

**Discussion of Next Steps, Work Plan, and Final Work Product for Pharmacogenomics**  
*Facilitators: Emily S. Winn-Deen, Ph.D. and Cynthia E. Berry, J.D.*

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DR. WINN-DEEN: What I'd like to do now is actually ask people to turn to Tab 5 of their books, because we don't have slides, and I think it actually is useful to just look this over a little bit.

At Tab 5, we have a couple of things that we had identified. One was a list of key issues as summed up the basis of discussion at the June meeting. What follows that is then a proposal for an outline of a potential SACGHS report on pharmacogenomics.

I'd like to have a little bit of committee feedback on whether this is something that if you look at the scope of this potential report, it is a report that's going to be a nontrivial task to write, even with some help.

So I would like to know before we ask the staff to start such a thing, that this would be something that we feel would be useful. I'd particularly like to hear not just from the committee, but also from some of the ex officios about whether it would be useful to you in your own organizations to have some kind of internally written HHS report on sort of the state of the state right now in terms of what pharmacogenomics is and what are the issues, and what are various agencies doing about it already? Where are we in good shape, and then of course our task is always to identify places where we want to make recommendations primarily about where we see gaps, although I think it is useful for us to also commend good work when we see it and point out to the Secretary not just the things that are going wrong, but also the things that we feel are going right within the organization.

So are there any comments? I know this is a very extensive outline, and we could go through it line by line, but I'd like to get just some sense of whether the group as a whole feels there is value in going through the effort of doing a report.

DR. LICINIO: I have a couple of specific comments, but you don't want them right now, right? You just want to get the general idea of whether we should do this?

DR. WINN-DEEN: What I'd like to do is if we think it's a generally good idea, then we should go through and make some specific comments about things that are either missing or need more work, particularly if there are areas that we could highlight where we think we might want to make a recommendation, even if we haven't totally formulated that recommendation. It would be I think helpful to staff to know that this is a point where we want to say something, and then the task force can go back and do some work.

DR. LICINIO: I think it's a wonderful idea, and I think it's particularly relevant. Because what I have, and I may be wrong, but I don't think I am, within agencies, let's say within NIH, for example, there are institutes like NIGMS and people like Rochelle Long who are very supportive.

There are other institutes who don't see it as a big priority. It is like very uneven. So even within specific agencies, there is like, you know, some people think it's very valuable, and others don't think and it should maybe be investing in something else and not even understanding it very well.

So I think that to give like kind of a department wide like recommendation, or like at least kind of a consensus or review I think would be very useful.

DR. WINN-DEEN: Alan?

DR. GUTTMACHER: So I'm not sure that it will level the playing field of the NIH exactly. If anybody has any ways of doing that in general, I'd love to hear about them. But I do think, speaking for the NIH, first of all, I think it generally looks very good.

Second of all, I think it's useful simply as a summary of where things stand and where they ought to be, and third of all, I think the idea of including some specific recommendations to the Secretary is also useful. So generally it looks great. Yes, it would be useful to us as an agency, and specific recommendations from the Secretary would also be helpful.

DR. WINN-DEEN: Any other agencies that have pros or cons that they'd like to chime in on?

DR. KHOURY: I don't have any pros and cons, but I think as we think about pharmacogenomics and sort of the public health implications of that, it is very important to cover the whole spectrum from the bench to the trench, as somebody said yesterday.

When I think about CDC and some of the other public health agencies, you know, drugs, pharmacology in general, drugs in general don't have really a public health home in the sense that diseases have, like infectious outbreaks and things like that.

Drugs, medical errors, and drug adverse effects. I mean, with the exception of adverse immunization events, because immunization is sort of a public health activity, but drugs have a much more far reaching implication as far as the health of populations and access issues and some of the ELSI things that we heard from Wylie.

So I would hope the committee will sort of take the whole landscape from the NIH research agenda in how to incorporate pharmacogenomics with the right kind of research, all the way to the integration of evidence, a la EGAPP and some of the other processes, to cover some of the FDA issues. Then on the services side, HRSA.

So just look at the whole department. I basically don't see where, you've summarized what we all do. I don't see it here, and maybe I'm missing a page. Do we have some kind of a table that says what the feds are currently doing?

DR. SHAMANSKI: We're working on that.

DR. WINN-DEEN: There is, in Tab 5 behind the outline of the potential report, a one-page thing called Agency Feedback and Pharmacogenomics Policy Priorities. So this was the first level of feedback that we got.

We are still trying to put together a more comprehensive table, but this at least gives you some idea. It is pretty clear that the responding agencies are the ones that have the biggest stake here, but I don't want in any way to have the non-responding agencies unrepresented as we go forward. These are just the ones who chose to respond to our request for what is going on.

Go ahead.

DR. SHAMANSKI: I was just going to note that this first document was, as it says, the issues that the agency thought were most important. The subsequent work we're looking at is on the activities that are actually going on. So it's a slightly different focus of these two documents that

we're putting together. So the one that's in progress now is really focused on the activities. That's the one that we can use to look at gaps, overlap, and what is actually happening. This is more what we think should be happening.

DR. WINN-DEEN: Suzanne?

DR. FEETHAM: Speaking from the perspective of HRSA, I would reinforce what Muin was saying. I put it in the context as of yesterday where we really had the shift from the biological research to the broader context of the public's health.

I think, again, if this report can be done in that same way of looking at pharmacogenomics across all of these issues, the point of it is to inform where we need to go for the public's health. I think it will do the same kind of advantage of our discussion yesterday on the large population studies

Again, our focus is on the underserved populations. Every lens through here needs to be the basic point of access to care in all of these products.

DR. WINN-DEEN: So since we didn't do the Reed Tuckson table, we didn't get a chance to reiterate that there are certain overarching subjects, of which access is one, that inform and are important for basically all of these subtopics, so I think to your point, those things need to be considered throughout any document that we would consider writing.

So I'm going to ask then if people have any specific comments on the outline that they want to make now, and also to invite, if you don't have any specific comments because you really just need to think about it a little bit more, that you use Fay as a central conveyance point to send any additional thoughts you have after we leave here today.

James, and then Joseph.

DR. EVANS: One of the things I think is very important to have explicit in the report in the outline is the issue of real demonstration in a prospective way of efficacy, whether you define that in purely medical terms, which is important, or also whether you include financial issues, which I think are important, too, as we heard today.

So, for example, under 2B, factors influencing uptake, I would think the very first thing there, if not as a separate subheading completely, but the very first thing should be demonstration of advocacy. It is what really will drive all of those other things, at least in the long term.

PARTICIPANT: (Inaudible.)

DR. EVANS: Well, in a way. But again, I think it should be highlighted much more importantly, and I think that under improved health status also would be outcomes with regard to financial issues, which would drive payers.

We just simply don't know if those things are going to pan out in the broad canvas, although we certainly hope they will.

DR. WINN-DEEN: Joseph?

DR. TELFAIR: Just on the side, I would agree with James on that issue. But on the other issue related to this, one of the things, and this is really not an area for me as everybody else's, but my

concern has to do with we are going to put together a document that has recommendations to be able to tackle some of the bigger issues.

It seems to me that one big issue is, again, the infrastructure issue that I brought up a little bit earlier where you are taking on the topic providing some means by which a real good understanding of issues like admixture, a lot of things like the way that we think about the populations that are involved.

Something to the effect of what kind of regulations can be made that then allows us to best look at that population, research that population, or even look at ways that policy needs to be changed to better service that population. The focus would not be just on health care providers, but also decision makers in the process.

DR. WINN-DEEN: So let me just ask you a clarifying question.

DR. TELFAIR: I know it's rambling.

DR. WINN-DEEN: No, no, it's not rambling at all. I think what I'd like to understand is currently there is some guidance when you set up a clinical trial that you should try and balance it by age and gender and sort of racial whatever that reflects the population you're planning to treat. Do you think we need to think about making some changes in the way FDA guides companies to set up that kind of diversity in a clinical trial situation? I'm just trying to get a little more granular on where you think we should be focusing that issue.

DR. TELFAIR: Well, I would say yes to that with the caveat that those who understand the functionality of clinical trials look at that recommendation closely.

I would suspect that given in ways that I have participated in recruitment and other things related to clinical trials, it seems to me that more attention needed to be paid to that aspect of it than what it usually does to begin to be able to focus a little bit more on how populations are selected, what gets population involvement, participation in clinical trials, you know, the kinds of more sort of basic, fundamental things that you do to achieve sample size, to achieve the integration, and those things that you are expected to have.

But I think those who are much more familiar with that should look at that. That's what I would recommend at a ground level, because that's what my involvement has been. But also in other research I would suggest the same thing, that also somehow or another there should be a criteria that requires that you look more closely at the population than just representation, not being a face representation, but another also representation of the population.

You can have, for example, African American groups that you're involved in, but you know evidence is, like we just saw today, the heterogeneity within that group. Paying attention to that heterogeneity is something that you really should be paying attention to, which doesn't always happen. It should be something that I think also needs to be evidenced in any kind of application that you have, that you recognize that for what it is.

Not everyone does that. I think that was some uniform way that we can make a recommendation that that is done, yes, that's the direction that I'm kind of moving in.

DR. WINN-DEEN: Kevin was next.

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DR. FITZGERALD: We can put this in the recommendations, too, because I think it addresses a variety of the points, particularly the ethical/legal/social area.

But from what we have heard yesterday and even this morning on the genetic discrimination survey, I think we could put in there that we'd begin public engagement now on this issue. Why wait? It doesn't have to be on the same size or scale as we're talking about the large population studies, because that's, you know, the impetus for that is a little bit different.

But still, I think some of the response to the survey data earlier today on genetic discrimination, people are saying this is the kind of data we want to have so we can put things into the bigger context. I think we could start on this, too, the same sort of thing.

Again, something that we don't have to necessarily look into, the Secretary can have someone look into. How should it start?

DR. WINN-DEEN: Right. I mean, it's not like we would lay that whole public engagement process out, but I think we can definitely get to a point where we say there needs to be a --

DR. FITZGERALD: Something has got to start now.

DR. WINN-DEEN: There needs to be a process, and whether it's related to, you know, sort of an early alert system from FDA that something is coming that might want to have an education of the public component to it.

DR. FITZGERALD: Right. But I'm thinking even beyond that, what we've heard say with certain interactions with Native American groups, and other groups. Again, not necessarily groups that are categorized by even traditional sort of categories as "minority" or "racial," but start this broad public engagement now to even perhaps recognize for the first time that there are other sorts of delineations of which we are not yet aware that we wouldn't become aware of until of course we trip over them for some reason or another.

DR. WINN-DEEN: So you're talking about maybe not so much a pharmacogenomics thing, but an education on, you know, race is not race kind of thing?

DR. FITZGERALD: Again, it is pharmacogenomics in a sense, because again, what we're talking about, you keep listening to what our targets are. We are always talking about the public health and the benefits to the public health.

Well, what is public health except what the public thinks about it's health. I mean, why are we always dictating to the public what health is? I'm sure there were many of the researchers who were just shocked to find out that some small tribe in the Grand Canyon wasn't interested in finding out where they came from. I'm sure they were stunned to find that out. Who wouldn't want to know? Right? That's the kind of conceptual thing we can at least --

DR. WINN-DEEN: That's the difference between being an immigrant who wants to know where you came from and a native population who already knows where they came from.

DR. FITZGERALD: They want to know where we came from, right?

DR. WINN-DEEN: And why.

DR. FITZGERALD: And how do we get home?

DR. WINN-DEEN: Julio?

DR. LICINIO: There is an item at the last page about the issue of race what Wylie has just discussed. There is something that could be subsumed there, or it could also be its own separate issue, which is that if you study a group, like if you study a group because of its ethnic capacity and characteristics, in other words, if you recruit somebody not because they are hypertensive, but because they are hypertensive and Chinese, then NIH has been strongly recommended to do community consultation as well, and I think the issues of community engagement at least.

So I think that there could be like a subitem there, like community engagement just immediately after that one, because I think one would lead to the other. But just like studying people, like discussing the pros and cons of studying different groups without saying what you need to do once you study them, I think would be like a gap there.

DR. WINN-DEEN: Steve's making faces like he has something to say.

DR. GUTMAN: Yes, I do. I actually think this would be a fascinating report. It would be a panoply of activities, a mosaic that would be very hard to put together, but it would be a wonderful report.

I have no particular interest in any subject that would be in the report, but I have a great interest in if you were to step back and ask the question as you put this together and it plays off of what Alan said, getting different parts of NIH to be on the same wavelength is challenging. Certainly getting different parts of FDA is hard as we work with drugs and with biologics is challenging.

Of course getting FDA and CMS or FDA and CDC to work together becomes even more challenging. So I think it would be interesting to step back and actually ask. There's a lot of passion, there's probably not enough money, but there is a lot of intellectual capital being thrown at genomics probably in almost every nook and cranny of the Department.

The question I would have is is there some mechanism for better integrating, synthesizing, or coordinating that activity, prioritizing that activity in making sure to define public health? It does seem to be aimed in the right direction.

As I recall, one of the swan song refrains from SACGT was this outrageous suggestion Reed put on the table. I believe it was Reed, that what the Department really needed was the equivalent to a drug czar for genetics. Maybe what the Department really needs is an equivalent, and maybe that's just delusional to think that's possible, but maybe it wouldn't be impossible to have a drug czar for pharmacogenomics to have someone at some higher level, at Mr. Leavitt's level, one of his deputies' level, who actually mapped out for the Department as a whole what it was doing, what it should be doing, where it was going. At least put that question somewhere.

Maybe it's just dumb. I mean, it's called truly impossible, or it is scientifically and financially unnecessary.

DR. WINN-DEEN: Well, you know, all suggestions are welcome at this point. I think what we'd like to do is probably, and I'm sort of speaking for staff at this point, but to try and ask the staff to go ahead and do some of the things that are outlined here.

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We do have the offer of assistance, I forget which, yes. So we are not going to be doing this alone. So I'll recognize you in just one second. So I just want to make sure that we all think, just sort of nods of heads, that this is worth the task force continuing to work. We are interested in your feedback, please. Can you introduce yourself?

DR. RANDHAWA: Certainly. I'm sorry. I'm Gurveet Randhawa. I'm subbing for Francis Chesley. He's my colleague. This is a report which is pretty near and dear to my heart.

I wanted to just discuss two points that I think may be useful, at least from our perspective. One is as I was quickly leafing through the proposed outline, and I didn't really see the two that are nearest and dearest to our hearts, outcomes research.

DR. WINN-DEEN: We'll write those words down. No problem.

PARTICIPANT: DNA.

DR. RANDHAWA: DNA.

DR. WINN-DEEN: He's right, it's there.

DR. RANDHAWA: Just to expand on that for two issues. One is I heard additional demonstration of efficacy. The outcomes when you talk about efficacy are usually the outcomes you talk about in effectiveness.

That actually is the biggest area that our agency is concerned with. So to the extent that we can focus on not only identifying more outcomes that are useful, but also distinguishing the efficacy from the effectiveness outcomes.

The second part that I was hoping the report would highlight is trying to distinguish near-term initiatives from long-term initiatives. So when you're talking about launching new multidisciplinary research projects, I think they are rather long term.

We already have existing initiatives of ongoing collection. All that's required is linking them better and using better and hopefully uniform standards of collecting information so that the clinical outcomes in an HMO research network capture the same kind of data as another hospital or organization.

Those are thorny issues to sort out when we're doing outcomes research. So I was hoping that would be a point of emphasis in the report.

DR. WINN-DEEN: Well, I think for sure a point of emphasis in the report is to have agencies which fall under the HHS umbrella work as well as they can among themselves. It's a little more difficult for us to recommend to the Secretary working with external agencies, but we can certainly point out that there are significant external stakeholders that need to be engaged, that this is not just an HHS issue, that it has to involve the significant stakeholders that are out there, corporate and, you know, from the insurance world, all the different ones.

Muin?

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DR. KHOURY: Just to add to what Gurvaneet just said, and if you look at Section 3D, number 3, which is under surveillance mechanisms needed, this is sort of the presentation you kind of heard from Bob Davis a couple of meetings earlier.

Under 3A, you have effectiveness. Maybe what we should do, and we can help you with drafting the report, is add to surveillance mechanisms needed, surveillance and outcomes research infrastructure needed. Because as part of let's say HMO research, networks and other kinds of similar activities, that's where you distinguish effectiveness from efficacy, sort of real world utilization.

DR. WINN-DEEN: Right. I think it helps to say the word "efficacy" by itself, and to say "cost effectiveness," which I think is what I mean when we say effectiveness. Is that what we're talking about?

DR. KHOURY: Not necessarily. I mean, you can look at effectiveness in the real world in the absence of cost.

DR. WINN-DEEN: Right.

DR. KHOURY: We're all subscribing to the economic model here. But suppose something works in a randomized clinical trial, would it include people all of the same, you know, race, ethnicity? And then you throw it out in the real world where you have three people come in with other preexisting conditions, and the efficacy or you think the efficacy of that drug may not lead to the same effectiveness in the population.

DR. WINN-DEEN: Okay. So you are talking about the translation from a small trial population to the general population?

DR. KHOURY: Yes. I think that is what Gurvaneet is referring to.

DR. WINN-DEEN: So this is, again, one of those things that the staff is sitting here writing madly because you're going to have all these definitions so that we all know what we're talking about, much as we had to do in the coverage and reimbursement report so that we could agree on terminology.

Do I have other comments that people would like to make at this time?

(No response.)

DR. WINN-DEEN: Because if not, we will be having a task force meeting between now and the next, in fact, we'll probably have a couple task force meetings between now and the next full committee meeting. I think the next full committee meeting is not until February or something.

PARTICIPANT: March.

DR. WINN-DEEN: End of March. Oh, well, we've got time for five or six committee meetings. Anyway, I think there's a lot to do if we're going to go ahead and do this. It is very helpful to the committee and to the task force in particular to have the help of as many brains and hands as we can get to make this happen.

DR. KHOURY: Emily? Am I on the task force? I don't remember.

DR. SHAMANSKI: Yes.

PARTICIPANT: You'll remember when the report starts to get formed.

DR. WINN-DEEN: On the 15th version of the report that you have to read and comprehend.

I think there were some other general committee business, but I think as far as I'm concerned, we've sort of beat this horse to death at this point. So I yield the floor to our acting chair.

MS. BERRY: For the final blow?

DR. WINN-DEEN: Yes. She's probably going to have us read another red line or something.

MS. BERRY: Okay. A 10-minute break.

(Recess.)

MS. BERRY: Let's finish up. What's up on the screen you don't have, we don't have. We're going to go through this together, though, and it's an attempt to summarize our deliberations and discussion over the past two days.

Of course the first issue that we tackled yesterday had to do with the large population research initiative resource. You can just take a brief moment or two to review. Does everybody have this now? Okay.

Just read it on the screen and see if that accurately summarizes yesterday's activities and the thinking for moving forward.

DR. FITZGERALD: In that first paragraph, sorry Sarah, back on the top paragraph, I understand that it could potentially fit under ethics, or even if one wants to talk methodologically, under scientific. But actually I think the public engagement panel could even be set up there separately. Because in a sense, it is something new. It has its own kind of methodology, it has its own sort of science to it. So we'd have scientific public engagement and ethics panels.

MS. BERRY: Joseph, did you have a comment?

DR. TELFAIR: I'm not sure what the first paragraph on the next page is going to say. But one of the things that we agreed to I think was that we would take into account the things that Kevin just mentioned by going back to the, if we could, go back to the reports, or presentations from those folks and include them in the conversation. I mean, in the deliberations.

If we need a subgroup or an ad hoc group, we'll be able to then take those recommendations and use those as part of the additional work of that task group. That's what we had agreed to. I'm not sure if that is exactly reflected in that, but I'm just expanding a little bit more on what is said in that paragraph.

It wasn't if needed, it was just that was something we said we would do. It was more definitive than that.

MS. BERRY: Is everyone in agreement that we are going to produce some sort of work product, some sort of report to the Secretary on the large population research project resource initiative?

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DR. TELFAIR: I thought we were yesterday.

MS. BERRY: Okay. So we're going to do that, and the task force that already exists is going to lead that charge, and it will include some additional outside members who will help in putting this together.

DR. TELFAIR: And the content, in addition to the additional content areas, will be those that are covered earlier around the research, ethics, and public engagement part.

MS. BERRY: The last item, the last paragraph here in this section, this goes to the request from NIH for a formal statement on our part with regard to the public engagement initiative. While not all of us were here at the bitter end, there was some discussion about whether that's within our purview, within our charge to do.

So it would be good to have everyone's input as to how far you think we should and can go. I think everybody felt that public engagement was critical and should proceed, but to what extent we can make a statement to that effect and to whom, I think that would be important to nail that down.

Kevin?

DR. FITZGERALD: I mean, I understand your concern, and I agree with it. So could we not interpret what Francis asked us as would we be against, or would we want to postpone or inhibit his looking into it for some reason now, before our report comes out.

We could just say no, we don't have to then have any charge or whatever in order to proactively tell them to do it, but we could certainly say that we responded in such a way to say we didn't see any problem with them going ahead and doing it, as far as interfering with anything we're trying to do. How's that?

MS. BERRY: Any other thoughts?

(No response.)

MS. BERRY: Sounds good.

DR. GUTTMACHER: My sense of it, again just sort of watching from across the Web, was it wasn't just efforts to engage support for the concept, it was to engage the public about its views of the concept. That is that the public, it's not a question of voting yes or no, but very much how the public thinks such a thing should be done, what kinds of questions it ought to be able to answer, what are the priorities, those kinds of things.

DR. FITZGERALD: Actually, that's right in the sense, too, that you don't presume their support.

DR. GUTTMACHER: Right.

DR. FITZGERALD: Right. Because they may not be.

DR. GUTTMACHER: And one would hope to find out what the opposition to it is.

MS. BERRY: Muin?

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DR. KHOURY: I guess I have no comment on this paragraph. But if you all remember, a lot of the discussion was about having the public health sort of voice at the convening function, both from health departments and other stakeholders.

So you don't want to inhibit NIH to do what it wants to do, which is engage the public. But if you want the maximum bang for the buck, I think these efforts should start early on involving the whole department.

I think that would be a good thing that would come out from this group, but you're not ready to say it now I guess until the final report. You don't want to inhibit Francis from doing what Francis does, but your recommendation will go out to the whole department.

MS. BERRY: Did you have a comment?

DR. HANS: I just was going to ask Sarah to get rid of the word "study" in the second bullet, just make it initiative or whatever it's going to be.

DR. KHOURY: Large population research initiative, LPRI.

MS. BERRY: Sylvia?

MS. AU: Maybe we should go back to Hunt's offer of doing that interim letter with the recommendation for the community consultations before the report comes out. The report's going to take awhile.

DR. KHOURY: But would you do it to advise NIH, or to advise HHS?

MS. AU: It would be advising the Secretary that HHS should, I think that was Hunt's offer. Well, Hunt's offer was to the NIH, but I'm sure that he would expand it to HHS. That would be a quicker document to come out than the report.

MS. BERRY: But are we ready to come up with recommendations in advance of completing the work?

MS. AU: I think it was just a letter supporting that discussions with the communities should begin as soon as possible. We're not telling them how to do it, we're not telling them who to ask. I think it was just that concept.

DR. EVANS: Would we need to do that?

DR. GUTTMACHER: Yes, I don't think we need that. I mean, you can believe we heard you, we heard you. We agree, and that makes sense to us. We're going to do it, even.

MS. BERRY: Any other comments on this section? Does this adequately summarize what our deliberations and conclusions were?

(No response.)

MS. BERRY: All right. Let's move onto gene patents. There is, as we know, an upcoming NAS report. It is due I think November 9th if my memory serves me correctly. Debra graciously agreed to lead a group, and we already have some volunteers, and there may be more to follow, to

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review the report when it comes out and advise us if there are any issues that the report raises that we should consider.

DR. WINN-DEEN: Are we going to only send that report out to the subgroup? Or are we going to send that out to everyone for their reading pleasure?

MS. CARR: Everyone.

MS. BERRY: I think everyone will have it, but the subgroup gets the extra duty.

DR. WINN-DEEN: That's fine. I would like that clear so that everybody's expectations are the same.

MS. BERRY: Right.

DR. WINN-DEEN: Since I'm on the subgroup, I get it either way.

PARTICIPANT: May I ask the question, is Sarah going to buy a copy for everybody?

DR. SHAMANSKI: I've already been in touch with the committee, and we'll get copies.

PARTICIPANT: I was just going to clarify that it has been delayed to November 17th the last I knew.

MS. BERRY: Hot off the press. Any other items to discuss on that section on gene patents?

(No response.)

MS. BERRY: Okay. Coverage and reimbursement. Not much to discuss there. It just summarizes the fact that we had some edits that were approved today by the committee, and the report will be finalized and sent to the Secretary.

Genetic discrimination. The first item, this was Agnes' idea, right? Am I remembering correctly? To transmit the findings to the Secretary.

The second bullet deals with the fact that there were some questions that we had as a committee that we thought might be useful the next time that they conduct their surveys.

Joseph?

DR. TELFAIR: The audience was going to be also the public, as well as providers. I don't know if that needs to be clarified, but I think we would have questions for both audiences that they are looking at.

MS. BERRY: Right.

Kevin?

DR. FITZGERALD: Shouldn't we also mention that we get an update on the legislation H.R. – I'm trying to find it here.

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MS. BERRY: 1227.

DR. FITZGERALD: 1227, right. Just so that we put that down.

MS. CARR: In the letter to the Secretary, you mean?

DR. FITZGERALD: No, this is just our notes, right?

MS. CARR: Yes. These are actions, next steps.

DR. FITZGERALD: Okay. I'm sorry.

MS. BERRY: Does anybody have any action items pertaining to the legislation? And we can't really -- I mean, we're constrained. Anything to add to this section on genetic discrimination?

(No response.)

MS. BERRY: Pharmacogenomics, our last section. I'll give everyone a minute or two to look at those bullets. Is everyone in agreement that a comprehensive report along the lines similar to the outline that was presented in our briefing books will be prepared? The task force will lead the charge.

The goal will be to have a draft ready for our next meeting, either March or possibly in June. Any other additions to that?

(No response.)

MS. BERRY: Hearing none, it's a wrap.