definitions scientifically, and so we hope that you'll look at not just things that are now called the human genome, but that other 98 percent as well, when you look at your recommendations.

Basically, we think that DNA sequences are facts of nature and simply should not be patentable. This is the 403rd anniversary of Galileo discovering the moons of Jupiter, or the first four moons of Jupiter. We would hope that if that were happening now, the Patent Office

would not grant him a patent on the moons of Jupiter, but rather grant him a patent on his much improved telescope with which he found the moons of Jupiter.

I would think you could also grant him a patent on how he used the moons of Jupiter to determine longitude. It didn't work very well, but it was original.

That's not in our -- this is my interest in history of science, it's not in our written comments, I apologize.

We also note that there are a number of issues dealt with in the Prometheus decision that should instruct you even before the Supreme Court makes its Myriad decision, and in that decision, the Supreme Court, in a 9-0 decision, made clear that patent holders should not have been granted patents on inventions that "consist of well-understood, routine, conventional activity already engaged in by the scientific community".

We would suggest that a test that used genetic material for diagnosis should be called

into question by the ruling.

I will skip, because you have and you will post on your docket all the comments.

I would note that the cost of sequencing the whole human genome is falling rapidly and while we can debate, you know, how rapidly that's going to fall or whether it will -- patenting will impact that sequencing, if we weren't patenting genes, we wouldn't have to worry about it.

So, even if the PTO decides not to revisit the question of gene patents until ordered by courts or by Congress, numerous studies have shown that patents on genes and DNA sequences have limited patients' access to independent opinion and I would point you to the studies that Dr. Leonard, who's left for the day already, but she has some very good studies and I would, you know, have you look again at her testimony from CAP.

I will wrap up. But before I wrap up, I think it's very dangerous to assume that things won't change. My family used to be slave owners. They argued that that was their property and they

should not give it up. They don't own slaves anymore. They lost that property. Some things are wrong in the first place. The Patent Office was wrong to grant patents on genes in the first place, just as we were wrong to start slavery in 1670 in Virginia where I live now.

So, again, my personal opinion, not the opinion of the International Center for Technology Assessment, though it probably is, actually, but not in our testimony.

So, the final step, really, is to stop patenting all genes so that medical scientists can develop any new test they need for any genes or any DNA sequence. We think halfway measures, such as compulsory licensing, should not be used to address this problem of confirmatory genetic tests. Compulsory licensing could still require a testing facility to get approval of the patent holder. The patent holder could easily slow down even mandatory licensing processes and be able to set the fees of the license, thus preventing the development of cheaper, more accessible tests.

Thank you for your patience at the end of the day.

MS. GONGOLA: Thank you, Mr. Hanson. Now I'd like to open it for other members of our audience who would like to come forward to share any remarks, commentary.

No? Questions or items of discussion from really the panelists or anyone in the room? Like to share any questions? Commentary?

DR. KLEIN: I would make one comment, because the issue of whole genome or next generation sequencing has come up and with today's -- the status of today's current technologies, it's recommended that all mutations be confirmed. So, irrespective of -- be confirmed by Sanger sequencing, so irrespective of how the debate about the utilization of these tools and with respect to infringement comes out, there's still a requirement to use Sanger sequencing to do second -- to do a confirmation on the result, and that's probably going to continue for a while.

MS. GONGOLA: Thank you, Dr. Klein. If

you do have a commentary, for our court reporter, please mention your name first.

Other comments? Questions?

DR. ELLIOTT: I have one. George Elliott from the Patent Office. I wanted to ask Beth Peshkin if she has any experience, from your genetic counseling experience, that can -- that would allow you to give us an idea of the importance of a confirmatory test to the people that you work with.

MS. PESHKIN: Thank you for the question. I think there are two types of results that we need to think about confirming -- well, three types really, the first is a positive test result, a deleterious mutation is identified and we -- and consequential medical decisions may be based on that.

The reality is that when we have good sample and quality control, we know that the likelihood that a deleterious mutation, particularly one that we've seen before such as the common mutations, the likelihood of a false

positive is very low.

However, I'm a proponent of patient autonomy and understanding that life altering decisions are made on that basis, I would certainly like the opportunity for patients to be able to confirm those test results in an alternative lab if they would like, and that can be done now because Myriad, I believe, does license that aspect and a laboratory can test for a single mutation.

I think the bigger issue comes with negative test results, in other words, a $3,000 test is run and no mutation is identified, or an extensive test is done and a variant is identified, and as has been brought up before, I think it is patients -- that is the most common result that we get in a clinical setting and it's the most problematic, and we know that if another laboratory or another method was able to do more comprehensive testing, we could give a more complete result to those patients, and that question does come up quite a lot.

DR. ELLIOTT: Okay, just to add on to that, can you give us an idea of how many of your patients with positive results ask for a confirmatory test?

MS. PESHKIN: Very few.

DR. ELLIOTT: Very few?

MS. PESHKIN: Very few.

DR. ELLIOTT: Okay. Thank you.

MS. GONGOLA: Yes, Sara.

MS. SCHLAGER: I'm sorry. Can I jump in? Lisa Schlager with FORCE. I do think that in the high risk community there is common knowledge that Myriad's the only company that does this testing, so most people don't ask for a second test because there's knowledge that only one company does the testing, so it's not broadly known that there is an option to have a confirmatory test, as Ms. Peshkin just noted. Thank you.

MR. VISHNUBHAKAT: So, I have a question for Dr. Klein. This is something that I believe was in the 2010 report of the Secretary's Advisory

Committee on Genetics, Health, and Society, and it's something you reiterated as well, that insurance reform won't be enough because the patent holders would remain free to decline any insurance payer that they wanted to, and I was just wondering, from an economic perspective, what incentive a patent holder would have to decline a payer -- to refuse to work with an insurance payer?

DR. KLEIN: I think the -- I guess the question's probably best directed to people who are the ones declining to work with certain insurance companies. And that does happen.

I suspect it's the reimbursement levels, so that if you have exclusive rights to perform a test or service, and you do not want to perform that service below a certain price, you may be inclined to refuse to do it and that, I think, would probably be the reason. I mean, you see this in -- look, you see this in all sorts of economic life where if reimbursement offered is below that which the provider is willing to do the

work for, they're free to choose not to do it.

MR. VISHNUBHAKAT: Thank you.

MS. GONGOLA: Mr. Hanson?

MR. HANSON: Yeah, this is a suggestion for an area that you're not really directed to respond to, but one of the things that is in the Patent Reform Act is a process for people outside the Patent Office to request review of patents, and if the Supreme Court doesn't just strike down patents, it would be very interesting to know how you will deal with reviews of gene patents in particular and challenges to it. I ask because our organization has challenged some other patents and you did overturn a rabbit patent that we had asked that you re-look at, but we haven't asked you to look at gene patents and it would be interesting to know how you intend to do that in the future under the new law.

DR. ELLIOTT: I may start this -- this is George Elliott again -- but I might turn it over to Deputy Director Rea, who can also fill in.

Essentially you're asking how we would

handle a request for a third-party review or a third-party request for a review of a patent that's already issued?

MR. HANSON: I know you handled them under the old law. I'm just asking where, under the new law, how you're going to be handling that? I mean, it seems that one of the issues is that companies that had an interest in this or other researchers that had an interest in a patent not being granted could challenge the granting of it under the new law. Or am I reading it wrong?

DR. ELLIOTT: I believe under the new law anybody can challenge. There is a threshold level of showing that you have to make -- that there is a question of a reasonable likelihood, actually, I think, that you would succeed in challenging something.

There is also, under the new law, a provision that makes it somewhat easier to present evidence during the examination process itself so that if you were aware, through the publication of applications, that there was an application that

you were concerned about, there is a mechanism, again, with some restrictions, but for providing evidence that you think would impact the decision on patent-ability, but essentially the third-party requested review is fairly similar, I believe, to what used to be -- although the criteria for determining that the review goes forward is slightly different and the decisions now are made by the Patent Trial and Appeal Board rather than going back to an examiner.

Does that help?

MR. HANSON: Thank you.

MS. GONGOLA: Do we have additional commentary or questions about our conversation today? Well, we have received a tremendous amount of feedback and we thank everyone for attending and participating in the conversation. A transcript of today's event will be available very shortly.

Additionally, for those of you who did provide remarks to us, we're asking you to submit your written statements within 30 days of this

hearing. From that we will go on to develop our report that we will be submitting to Congress.

So, thank you, again, for your participation and have a very good evening.

(Whereupon, the PROCEEDINGS were adjourned.)

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I, Stephen K. Garland, notary public in and for the Commonwealth of Virginia, do hereby certify that the forgoing PROCEEDING was duly recorded and thereafter reduced to print under my direction; that the witnesses were sworn to tell the truth under penalty of perjury; that said transcript is a true record of the testimony given by witnesses; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this proceeding was called; and, furthermore, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

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