Roundtable Discussion

DR. McCABE: Thank you very much, Dr. Veenstra, and thank you to all of the presenters for these very informative and helpful presentations. Now we can explore these in a roundtable.

Just while you're sitting down, Dr. Veenstra, you talked about the complexity of these issues, and one point that wasn't raised, but one of our fellows presented some work at the Western Society for Pediatric Research and has a manuscript in preparation. What he found -- this was in a study of newborn screening for severe combined immunodeficiency, SCID -- was that it was most sensitive, looking at newborn screening, to the sensitivity and specificity of the test to the test parameters because that determined the false positive rate and those sorts of things.

So there are even additional issues, and that analysis was much more sensitive to those issues than to the frequency because of the cost implications in a screening test. So I think these are just incredibly complex issues as we move forward and it will depend on the setting in which the testing is performed as well.

Now it's time for the committee to ask questions and make comments about the presentation. Yes, Joan?

DR. REEDE: One of the things that was very striking to me was bringing home a clear recognition that as we talked about the need for more evidence and the challenges that we're facing or going to be facing for those who are insured is the widening gap for those who are not insured, and the fact that these issues just sort of see us moving toward a potentially two-tiered system, that as we move towards advancing technologies and use of these technologies and trying to figure out how to pay for them, there is a huge portion of our population where these will not be accessible.

I'm wondering, from any of the presenters, if you could give any comment to what might be done in terms of addressing this part of the population that has been left out of this discussion.

DR. McCABE: Members of the panel? Marc?

DR. WILLIAMS: I'll take a crack at it. I mean, I don't see anything different here than what we're facing in medicine in general. I mean, the issue is we have a two-tiered system. We have rationing. We may not want to use those terms, but that's the reality. We have a limited budget and limited resources, and so in some sense it does seem a bit silly to be arguing about who gets what when we know that there's a large population of people that probably don't have access to much of anything. But I don't know that there's anything specific to the genetic piece that separates that out from that issue. Pick any sort of access to service.

I can tell you that in my own clinical practice, that because of the nature of genetic disorders, that a lot of these children and adults do qualify for coverage under some of the special needs pots of money that are somewhat separate from other Medicaid pots, KBAC and other of those sorts of funds.

So at least in Wisconsin, we haven't had a tremendous issue with children and adults affected with certain genetic disorders in terms of getting them qualified, and thus eligible for services. So I think that in some sense having a genetic disorder may actually make available some reimbursement systems that aren't available to those that, by nature of lack of employment or

whatever, don't have any coverage at all.

DR. McCABE: Michele, I'm going to put you on the spot. Does that come up at all in your advisory role?

DR. SCHOONMAKER: Well, I've just been with CRS for only a few months, so I'm not really at liberty to discuss what policies Congress may or may not be considering, but it is a fundamental flaw, if you will, with our health care system and the way health care is delivered in this country. Perhaps if that's something that the committee could contribute to by framing policy issues or making recommendations, I would encourage you to contact your members of Congress or the committees that would have jurisdiction over those issues and presenting an argument.

DR. McCABE: Just to remind everyone, though, don't get so excited and call them tonight because you can't do that while you're a special federal employee.

Sean?

DR. TUNIS: The only thing I would add is it's become a standard part, when I talk about coverage and reimbursement for a new technology, to talk about all of the existing unmet needs for technologies and services that are very high value, very cost-effective or cost saving, that are not part of a benefit package or not particularly highlighted or talked about.

I think it's an excellent point to raise here that, even within the realm specifically of genetic services, there may be those that are extremely high value to populations that we tend to forget about, and to take the opportunity to highlight those, rather than entirely being attracted to sort of what's five or 10 years over the horizon in terms of the fanciest stuff for people who have insurance. I think that's an important element to every discussion about new technology. We've got a limited amount of resources to spend in health care and I don't necessarily think that we're attentive enough to the notions of getting the best value for resources.

DR. McCABE: Anyone else on the panel want to take a shot at that?

(No response.)

DR. McCABE: If not, Hunt, and then Cindy.

DR. WILLARD: I was struck, and Marc, I think you said it most eloquently by saying you were whining, but four or five of you, the obvious take-home lesson from everything you've presented was we want to be paid more for our laboratory tests or we want to be paid more for our clinical services. Yet I've spent enough time in hospital CEO offices to realize that that's not going to happen anytime soon.

So the ray of sunshine here was Dr. Veenstra. So my question to him, and the whiners can chip in as they will --

(Laughter.)

DR. WILLARD: My question to him is how large a group do you represent? I know of only a few groups like yours nationally who are really trying to address this issue of cost-benefit analysis in order to make an argument to someone that in fact this does eventually pay the system back or even save money in the long run, even though in the short run it's probably much more

expensive. So how rare a bird are you?

DR. VEENSTRA: An N of 1.

(Laughter.)

DR. VEENSTRA: No, my perspective is definitely coming more from kind of the pharmaceutical reimbursement area, and I think 10 years ago there was a lot of cost-effectiveness analysis. I think really the methods had been fully developed and there's a lot of research in the area. You didn't see them applied too much. There were guidelines in Australia for requiring cost-effectiveness analyses before reimbursement of tests.

Now, we have a situation where in a lot of countries, and in particular in the United Kingdom, there's a National Institute for Clinical Excellence, NICE. A lot of people call it not so nice, but they look at clinical evidence and they also look at cost-effectiveness before they make coverage decisions, and it's having an impact on the way drugs are brought to market and it's starting to impact the pricing, and what I explained to you about this AMCP format, that's really grown over the last few years, and so you're starting to see somewhat of a change of a perspective there.

So I would say that there's a strong academic community, but in terms of actually influencing decisions and playing a role in decisions in the real world, I think it's really just starting to happen now.

DR. WILLARD: Because I must say, in terms of what the committee might do, that focusing on that issue going forward of how we might take advantage of that body of expertise to examine the future of applying genetic and genomic technology for a larger and larger set of patients is more likely to be well received than simply arguing that a group is underpaid for the services we're already providing, and therefore we'll really be underpaid when we start providing even more. But if we can wrap that around an argument, assuming it works out that way, that this does have a positive cost-benefit ratio, then that would be time well spent.

DR. McCABE: Marc, and then Michele in response to that, and then we'll move on to another question.

DR. WILLIAMS: Yes, I think that's certainly reasonable. I think, though, it's also fair to look at what is happening in the private sector, and I think Ron's example in Kaiser and to some degree even in our relatively small integrated health care delivery system, there is the recognition, even though we don't really have the capability -- at least our group doesn't, and Kaiser probably does -- to actually internally do those types of studies, I think what you recognize is that some of the relatively low-cost interventions that we do, like taking a family history and doing genetic counseling and providing those services, actually in many cases reduces the number of higher-end technologies that are being utilized. Of the patients that are referred to our cancer susceptibility clinic, only about 1 in 10 actually go forward with a test.

So I think there are savings to be accrued to the system by doing things well in the front end, and while I think you're right, particularly when you look at the editorial panel and the fact that there are no family practitioners, internists, or pediatricians that are actually a voting member of that panel, it does tend to understand a little bit about why there's a skew between procedure versus, if you will, cognitive services in this country.

But there are cases to be made and within an integrated health care delivery system, I think those

cases are being very effectively made. The problem is that that doesn't necessarily translate into the way the care is generally delivered in this country.

So I think beyond the academic approach to cost-effectiveness or cost-utility, I think there's some practical experience in well-integrated systems that would demonstrate value and quality as well.

DR. McCABE: Michele?

DR. SCHOONMAKER: Thank you, and again, these are my own views.

I think a problem that precedes whether or not we can use cost-effectiveness information is a problem that we need a better way of collecting data to assess effectiveness. As you heard Sean say, CMS and FDA are both bound by the legislation and the regulations that say that they look at safety and effectiveness or medically necessary and appropriate, and perhaps one thing that the committee could explore would be a better way to or a way to promote the better coordination between those two agencies in the evaluation of new technologies that would enable you to collect the type of data to make effectiveness determinations, and then adding the cost may be relatively straightforward or not. I see it as a way of more efficiently handing the baton from one agency to the other one without stifling the innovation that's going on in the field.

DR. McCABE: That was a windmill that we tilted at under SACGT. It would require legislative change because of the way the laws, the enabling laws, for the two organizations -- and the cultures of the organizations. These fundamentals are firmly embedded. So we had decided not to, while we recognize that it's a fundamental tension between those agencies, because where one determines that it's safe and effective, the other determines that it's not valuable enough for reimbursement, so it does create problems and it is a problem in the system. We could decide if we wanted to take that one on, but it's fairly deeply rooted, as we learned during those previous deliberations.

Cindy?

MS. BERRY: One of the frustrating things in trying to change a policy, particularly in federal programs and Medicare in particular, is the fact that to get a change in the law, the Congressional Budget Office has to look at the proposed law and determine how much it's going to cost. Unfortunately, CBO is dealing with narrower budget windows, where maybe we're dealing with five or 10 years, and maybe some of the research that's out there that demonstrates real cost-benefit and effectiveness is looking farther out than that.

Then on top of that, I think, even though they might not admit it, but you're cheaper if you're dead than if you're alive according to CBO.

So does anyone have any strategies or ideas for how we can combat that? Because to the extent that some of the changes that we might want to see made require legislative change, legislation actually passed by Congress, we're going to have to deal with the Congressional Budget Office and its way of analyzing these things. So it's a perennial challenge, I think.

DR. McCABE: First, I'm going to toss that one to David, and then have you chime in, Marc, but my understanding at a very superficial level is that's one value of the cost-utility models because it does put a premium on survival.

DR. VEENSTRA: Yes, I think that sums it up pretty well. If you're doing a cost-utility analysis,

you're looking at quality of life and life expectancy as your output. That's what you're producing. That's what we're all here in the business of, is improving people's lives and helping them to live longer.

So when you're doing that type of analysis, it works well, and it's not best to let everyone die, but if you are just looking purely at cost and if you don't have any way of assigning even a monetary, economic value to someone's life, then you're correct. You're always going to end up that it's cheapest for everyone to pass away.

That can be a serious challenge and I think the use of cost-utility analysis is pretty well entrenched in the academic community, and if there's a need to encourage the use of it, I think there are a lot of folks that would be willing to help out.

DR. McCABE: Marc?

DR. WILLIAMS: I think that a lot of the things we're talking about don't have that long a window. There is evidence emerging in the BRCA group that cost savings accrue to health plans who cover testing, predispositional testing, to women based on the decisions that they make then to perhaps undergo either hormonally-based therapies, preventive therapies, or surgical preventive therapies, that the cost savings in a large group of insured actually accrues within one to two years. So we're not looking at a 10, 15, 20-year window.

I think also with some of the ability to detect susceptibilities to drug reactions, a couple that were mentioned today, and then the other one I would put on the table would be malignant hyperthermia, where we have the ability to identify about 80 percent of the individuals that are susceptible to malignant hyperthermia reactions to anesthetic agents and those can be easily avoided then.

The cost there would be immediately recognized as soon as that person either was going to be exposed to that drug or underwent that procedure because then we would be avoiding a medical catastrophe that would have attendant costs associated with it.

Again, I think some of the graphs that were presented by Dr. Veenstra clearly showed that at even relatively low prevalence levels, these can be identified and be very cost-effective. So I don't think, even when we're looking at chronic diseases, we're not necessarily looking at a 15 to 20-year payback on some of the investment.

DR. McCABE: Yes, David?

DR. FEIGAL: Is there any estimate in the genetic testing area or from any of the advocacy groups what percentage of that testing ends up being out of pocket for patients? I remember when the SACGT was meeting, there was some testimony presented. I remember one scenario where they had to pay $2,500 per family member per test, and it could only be run if they paid for the test because it wasn't covered.

We've got the figures in round numbers for drugs. Do we have the same thing for diagnostic tests?

DR. McCABE: Andrea?

DR. FERREIRA-GONZALEZ: Yes, I don't currently have those numbers and it may be a little

difficult to get to those numbers because a portion of the way we track the reimbursement, like at a large academic center, you bill as a global billing, where the patient comes in, sees the physician, and there's radiology, pharmacy, and laboratory practices. So a bill is sent to the third-party payers, but also the division might choose to pay out of pocket the genetic test. So they will be assigned a different account and so forth. So it would be very difficult to track that information.

We can try to get that information for the committee for the future. I think it would be very interesting to see that.

DR. FEIGAL: Part of what makes this challenging is sort of the increasing practice that you don't have to go to the laboratory to get your test done because the samples can travel to central laboratories, and so there may not be a physician interaction and there may not be an institutional interaction. Some of the examples are actually from academic medical centers, where they might be providing a scarce test for people all over the country, and when you've got that kind of arrangement, I imagine it's more challenging to figure out the billing, but it would be interesting to sort of look at that dynamic.

DR. McCABE: Debra, you want to follow up on that? And then Marc.

DR. LEONARD: Well, as a laboratory director, that's hard to determine. My laboratory does get testing from across the country and even internationally, and we ask everyone outside of the University of Pennsylvania Health System to pay upfront for the test. So there's this trickle-down effect that we aren't going to eat the cost because the reimbursement is so poor. So therefore, we ask for full payment of our charge, but then downstream, the patient has to work with their third-party payer or the health system has to bill or the health care provider or the genetic counselor, and then they get the poor reimbursement. So we actually prefer to do testing outside of the University of Pennsylvania than for our own patients because the reimbursement is close to 100 percent.

DR. McCABE: Marc, is your comment on this point?

DR. WILLIAMS: Yes, and I think the point that we don't want to miss here is that looking at it from the laboratory perspective backwards, in addition to the problems noted about that, it's going to miss the other side of the equation, which is those that chose not to undergo testing when they realize that it's going to be out of pocket.

As the person that sits down with the patient and works with the insurance companies and tries to get the payment for the testing upfront, I can say that we probably are successful, depending on the test, anywhere from -- well, anywhere from 0 to 100 percent, but for the common ones, the BRCA and the HNPCC, we probably bat about 400 or 500 in terms of getting third-party reimbursement, and then those other individuals are left either to pay out of pocket or we actually have established a fund for those that are really in dire financial need. We can actually subsidize testing in those individuals, thanks to a generous donation.

But it's going to have to be a two-pronged approach to try and get a handle on that because I think there really are a lot of people that would like to be tested, but choose not to be tested because of the out-of- pocket expense.

DR. McCABE: And certainly, that gets back to the stratification issue that Joan pointed out before.

Emily?

DR. WINN-DEEN: I guess I want to put the CMS guys on the hot seat for a second here because, despite all these presentations, I still don't get it.

If I have a new test and I come out with that, I can put all my stackable codes together and figure out how many PCR reactions and how many probes and what the Medicare default reimbursement might be, but if I had an excellent health economic argument, what I heard is that CMS still wouldn't change the reimbursement. They would only use that to determine if something would be reimbursed.

So it sounds to me like despite whatever value a test could bring to the overall health care system, that at least for the next five years until 2009 when lab fees are unfrozen, that we're stuck.

DR. McCABE: Don?

MR. THOMPSON: Sure. It's multiple parts to the question, but let me try to address it in pieces.

To the extent that this new technology or this new test could be broken down into existing CPT codes, you are correct that it would be frozen until 2009, and the only avenue that CMS has available to it, and we're not quite there yet, is what I spoke about inherent reasonableness, which is our ability to look at a fee and say this is inherently unreasonable and there is a rather long process in the law for changing that payment amount.

The reason that's a long process is they were more terrified about us reducing fees than they were increasing them, but it's the same process. The sword cuts both ways.

So to the extent we have a new technology covered by existing CPT codes, we're a little bit handcuffed in our ability to change those payment amounts, though I did mention IR, inherent reasonableness, is in the future and one of our first candidates is the HIV/HCV viral loads. That's one avenue, but that is again kind of a brick-by-brick approach.

Now, to the extent that you have a new CPT code for this test or there's no way to add the component pieces in the existing codes or we require a new CPT code and that comes into play, now it goes through the CPT process and the code is approved, in that scenario, that's where kind of the 942(b) comes in, the ability that Congress said, well, publish some regulations on how you want to go about doing new lab tests.

Again, one might argue that the directions they gave in the statute would mean just take your current process and put it in regulations, but that's why we're going through notice and comment.

So it's kind of a little bit of a, like I said, window, a small ray of hope, if you will. To the extent that you get a new CPT code, there is some flexibility in there on how we might set the price.

So is that helpful? Probably not.

DR. WINN-DEEN: Yes. I guess I'm still concerned that you could have a test that has got a huge amount of economic value and CMS still would not recognize that economic value, no matter what your health economic argument would bring to bear.

DR. McCABE: Sean?

DR. TUNIS: Yes. You know, the fact that for the most part Medicare doesn't use cost-effectiveness or economic evaluations as part of either coverage or reimburse has been 20 years of intense lobbying by the medical device industry against that, and the reason for that obviously is they'd like to be able to charge high prices for things that don't create a lot of value, but the downside of it is that you can have very high-value things that you don't get fair prices for.

I think, and maybe this committee wants to take it on, that there is no sensible way to get good value out of health care resources, whether it's Medicare or elsewhere, without having the ability to do the kind of work that was discussed here today and make it influential in coverage and payment policy.

But it's not because -- you know, Congress put those prohibitions in place pretty much under pressure from industry lobbying efforts that have undermined several efforts to make cost-effectiveness a factor in reimbursement policy in Medicare.

DR. McCABE: Debra, a comment on this point?

DR. LEONARD: Yes, a question. Wouldn't Section 942(b) apply to the new alphanumeric modifiers? So with this whole alphanumeric modifier system that was proposed by the Genetic Testing Work Group that we could do something for genetic testing reimbursement?

MR. THOMPSON: That's one of the things we intend on seeking comment on in the new regulation on the 942(b), is when is new new? And that's an open issue.

DR. LEONARD: Because this is completely new.

MR. THOMPSON: Right. Understood.

DR. McCABE: Yes, Andrea?

DR. FERREIRA-GONZALEZ: But these new codes are going to modify existing CPT codes.

DR. LEONARD: Don't point that out. They're new.

(Laughter.)

DR. FERREIRA-GONZALEZ: They know that already.

DR. LEONARD: I know that.

DR. FERREIRA-GONZALEZ: But we still bring in new technology or new tests that have clinical necessity and will be effective in treating the patient, but even the modifiers, the only thing it's going to allow is for third-party payers to identify what they're paying for.

Now, the new CPT codes that are going to be coming down the pike, hopefully to address microarray technologies, et cetera, hopefully they will be put in a different pot and seek advice from laboratories, end users, and advice from community associations to see what is the level of reimbursement and so forth.

That's a statement and a question.

MR. THOMPSON: Again, not to be evasive, but I don't like to get in front of my chain of command in terms of the clearance process. We are going to go through notice and comment rulemaking in the issues you just brought up with the modifiers, and without question, the issue of the new CPT code, that does fall into kind of the new technology pot.

That's not to say that if you get new CPT code and we look at it and we see it as cross-walking in a straightforward manner to an existing CPT test, that we might not be in position where, again, we'd be somewhat handcuffed, but granted at least it's in the new code process. The modifier is a little more of an open issue, but at least if you get a new CPT code, it definitely runs through that process where we have a public meeting, we get input, and we decide gap filling versus cross-walk.

DR. McCABE: I just want to make a comment and point out something that was said by Sean, and that is that there might be some benefit to looking at cost-effectiveness for these tests, and also to remind everyone that coverage and reimbursement was in a Category 4, which suggests that it needs more discussion, and that we have both agency public representatives and representatives from private companies here and we've been told that the reason we have this system is because of lobbying by medical device companies, but in fact for testing we have those individuals represented on this committee.

So as we're thinking about our deliberations and how we are positioned to look at recommendations, it seems to me that we have a forum here with the appropriate people sitting around the table for pursuing these discussions.

Chris?

DR. HOOK: Thank you.

I want to just throw a question out to Dr. Veenstra. One of the issues that we're going to be talking about tomorrow is to pursue a bit further the question of pharmacogenomics on a larger scale, and I'm not aware, but I don't know if anyone has informally done the thought experiment along the line of if we look at the JAMA study from '98, 106,000 people per year dying from attributed drug reactions, of which only 5 to 10 percent were probably preventable because of clerical error or physician misprescription and so on.

If the country or if the FDA were to go to the effort of or have the law modified to require now submission for new drug approval require pharmacogenetic information be included, what's sort of the cost-benefit analysis that that might bring?

DR. VEENSTRA: That's a great question. From what I understand in swapping voicemails with Katherine Phillips, I think basically planning for doing a study like that is underway right now. I think we'll be working with the FDA as well as some other folks in trying to get a general ball park idea of what that might look like.

It is going to be a bit of a thought experiment because we don't have a lot of these association studies, but just laying out the basic parameters, where do we end up? How many lives are saved in general? Is there any chance that it might make sense? So I think it's a great question and it's something we're going to try to look at.

DR. McCABE: Before we go to Joan, Sarah was just showing me on her Blackberry here one of her latest entries is "Gene Testing Families Risk Overheating Updated." Monday, March 1st, at 4:27 p.m., so extremely current, and it's by an AP medical writer, Lauren Neergaard, N-E-E-R-G-A-A-R-D, and basically about Uncle Joe waking up from minor surgery packed in ice, so it was the malignant hyperthermia, which not only has morbidity but also mortality still associated with it. We didn't scroll down to read the whole article. I'll leave that up to you tonight to catch it on CNN, but certainly very timely.

Joan?

DR. REEDE: Just a point because we had the other earlier discussions about population studies, and one of the concerns I have when we start talking about pharmacogenomics and these types of issues are assumptions that end up being made that the answers that you get from these studies are able to describe or explain variation that may also have, and most probably has, environmental or other factors involved, and real risk. I think here about some of the discussions that I have had with people who make assumptions that many of the health disparities and other things we see can be explained just on the basis of genetic variation.

I'm just concerned that as we go down this path of pharmacogenomics and we start looking at cost-benefit and we start getting into these fine numbers, that we leave out the environmental influences and just want to make sure that as a committee we don't fall sway to the idea that genetics by itself is going to answer these types of issues.

DR. McCABE: Emily, you want to comment on that, and then we'll go to the panel?

DR. WINN-DEEN: I just wanted to also encourage you while you're thinking about this thought experiment to think about the fact that the really severe ADRs, the ones that you would most like to prevent, are the ones where we'll never have enough statistical power, probably, to find out what the underlying genetic lesion, if it was there, was because you're never going to leave something on the market long enough for the right statistical number of people to die to do the study.

So it means that that adverse drug reaction benefit to genetics is not in the really severe, severe reactions. It's in the sort of moderate, like the hyperthermia kind of things, but things that induce people to die, I mean, we've seen how many drug withdrawals in the last five years because of unexplained deaths. I mean, it's not ethical to leave those kind of things on the market.

DR. VEENSTRA: That's another potential study where you're thinking about what's been the loss to society of having to pull those drugs off the market? All the money that was spent to develop them. They could benefit patients, but maybe because of genetic variation, we've had to pull them off the market. So I think that's a strong belief of mine is that most of the drugs that cause a lot of problems because of pharmacogenomics aren't on the market.

DR. WINN-DEEN: Yes. The question is just can you ever actually find out? It's not that I don't believe there might be a genetic source to that adverse drug reaction, but can you design a statistically valid multivariate study to actually find whatever the genetic lesion or combination of six or eight genetic lesions that cause those few individuals to have this very severe reaction? You know, it's a statistics problem.

DR. McCABE: It is influencing care. I think I've mentioned before at this committee the fact that we had a threat of a pharmacogenomics lawsuit at UCLA when a child was on an

aminoglycoside, gentamicin, and failed the hearing screen when they were leaving the NICU, and the family threatened to sue us, having gone to the Internet and looked up aminoglycoside-induced hearing loss.

It turned out the child did not have the mitochondrial mutation, but I was speaking and actually presented this at a forum at UCLA recently, and the head of neonatology pointed out to me -- this was two years ago -- they had stopped using aminoglycosides as one of their first-line antibiotics and had gone to a much broader spectrum, cephlasporin, and now we're seeing the consequence of that that was predictable with a lot more Gram-negative-resistant organisms. So there are all kinds of consequences to these decisions that could be ameliorated by the appropriate testing.

Marc, did you have a comment?

DR. WILLIAMS: Yes. This is related to something that I maybe read between the lines appropriately or inappropriately about the comments that you were making, and I think it is an important issue because there are certainly a group of individuals that are looking at genetic variation with an agenda to say that, well, a lot of the disparities that we're seeing are really buried in this genomic variation, and of course then that also can sometimes get translated into other issues relating to race, ethnicity, and what have you.

I just wanted to let the committee know, if you're not already aware, that a group of population geneticists, particularly Dr. Len Jordy at the University of Utah, have been doing some really outstanding work looking at some genetic variation within certain disorders that we've recognized as occurring within a higher frequency with certain racial groups and have not really found that this is a race-specific variation, that this is actually much broader.

So I think that what's actually going to come out of the science as we begin to understand the variation more is that it's actually going to have less of an influence on the types of disparity, particularly racially and ethnically-based disparities, that have previously been looked at. But I think if this is work that you're not familiar with, it would certainly be reasonable to have a presentation on that.

DR. McCABE: Thank you.

Yes, Joan?

DR. REEDE: A follow-up to that. I think the important part here is also perception, and if you look at what the public perceives as what you're going to be able to do with genetic testing or pharmacogenomics, there's this sense by some of the public that this testing is going to tell you the difference based on race/ethnicity or deal with all of the health disparities, and there are many other variables that are there.

So I think there's a risk of going down a path that we've been down in the past that is not a healthy one for our country in terms of thinking that the science is going to be able to explain some things that it may not be able to explain.

DR. McCABE: Martin?

MR. DANNENFELSER: Just a clarification on two points for the folks from CMS. You talked about reimbursement and I guess through Medicare, it sounded like in your presentation, for the genetic testing. Is it only through Medicare or is there any kind of reimbursement through

Medicaid for genetic testing?

That's one, and there will be a follow-up on that.

MR. THOMPSON: Sure. Yes, but in the Medicaid program, again, that's kind of a decentralized program, so individual states are making individual terminations. Some of them look at our fee schedule amounts when they're setting those rates. As I think some of the earlier slides showed, they look at our kind of national limitation amounts in setting those. That's not something we control at CMS. That's kind of more at the individual state level, although many of them do mirror the clinical lab fee schedule.

MR. DANNENFELSER: But they have the ability or allow the use, if you will, for a broad range of genetic testing at the state level?

MR. THOMPSON: I'm speaking from a payment perspective. I'll leave it to Sean from a coverage perspective.

DR. TUNIS: It's pretty much the same situation regarding the medical necessity issue in that it's a decentralized decisionmaking subject to state laws, state policymaking, sometimes more generous than the Medicare national policy. Sometimes they look to the Medicare national policies or they'll look to some of the local policies within the state, but there are no mandates from the Central CMS on what the state Medicaid programs would cover.

MR. DANNENFELSER: And with respect to Medicare, are there any eligible, is it people, in terms of Medicare who would be seeking reimbursement for prenatal genetic testing or is it other kinds of genetic testing?

DR. TUNIS: It's possible under the -- you know, since it's elderly, disabled, and end-stage renal disease, presumably within the disabled category there are some folks who would be seeking prenatal testing. It's just not particularly common.

MR. DANNENFELSER: Thank you.

DR. McCABE: Debra, and then Brad.

DR. LEONARD: Could I ask for clarification? From the private insurance perspective, it's said that you had to have the test be FDA-approved or cleared in order to be paid, and then you guys said that you would also consider laboratory-developed tests for payment. So can you clarify whether tests are only paid for if they're FDA-cleared?

DR. McCABE: Michele?

DR. SCHOONMAKER: I'm sorry. That was FDA-approved or those that conform to the CLIA requirements. So if they're performed in a CLIA-certified laboratory, then that would be the regulatory approval that would be pertinent.

DR. LEONARD: So FDA approval is not required.

DR. SCHOONMAKER: Not for tests. Right.

DR. LEONARD: As long as they're performed in a CLIA-certified laboratory.

DR. SCHOONMAKER: Right.

DR. McCABE: Marc?

DR. WILLIAMS: It ain't that simple. The problem is that each private insurer can make their own decision and they can decide that they will only pay for FDA-approved laboratory tests.

So while many insurers will look to CMS regarding coverage and payment, they're certainly not obliged to follow that, and there are no other national things that they need to follow, and so basically they're all on their own, which leads to the frustrating situation that I know you've experienced, because I know we've experienced it, which is you have to go insurer by insurer and basically fight that battle with every single one of them. There's no shortcut to be able to do that.

Again, the FDA approval has to do with a situation where you have to have something that says somebody's looked at this, and that's sort of been the standard, but it just doesn't fit the paradigm of these individually-developed tests.

So we've actually referred insurers to the American College of Medical Genetics testing, voluntary testing, and saying this is really the standard that the industry is using and so this is really what you should be asking the laboratories about because the FDA, at this point at least, does not have the full jurisdiction over these.

DR. LEONARD: Well, with the coding system the way it is, also I don't know how payers know, since all genetic tests use the same codes, what would be FDA-approved and what wouldn't and what would be laboratory-developed and what the testing was even for.

DR. WILLIAMS: You've got that right.

DR. McCABE: Brad?

MR. MARGUS: Just in response to Joan, I wanted to mention that my company is involved in doing massive association studies with large numbers of cases and controls and what we think are sufficiently powered enough to find things that are real, and while a lot of scientists publish those things all the time, I think most geneticists are now arriving at the conclusion that you really need to replicate in other populations and other environments. So there is pretty much an effort in place to not jump to conclusions that you definitely know it's genetic until you actually can prove it in different environments and replicate it. So you should feel better about that.

I really appreciated the tutorial today for all this. I guess I have a question about if you came up with a new association, an anomalous association that has tremendous value, even though I understand CMS may not care, and you go about making a CPT for it, my first question is how long does it typically take to get a new CPT?

Then the second question is this subject of cross-walking and gap filling. So if the new test, the content for that test, the loci that you're interrogating are new but the approach is still a PCR-based assay that just has different primers or something like that, do you then conclude that it's cross-walking and you actually can easily find and you already have an established ancient rate that you apply to it or does the fact that it's a novel test give it a chance for a new rate?

DR. McCABE: Don?

MR. THOMPSON: Sure. The approach that we take, it's on a case-by-case basis. So during that kind of public meeting process, we kind of rely on the industry and clinicians. Any member of the public can come in and give us recommendations, and based on that information we have, we kind of huddle with our clinical staff and our clinical folks and our contractor staff, and we look at that case by case. So there's no blanket rule for when you cross-walk and when you gap fill. It would be dependent on the individual situation and the public input.

Then your first question, I'm sorry, was?

MR. MARGUS: How long for a CPT typically?

MR. THOMPSON: Rapid is not a word that comes to mind.

(Laughter.)

MR. THOMPSON: It can be a multi-year process. Unfortunately, or fortunately, depending on how you want to look at it, we have kind of relied on the AMA and they have kind of formalized CPT process that they go through. It's a deliberative process, so anybody can request a code, but it is, again, not rapid. It can take a year or two years, and sometimes they can table the code and come back and they may seek additional information. So it can be rather involved.

MR. MARGUS: So what repercussions or impact do you think that has, the time it takes? Does it hurt things or not too much?

MR. THOMPSON: A loaded question, but if you're asking does the fact that you can't get a code or you don't have a code in a rapid fashion for a new technology have an impact on access, going back again to some of the earlier presentations, there are kind of miscellaneous codes that you can go under, but the problem is there's a certain administrative burden associated with going down that road. If you have your own code, it's in the system. It's a much more rapid administrative fashion. You can have a public discourse on the price at a national level, whereas when you go with some of the more miscellaneous codes, you may be able to get access, but there might be an administrative burden associated with that.

I'm sure, given the reaction from both sides, I think, that we have some thoughts on the CPT process.

DR. McCABE: If this is a comment on this, and then Joan and Hunt, and then we're going to wrap up.

Andrea?

DR. FERREIRA-GONZALEZ: I want to bring an additional issue. It seems to me that a way to look at changes in the reimbursement for Medicare is through the inherent reasonableness. My question is when can we expect this process to take effect and maybe if there is anything that this committee can do to provide reinforcement to the Secretary to move this process faster?

MR. THOMPSON: Sure. As I mentioned, we were under a congressional moratorium with respect to inherent reasonableness for many years. Again, I think out of fear that we were going to reduce prices. That moratorium has recently been lifted and in the wake of that, we are now struggling with coming up with instructions for how that process is going to work because we

want to ensure that we have a kind of fair and equitable process because it will be used in both directions. You know, prices can come down and prices can go up under it, and it's going to be the same process either way and we make sure, given the additional congressional input that we received on inherent reasonableness, that we follow that. So our hope is that this year that we will be able to issue those final instructions on inherent reasonableness and then begin the process for changing those payment amounts.

Again, both up and down, and this is kind of focused on genetic testing, but in kind of looking philosophically at the clinical lab fee schedule globally, we have a number of tests that one could argue, and some have argued, are in fact overvalued. For example, if one looks at urinalysis CBC, some of which are kind of the bread and butter of some labs, and even some, I would argue, at VCU, to the extent we're overpaying for those and we decide to go after some of those high-volume tests, which may represent 50 to 60 percent of the clinical lab fee schedule, the hue and cry if we don't get the process right will be loud. So we've got to make sure we get it right for both the increases and the decreases.

DR. McCABE: And a follow-up on that, is there anything this committee could do?

MR. THOMPSON: At this point, I can't tell you the internal pressure to get those turned around, so I can't imagine adding another voice would cause the process to be any more rapid, but again, the committee may feel otherwise.

DR. LEONARD: Can I clarify something on Brad's comment?

DR. McCABE: Yes.

DR. LEONARD: Which is that the understanding is that you do not add new CPT codes for every single genetic locus. Otherwise, we could end up with 25,000 times however many mutations there are per gene.

MR. MARGUS: So it has to be a new technology for even analyzing.

DR. LEONARD: It would be technology-based. Right now, a laboratory implements a new test that classically would have gotten a new CPT code using these -- isolate DNA, do a PCR, run a gel codes, and so we don't go through the new CPT code process.

MR. MARGUS: But if it were just a new set of SNPs tomorrow for looking at something else, they already have a CPT for it, they'll apply that rate, and then it's five bucks whether it's worth $50,000 in savings --

DR. LEONARD: Yes. You've got it. So all the new genetic tests that are going to be coming out are constrained by this CPT coding reimbursement process.

MR. MARGUS: Everybody just closes their eyes and says wait until 2009.

DR. LEONARD: And it's not clear that in 2009 it will be freed up. It could still remain frozen, right?

MR. MARGUS: So one question is, Ms. Lab Lady, aren't there any drugs, aren't there any tests --

PARTICIPANT: She's Dr. Lab Lady.

(Laughter.)

MR. MARGUS: Sorry. Dr. Lab Lady, aren't there any tests over the last five years or whatever since the prices were locked in where a technology has helped to reduce the cost and now you're making buckets?

DR. LEONARD: No. I can emphatically answer that no. There probably are technologies out there that would reduce costs, but because of the health care finance system, we have no capital equipment budget, so we can't buy robots for automated nucleic acid extractions and 96-capillary electrophoresis instruments and those kinds of things. So technologies may be out there, but the hospital systems in academic health centers where this testing is performed generally don't have capital equipment budgets to be able to be proactive and think about reducing costs in these ways.

DR. McCABE: For example, when they got the capillary system in our sequencing lab, then they were able to decommission the old gel-based systems. We gave the one that we had contributed years ago to the sequencing corps, we gave that to our orphan disease testing lab, so they could start doing sequencing. So they're using ancient technology, but it's because it was free, and that's the nature of the capital improvements in our academic health centers.

Joan, I'll give you the last word for the day.

DR. REEDE: Thank you.

Not withstanding the research and the work that Marc is mentioning is being done or the work that Brad is mentioning with regard to his company, I think that we would be remiss if we did not also take into consideration the fact that not everybody is of the same opinion or sway that we are. So if you look in the literature, you can see articles written by physicians talking about "I am a racially profiling physician," using our genetic information as their justification for racial profiling.

So I think, as we talk about our prioritization and we talk about issues such as education and we talk about issues such as making the public aware and moving forward, that we have to be cognizant of the fact that not everyone is going to use this information in a way that we may think is appropriate.

DR. McCABE: Thank you very much. That's a very good way to end the evening. Thank you everyone for putting in a long day today.

Let me remind you that you do not fill out your second straw vote ballot tonight. We will hold that for tomorrow.

I want to thank our presenters again for your time and your participation. It was extremely helpful.

I want to remind those who are joining us for dinner -- committee members, ex officios, presenters -- please meet in the lobby at 6:40 p.m. and we will then take cabs to the restaurant. Our reservation is at 7:00 p.m.

Just to remind you, because we have two busy days, we are starting earlier than is our custom tomorrow. So we will be starting at 8:00 a.m. tomorrow, and that will be with public comment,

so I would ask all of the committee members to be here to be respectful of the public comment session. Thank you. (Whereupon, at 5:35 p.m., the meeting was recessed, to reconvene at 8:00 a.m. on Tuesday, March 2, 2004.)