Full Committee Discussion and Next Steps for Pharmacogenomics
Facilitators: Hunt Willard, Ph.D. and Emily Winn-Deen, Ph.D.

DR. WINN-DEEN: On to discussion. I personally have a lot of notes from today's session. So I guess what I'd like to do is see if we can figure out if there are some particular areas -- well, two or three things that I think we should work on. One is are there some things that we heard today that just stimulate us to want to hear more about any particular subjects, and if so, do we need to try and ask staff to put together a Part 3 to this program? We had Part 1 this morning, Part 2 this afternoon. Do we need another half-day or so of information gathering and education?

The other is can we try and bin some of these things into different areas? Are there research issues? Are there ELSI issues? Are there consent issues? Into some kind of logical groups that we then could tackle in trying to make some kind of a summary report of where things are, and then some specific recommendations for what this committee would like to see happen in the area of pharmacogenetics. I think we have some people who want to say something.

DR. WILLARD: Let me take the chairman of the day prerogative to try to frame this the same way we dealt with large population studies yesterday, which is to get the committee to focus on what kind of direction can it give to the task force so that the Task Force on Pharmacogenomics can make best use of its time between now and the October meeting.

The real issue, as I was listening today, is for the committee to decide are there still issues and gaps where we feel none of the existing groups are tackling them and/or where we simply lack information. It's going to take some discipline to keep our discussions along that track. There are many interesting and chewy questions around pharmacogenomics, but some of them may well, we decide, be under control and are well attended to by existing groups, in which case we don't have much to do except pay attention to that and monitor that as time goes on.

So I think if we can focus our discussion on how best to recommend to the task force so that they, with a little more leisure, can decide exactly what needs to be done, and then have that task force come back to the full committee in October with some specific ideas, much as we're doing for large population studies.

DR. WINN-DEEN: People still have their hands up, so we'll go Kevin, Agnes, Cynthia, and Deb. So we have four people in the queue here.

DR. FITZGERALD: As a member of the task force, a couple of other things that I'd like to be able to see to get input. I think one of the things I'd like to pursue a little bit that did come up, and I'm not sure that the people that we had were set to answer, I'd like to get some more perhaps of the financial side from industry as to what their parameters are on some of these issues. In particular, we heard the desire for partnership with academia, with government and that sort of thing. I just want to get a better sense of how that would flesh out, that partnership.

Also, I'm just wondering where the judiciary is on this. That's a group we haven't heard from, even in the genetic discrimination sort of thing. How do they see this cashing out?

DR. WINN-DEEN: You mean are they waiting for the lawsuits to come?

DR. FITZGERALD: I'm just wondering. I'm just wondering what's their perspective on all this, what do they see as the red flags and things like that, that we're just not hearing. I don't know, I

haven't heard any of that yet. So I'm just wondering if it's possible to get somebody in October to speak to us on that.

DR. WINN-DEEN: Okay. On the financial aspects, we also really didn't hear from insurers. Is there some interest in trying to hear from insurers as well?

DR. FITZGERALD: Right, yes. I think we'd have to have that whole -- I don't know if it would have to be somebody necessarily from each industry, but somebody who has that information or studies that information.

DR. WINN-DEEN: Right. Okay.

Agnes?

MS. MASNY: I think Sam Shekar had brought this up earlier, about the electronic health infrastructure. I think that would be something we would need to hear a little bit more on both for the area of pharmacogenetics, and I'm sure it's going to have impact for the whole area of personal genetic information that we should be more up to date on.

The second area that I just have a question on is that for the task force for the large population studies, is there an overlap with what we're looking at in the pharmacogenetic studies in populations, possibly large populations, with the large population study that you're examining for our group?

DR. WINN-DEEN: Hunt, do you want to just take that?

DR. WILLARD: Well, there certainly are some questions that will be in common to those two groups, and there's also substantial overlap I think between those two task forces. So I think we just all need to be mindful of that as we go forward, but it's a good point.

DR. WINN-DEEN: Cindy?

MS. BERRY: Because I work with Congress, I tend to have to oversimplify things. So maybe this is too simple for this group, but I was listening to everything that people were saying, and I divided the remarks into kind of a flow chart. Over here was research, the pharmacogenetics, the research needs. Then once you get the research going and you've got some conclusions and all that, then the question was how do you integrate that into practice. So those were sort of two main issues.

Leaving aside the integrating into clinical practice, it seems to me that there are big, big gaps in the research that is being done or that has yet to be done. So I divided that further, research with regard to existing drugs, drugs that have already been approved, they've received FDA approval, so what do you do there? Who does that research? Is it the pharmaceutical companies? Do they have to go back and do some research on their own product that's already been approved? Is it academia? Is it government? And how do you coordinate those? I think we heard a little bit about that earlier today. There's got to be some mechanism to coordinate those things. Is there a systematic way of conducting pharmacogenetics research on existing drugs? In other words, that it's not ad hoc. It's not some guy at Vanderbilt decides all of a sudden I'm going to go look at this, and then maybe one pharmaceutical company says, well, maybe we'll go back and look at our drug. There's got to be some more systematic way to do it. So how do you coordinate that?

Then the other box is, of course, pipeline drugs. In that case, it seems to me that the burden would fall on the company itself because they're the ones that are inventing the product. I mean, nobody else has access to that. So if it's a pharmaceutical company, how do you get them to do that level of research? Do you have a mandate? Does FDA require it, or is it more an incentive-based system?

It seems to me there are lots of different questions and sub-questions in addition to ethical questions that we can put under each one of those, but that was my attempt at kind of simplifying what we heard today, the things that we're going to be faced with. So I don't know who else we need to hear from as far as that goes. I think we got a good base of it, but I'd like for us as a group to contemplate what can we advise the Secretary to do so that we can really encourage this kind of research both in existing drugs and then in pipeline drugs, and who is the best entity or industry or sector to do that.

DR. WINN-DEEN: And I would add even under "approved drugs," there's two bins. One is where you know the biomarker, and one where you don't know the biomarker but you know there's some kind of adverse events that you'd like to know the biomarker for. I think those are two different bins as well within that group. So I think the task force could definitely consider trying to make a flow chart and come up with some tentative outline of who might be best suited to do that to throw out on the table for discussion at the next meeting.

Debra, did you have some more commentary?

DR. LEONARD: Yes, about what we'd like more information on, and this kind of ties in with the framework that Cindy just presented, which was very nice.

I do believe that Japan has mandated that all existing drugs be evaluated for pharmacogenetic impact on the Japanese population, and maybe it would be useful to hear how they are doing that and how it's funded and what they're actually looking at. I don't know a lot of details about it. I believe Nakamura is one of the major researchers involved in that process with the Japanese FDA equivalent. I don't even know what that organization is called.

DR. WINN-DEEN: The Japanese Health Ministry.

DR. LEONARD: But like with the biobanks, that we heard from other people doing this, it might be interesting. I don't know if there are other ethnic groups or populations where this sort of thing is being done, but at least in Japan it is.

Then the second thing is with the FDA presentation, there was information that several submissions of pharmacogenetic information have been done. Are you willing to share what the FDA is learning from that process, and when? Because one of the things is, with drugs in development, Cindy, you were saying is there an FDA requirement for the pharmacogenetics. I think that's where FDA is moving. So can you give us an idea of what you're learning and what your timeline is to be thinking about making this part of the FDA approval process rather than a friendly submission of information? I don't know that you have to do it now, but maybe that's something that could be done in the future.

DR. FRUEH: I'd be happy to present you all these answers. Actually, I just put a presentation together for that very reason, because it's now one year since we started to get these submissions, and we have learned quite a bit. We're certainly not at the point where we're going to move it into a required type of submission, simply because the data is too complex and we need to make sure

we create the appropriate policies and guidelines for that. But we are moving in that direction, that's no doubt. I'm happy to share at any point what we have learned and what we are doing with that information as you deem it appropriate.

DR. LEONARD: Because maybe that would be useful to hear about next time. Maybe drugs in development, there's a process in place that will move in the right direction for drugs in development through the FDA. We may be able to say move it along faster or get more resources if you need more resources, or whatever. But I think one of the major issues is with the existing drugs and with the book that was shown by Dick. It's not a small task for the existing drugs.

DR. WINN-DEEN: I personally am still struggling with what do you really have to do to get something in a drug label. I'll probably keep asking you guys that question because it's not really clear to me still.

DR. LEONARD: It's not clear to me, either. I think that that's a very important thing to be clarified. If death doesn't do it, I'm not sure what does.

DR. WINN-DEEN: Tim?

MR. LESHAN: One quick addition. You might also want to talk with the Personalized Medical Coalition and get their perspective on some of these issues, as they're grappling with all the policy issues as they relate to personalized medicine.

DR. WINN-DEEN: One thing that was brought up to me during the break is that there apparently are differing standards for informed consent and what you're allowed to do with bank samples if you're a government agency versus if you're a private entity trying to do basically exactly the same research but under a different hat. Is there someone we can get from the human protection group that can clarify that for us, what's going on, why there's a double standard, if there is a double standard?

MS. CARR: Can you clarify? Where did you hear that there's this double standard? Did somebody say that today?

DR. WINN-DEEN: Yes.

MS. CARR: Who said that?

DR. WINN-DEEN: So you're volunteering. Do you want to come up and just make your comment to the committee, express your concern?

MR. YOCHER: Yes. The government agencies, which are going to actually have a workshop on biobanks next week, participate under a different set of regulations, 45 CFR Part 46. Industry has to operate under a different set, 21 CFR, Parts 50 and 56. Where trusted third parties are used to hold the keys to trace back to source documents, that system is allowed in the government. What's happened in industry is a part of FDA, called the Bio Research Monitoring Group, has said this is not allowed because they reserve the right to go back to the source documents, and without having to go through a trusted third party.

This has been an issue for quite some time, and we think since we're trying to do public and private consortiums working together on pharmacogenomics, we can't have two standards.

MS. CARR: Thank you for clarifying that. I now understand what you're talking about. I thought you were talking about a different standard for government agencies, but what you're referring to is the different set of regulations that govern HHS-funded research. It's true that the common rule and FDA regulations do have a different approach to research involving human tissues, and even the definition of a human subject is different, the allowance for a waiver of consent is different, and actually NIH, through its program, the Clinical Research Policy, Analysis, and Coordination Program, an initiative of the NIH Roadmap, is actually very interested in this problem.

We've talked with FDA. Joe Hackett's colleagues in his center I think are certainly looking at this issue, and I don't know if Joe can speak to it any further, but I think there is a consciousness at FDA of the fact that they have a different approach is an issue, and it's certainly a concern for NIH.

If you're referring to the workshop that NCI is sponsoring, I'm sure that will be an issue. I know there's also a group -- PRIMER has a tissue working group that's very concerned about this, too, and also may be making some recommendations about it as well.

MR. YOCHER: Thank you.

DR. WINN-DEEN: It certainly seems to me that if we're going to talk about doing public/private partnerships, that we have to be able to operate under one set of ground rules where all agencies are accepting of a set of ground rules that works for everyone. So I would like to see us talk about that a little bit more and see if in our role as an advisor to the Secretary there's anything that can be done to mediate normalization of things between agencies within HHS.

Other comments and concerns? Kevin.

DR. FITZGERALD: Just one other thing, and we can talk about it again in the task force, but it's something that kept coming up, and somewhat tangentially, during the various presentations is this idea of benefit and the therapeutic things that are going to be done, the clinical usefulness, that sort of stuff. At the end, one of the reasons I asked the question of the ethics presentation -- and her answer was you've got to get good language. That reminds me of the thing we face today, even, say, in Phase I clinical trials, where you have wonderful informed consent forms, and yet the patients still walk away certain that this is going to benefit them in some therapeutic way, in spite of the fact that this is a Phase I trial. It's called therapeutic misconception.

My fear is there's going to be a huge therapeutic misconception surrounding this sort of technology and it's going to be very difficult to get really good understanding out in the public. Some people who are very good at that sort of thing are some of the sociologists who have been starting to study this thing about risk awareness and different ways of conceptualizing risk and all that sort of thing. So that might be another area we might want to look at.

DR. WINN-DEEN: So you're talking about sort of the public perceptions of risk/benefit?

DR. FITZGERALD: Well, it's a little more complicated than just public perceptions. Different groups have different filters, different heuristic structures, different ways they interpret the very same words and the very same data and the very same material. How does one, then, address that sort of situation? It's one I'm sure the genetic counselors see all the time when people come in and they have to deal with this constantly. But it's also something a lot of sociologists have begun to look at in a more systematic way.

DR. WINN-DEEN: Agnes?

MS. MASNY: This comment relates not so much to a gap but just something for the task force to keep in mind. If we're going to be putting a document together or resolutions, whatever, that we include a section about the education for health professionals in this area. That was brought up many, many times for physicians, pharmacologists, nurses, other health care providers. I think it would just be something the task force has to make note of.

DR. WINN-DEEN: Yes, I actually made note of that in a larger context, because I think we heard from several people that education is not sufficient to create clinical implementation, and I would like to really explore what's going on with the clinical implementation piece both for things that already exist, whether there's a good body of evidence, what is really happening that's keeping that from happening, as well as is there some mechanism that we could propose going forward for best practices. When you get to the point where you have all the evidence, how do you turn evidence into implementation for better health care, and what are the steps you have to go through on that implementation side?

So I think most of the work that's been done to date has focused on how do you get to the evidence, and we've seen a couple of examples where even with evidence, we're not seeing full uptake. I think Eric Lai's little chart, where he compared HER2 and Herceptin with TPMT testing with 2D6 testing, all of which are "valid biomarkers" where we know what they mean, we're still seeing this variation in uptake, and we need to understand that a little better.

Deb?

DR. LEONARD: Just several points, two quick ones and then a question, I think for Tim.

We heard several times also today about gene patents and the impact that this was going to have on restricting the development of broader pharmacogenetic testing, and I know we're dealing with gene patents separately, but maybe we can remember this as we're hearing the report of the NAS task force that's going to have a report coming out this July, that hopefully we will get before our next meeting.

One point --

DR. WINN-DEEN: Can I just say something on that? Sarah, or whoever is going to be organizing this, since we're going to be having some kind of a report on that report, I assume, before the next meeting, can we ask whoever is doing that to talk about it both in the general as well as in the pharmacogenetics context?

Sorry. Go ahead with your other point.

DR. LEONARD: That's okay.

The second point is that one statement kind of struck me, which is that when there's FDA approval, then CMS should pay. We just finished a coverage and reimbursement document, and I don't know that that's in there anywhere, but it did seem like a logical connection between the two agencies. I don't know whether it exists. Don't worry, staff, we're not going to go changing the coverage and reimbursement document. But it was something to think about, I think, in the context of coverage and reimbursement and pharmacogenetics.

My third question is really in the model of the NCI cancer -- they're not core facilities, but they're basically resource facilities that are set up to help with certain types of cancer analyses that are done across many different kinds of research. What would it take to have the same sort of resource developed to support pharmacogenetic analysis of patients from clinical trials in a more centralized way? It could come out of the Pharmacogenetics Research Network. In fact, Dick said that they had applied for this and it wasn't funded. But it seems like that would be something, since they already have data analysis and statistical analysis and many resources within that network, that if there could be a type of laboratory created -- and I don't know what mechanisms would be needed, but could you speak to that a little bit, Tim?

MR. LESHAN: I'm not sure I can speak very specifically to that. We provide a lot of the basic resources for genomics research through bioinformatics research that we fund and that we do intramurally in our institute, as well as just the power of the convener on these kinds of things and having workshops to try to provide the basic kind of information for people so they can better understand these things. But I think it would require a proposal of someone to present to our institute as to how they think we should propose providing those resources. I think it's something we would definitely consider, but I don't think I know the best mechanism at this point. There may be others, Rochelle or whoever.

DR. WINN-DEEN: Hunt?

DR. WILLARD: Just to clarify, there are such cores that are out there. NHLBI supports major sequencing cores, which were mentioned in Rochelle's talk, where people can submit projects for gene resequencing, and pharmacogenetics would certainly fall under that. To me, it's not a core resource issue. Genotyping is dirt cheap and can be done in a thousand-plus cores and facilities around the country. So I don't think it's access to technology that's holding up any of these studies. It's a conceptual block to pulling together the large studies at the translational end, but getting the data out of labs I don't think is a major road block.

DR. WINN-DEEN: Sandra?

DR. LEONARD: I disagree.

Oh, I'm sorry. Go ahead.

DR. HOWARD: On the point that you had made earlier, I think you might want to hear from CMS themselves about the effect of FDA approval on their reimbursement policies. As you know, they have responsibility for the elderly and disabled population, and there's recently been a drug benefit added. You might want to hear from them about how these technologies may then impact their responsibilities toward these populations, and also their responsibilities in the area of cost containment, because they do have some responsibilities in that area. They don't address the totality of the population, but I know that insurers, that payers in general kind of look to them to see what decisions they've made about that in the populations that they address.

But they also have the other program, Medicaid, in partnership with the states. They don't make coverage determinations the same way, but certainly these technologies are going to impact upon those populations. So you might want to hear from them as well on that.

DR. WINN-DEEN: Deb, did you have a follow-up to your previous comment, or something new?

DR. LEONARD: I disagree, Hunt, because I think that a general sequencing facility or genotyping facility isn't going to have the pharmacogenetic information and pharmacologic information to say to an investigator who wants to investigate different responses to asthma drugs or antidepressants or whatever, you might want to look at these or help with designing what genotyping or resequencing you would choose to do, because I think many of these projects may come out of clinicians who don't have the genetics knowledge and the genomics knowledge, the statistical information, the bioinformatics information.

So to have a more focused pharmacogenetics type of core, rather than the generic sequencing kind of core, might facilitate this research.

DR. WILLARD: Then we're disagreeing only on what to call it, because to me, then, it ceases to be a core if you're really wanting it to be driven intellectually and conceptually by this core where physicians and clinicians around the country might be able to offer cohorts of patients, and from that would derive pharmacogenetics conclusions and data. So to me, that's different from a "core," but whatever we call it, then I might agree there's a need for such a thing.

DR. WINN-DEEN: I think a lot of the pharmGKB labs actually had a component where they both collected clinical samples that were well characterized as well as had to provide a mechanism for doing whatever resequencing or genotyping needed to be done on those. So I think within the individual awardees of those grants, there is that expertise, and it's a mixed expertise. So you've got clinicians as well as the high-throughput genotyping and sequencing support team to know how to sequence.

DR. LEONARD: But in talking with Dick afterwards, he was saying he had made a proposal for this type of thing that could integrate with various clinical trials that would be ongoing so that you could evaluate the specimens pharmacogenetically and use the resources within the Pharmacogenetics Research Network, and that was not funded.

DR. WINN-DEEN: Okay, I'm going to let Julio talk because he's in this network, and he also has a question. So you get the floor on both counts right now.

DR. LICINIO: The thing is that what you're referring to -- and I don't know if Dick is still here, but the network that was put together, it's not that it was not funded. It was part of a roadmap RFA for translational centers, and the whole RFA was canceled. So it's not that it was not funded as a specific project. The whole initiative kind of disappeared.

But I actually just very recently, a couple of weeks ago, wrote an editorial about this, because I think the point which you're bringing up, which is very important, we should consider maybe now or in future meetings. I think this field, having worked in it for a while, if you look at it very carefully, there are some people who do outstanding work on both sides, and I'm not talking about those. But where you see the biggest deficiencies are these people who work on the genetic side and have more of a genetic background.

The clinical material they just call samples. So as an example, years back I was asked to consult in order to do a collaboration with a company, and they asked me to calculate the cost of doing a pharmacogenetics trial that would result in blood samples that should be analyzed. They said the cost per sample is too high. If you do genetics research, I can go out there and get 1,000 schizophrenic patients for a study. I can get the samples in one day. Just go to a few large state hospitals and you can collect 1,000 people in a day.

But you cannot, for pharmacogenetics -- you have to screen the people, and then treat them and observe the results of treatment in a controlled way, which is extremely expensive. The people who do the genetics side, they don't understand the clinical issues, they don't appreciate the clinical issues, and they don't accept the cost, which is extremely high.

So you often see -- as the editor of two journals, I see this all the time. You see very sophisticated genetics on clinical samples that are of very questionable value. So in my own PharmGKB study, to get the first 120 patients into my study, I had to screen 2,111 people, because if you're studying the pharmacogenetics of a drug, ideally the person should have that disease and nothing else and be taking that drug and nothing else. So if you're studying the pharmacogenetics of an antidepressant, you don't want a depressed person who is also diabetic and taking insulin at the same time, because if they change, you don't know what's changing.

Out there in the real world, when you talk about the common and complex diseases, it's very rare to find a person who has that disease, only that disease, nothing else, and is willing to take that one drug and nothing else, does not have back pain, is not taking a ton of natural supplements, is not taking this and that thing. So the geneticists, they fail on that side.

The clinicians, they fail on the side of -- some of them who have more clinical backgrounds, they collect very good samples and they have very good trials with samples collected, and they don't know the first thing about the genetics, and that's maybe where this thing could be helpful. Then they just test a few polymorphisms here and there. They do things that don't have enough power. They do a lot of tests in a sample that's insufficient.

So what I see often are people coming from the clinical side, the pharmacologist side, without a knowledge of genetics, and people coming from the genetics side without the knowledge of the pharmacology. So maybe some type of interface between -- the Pharmacogenetics Network is wonderful, but it is relatively circumscribed to those people who are in the network. But the (inaudible) doesn't really at this point -- I know it's a goal for the future -- it doesn't reach to the clinician out there or the clinical researcher out there, and a lot of geneticists are not in the network. The network is not driven by geneticists.

So it should be important maybe for this panel to try to kind of bring those two communities together through a core facility, through some type of mechanism to integrate these two sides, because that's where the divorce happens.

DR. WINN-DEEN: Thanks. I think that's a really great idea, and we'll try and see if we can figure out a way to make some kind of task force recommendation.

Hunt, and then Alan.

DR. WILLARD: One point on that, and then another one following up on Pat Deverka's talk. I think Dr. Davis this morning made a very rational and impassioned plea to figure out how to do translational pharmacogenomics that is linked somehow to health outcomes. That is, as Julio points out, a very different kind of science that people who are trying to do the basic science in a laboratory, and it may be that these networks, which are valuable certainly for one area of science, don't necessarily completely bridge that gap, and the task force may want to look more closely at the mechanisms that would specifically lead to addressing not the basic science but, assume the basic science is there, how do you then take those discoveries and that knowledge base and push that through with a series of studies that would deal not only with clinical analysis but the pharmacoeconomics, the health system design and financing, et cetera, because there are a

whole number of different avenues that would need to come into play in order for there to be "success" and adoption of this or any other technological advance in the practice of medicine.

The other two things that I jotted down during Pat Deverka's talk that the task force might want to look at, which I'm not sure we or other groups have taken up, at least fully -- one was the issue of genetic exceptionalism again. This we dealt with two years ago, I believe, but it comes back up specifically in this context that I think is very relevant as she presented the issue of pharmacogenomics. I mean, is this really a truly new beast that everyone is going to have to figure out a way to deal with, or is there a way to slip this into existing paradigms, regulatory or otherwise? That seems to me is a reasonable task force question.

The other one is race and genomics and a follow-up related to whatever is happening today with the BiDil advisory committee meeting, but there may be other examples as well. There certainly will be other examples coming down the pike, and to address that from the standpoint of are there gaps in knowledge and what would the Secretary need to know about those issues where we might be able to be of some help.

DR. WINN-DEEN: Do you think it would be useful to hear a short synopsis of what actually happened today, whichever way it goes?

DR. WILLARD: That probably depends on what actually happened today.

DR. WINN-DEEN: Well, I mean whether it was approved or not approved, is there a lesson to be learned there? I mean as a potential topic for the October updates.

DR. WILLARD: Let the task force do what the task force will do. I think it depends on what happened today, what was recommended, and what other kinds of examples may well come along. I'm sure there will be plenty of opinions on whatever they did.

DR. WINN-DEEN: Alan?

DR. GUTTMACHER: Yes, thanks. I just wanted to rejoin the discussion that Debra and Julio and Hunt and some others were having, just to sort of state the obvious. The example of pharmacogenomics in this area of interdisciplinary research is a very edifying one but far from a unique one. It really crystallizes, I think, what is the challenge to the NIH, and not just to NIH but to academia, to private industry, et cetera, to think about how we do research in an era when nobody has the degree of knowledge in enough areas to be able to do the research anymore.

I think the PharmGKB network was a wonderful example of how to move into that area. It's not sufficient to do all of pharmacogenomics, and certainly NIH continues to deal with this, realizes it's a very fluid area and needs to come up with new models for doing it, but it's not just the funders that need to do it. It's not just the NIH among the funders. It's all the funders, but it's not just the funders. It also challenges academic institutions, and many are obviously trying to do this, how you come up with ways of putting this together.

It's further a challenge and perhaps an opportunity in this area since obviously this gets to an area of translational research where there are private industries that are interested in the knowledge gained here and how one creates interfaces with private industry as well. It's obviously interested in this kind of information. There are no, I think, easy answers to this, but everyone involved recognizes the fact that they don't have the answers yet. So any advice the committee could offer

-- I wouldn't just look at the funders. I'd look at them, but I'd look at other kinds of changes we might make in the way we approach these things.

DR. WINN-DEEN: Right. So I think part of our focus on funders might have to do with our charge to deal with HHS and not stray too much from our mandate to be a group that makes recommendations to the Secretary. But we certainly could talk about how HHS agencies can do outreach and work jointly with non-HHS entities, whether they're public or private, to move forward.

Other commentary? I think the task force has plenty of meat. We'll do our best to put together a program that's organized.

Sarah has some comments.

MS. CARR: Actually, it's more of a question. Does the committee want to talk or give any further guidance to the task force about the long-range goal here? It sounds like you're not ready to begin writing any kind of report. You're still exploring and needing to put together additional presentations and fact-finding for the October meeting but not ready to think about the product that will come out of all of this yet.

DR. WINN-DEEN: Well, I'm hoping that we will come out with some recommendations, but I'm not sure if we'll come out with a big book like Coverage and Reimbursement that within it has embedded recommendations, or whether the work product will be more like our letters to the Secretary on education and discrimination that just points out some specific things. I think this subject is so complex in many ways that you may have to have some white paper, at least, that frames the issue and then talks about the specific recommendations.

MS. CARR: Well, would the committee like to give the task force the latitude to think about what form -- I guess that's inherent in this, but I think it would be good for the task force to think about that early on.

DR. WINN-DEEN: Is there anybody that has any objection to an open thought process at this point for how we might convey whatever recommendations?

(No response.)

DR. WINN-DEEN: Okay, good. I'm seeing everybody in agreement that we can have some latitude.

Agnes?

MS. MASNY: When you mentioned about the white paper, one of the speakers, and I can't remember which one, had mentioned that there were four white papers that were published in this area.

DR. WINN-DEEN: Rochelle Long, NIGMS.

MS. MASNY: It would be very helpful if those could be made available to the committee.

DR. WINN-DEEN: We'll get hold of those when they come, as they come.

I want to thank everybody who participated in this session from the speaking side, and all the people on the task force who participated in getting us this far, in particular Fay Shamanski, who did all the work of organizing everybody to actually be here and put the program together. I certainly appreciate having everybody's help and believe in the Shaker saying of many hands make light work. It really does make a difference to have a lot of people participating. We thank all of you for your participation and look forward to additional input and discussion.

Did you have one more thing for the task force before we close this part?

MS. CARR: Actually, no. I was more responding to Debra. The translational research centers' RFA or PA that was canceled, I think they had a meeting a couple of weeks ago to think about what to do instead of that, I think. So we could hear from them. That could be something else you might want to do, and maybe the NIH Roadmap in general might be something that might be of use to hear about, if only for the task force or the full committee maybe.

DR. WINN-DEEN: Okay. I'm turning it back over to Hunt for the next steps and closing remarks.