Review of Process and Outcome of Inter-Meeting Priority Setting Project and Presentation of 12 High Priority Issues

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DR. WINN-DEEN: Well, first I want to thank everybody who worked on the committee, and that includes all the people who provided input both from our SACGHS committee, the ex officios, and all the staff support that we got. It was really a group effort.

As Ed mentioned, these are the individuals from the main committee that participated, but we did have, when we sent out things for votes to the whole committee, everyone had a chance to vote and participate.

The goal of the task force was to conduct a systematic identification of issues that might be appropriate for this committee to address, with the goal of prioritizing some very specific issues that we could and should address; and then as a result of that to try and develop an agenda for this meeting, and that work product is the agenda you see before you.

It was a multi-step process. We first identified a number of issues, and this came from feedback that was obtained at the very formation of this committee on what issues were of interest to both the ex officios as well as the members. We then reviewed the top ten issues and assessed how to frame those as short phrases. Then we surveyed the members and asked them to pick their top three to five priority issues. So they got a list of 19 issues that were identified as potentially relevant to this committee's work, and then everyone was asked to vote on which they ranked as the top priority.

Then Sarah and her staff organized the results of that first vote based on the frequency, and 12 top issues emerged. Then the full committee went out and worked on that.

So again, we surveyed all the members and the ex officios to rank the top 12 issues, and that guided the development of the position papers or background paper I should say, issue briefs that you find in your binders. We also identified that coverage and reimbursement was a fairly highly ranked issue among both the ex officios and the members of the committee proper, and arranged to have this as one of the sort of deep issues on the agenda for today.

So we went through and tallied all the votes, and these votes were from the committee, and this is sort of the result. The top-ranking issue was large population studies and education and training. They both received a total of seven votes. Coverage and reimbursement and access received six votes each. Then the next group was patents and access, nature of genetic information, oversight and public awareness. Next came the vision statement, direct-to-consumer testing, and pharmacogenomics. And then at the bottom -- and these were the issues that we ultimately decided we would drop, with one exception -- were enhancement versus treatment, bioterrorism, new health-related applications, genetic discrimination, scope of genetic technologies, informed consent, forensics, privacy and confidentiality. The one that we kept on the agenda as sort of an ongoing issue that we're monitoring is genetic discrimination.

As I mentioned, 11 issues rose to the top, and the genetic issue was retained because we had already identified this at our very first meeting as an issue that we wanted to at least keep some vision on, make sure that things were happening to take care of that. So the bottom seven were

dropped and the rest went on to the next round.

In the next round we asked the committee and the ex officios to think about the following questions in terms of trying to prioritize these issues. How urgent is the issue? That is, is there some lurking thing that we have to act on right now? Does the issue warrant the committee's attention? Is it an important issue but maybe not really within our scope? Is there other media attention or some event that's happened that precipitated a need for us to react to that? Of course, does the government have jurisdiction and authority? Because it doesn't do us too much good to work on topics which Health and Human Services can't really take action on.

Then the other issues are is there actually already some activity in the federal government addressing this issue? Is the issue of a nature such that the best place to address it is through the government, or are there already other agencies and private sector mechanisms happening to take care of that? Are there any particular moral and ethical concerns that warrant government intervention or leadership on an issue? And then finally, it's the "so what" stuff. Will the committee's policy advice on the issue significantly benefit society, or will the failure to address cause some harm? Does there exist a sufficient body of data from which we can actually deliberate and make a recommendation?

So again, we surveyed the members and the ex officios, and there were some differences that emerged between what the members thought and what the ex officios thought, and we'll look at that in a minute. Access was ranked first by members but only tenth by ex officios, so there's some difference in priorities or viewpoints there. Coverage and reimbursement was ranked second by the members and ninth by the ex officios. On the other hand, public awareness was ranked seventh by the members but number one by the ex officios. So I think we need, even within our own extended committee, there's some open issues and need for debate about really what are the priorities.

So this is the overall ranking, and I'll let you have a look at that. I highlighted the ones where there was sort of significant differences. I think there were not too many where there was obvious ranked number one by both, so we still I think have some sorting out to do at this meeting.

What we did then was we asked Sarah and the support staff to develop an issue brief on each of these topics to sort of flesh them out a little bit more. What people were voting on were these one or two or three-word titles. So it was clear that maybe as we had our task force discussion, not everybody's interpretation of what that title meant was quite the same. So we went through to try and really flesh out what we believe the issues are surrounding this word in relationship to the SACGHS charter, and we'll be going through that in a little bit.

I'll give you sort of the highlights of each of these areas on the issue statement, and then we'll come back and have some deliberations. Under access, the key issues that were identified were barriers to access to genetic services that might prevent the realization of the full benefit of advances in genetics, and the fact that access can be impeded in several ways. It can be impeded during the test development and marketing process, through the use of intellectual property patents that might be used in a way that would limit research in an area or increase the cost of tests through licensing royalties.

In genetic research, the choice of populations that are available to study might impact ultimately the access of individuals who would benefit from testing to that. So if we never do the studies to determine what the genotype/phenotype correlations are, we're not going to have genetic tests that

would benefit, and how do we deal with the rare disease issues.

The issue of clinical integration, how do we move from a research level into the practice of medicine; and finally, the sort of standard players in terms of financial barriers, lack of insurance, lack of coverage, inadequate reimbursement, and the cost of the test.

From the societal point of view, we also felt that access could be impeded if there was any fear from genetic discrimination or some kind of stigmatization that would create unwillingness for someone, even if it was paid for and available, to have a test, and that this could then, if there are specific groups that feel more likely to be stigmatized, that they might as a group have some disparity in access. Finally, the relevant policy question is are there specific things which the federal government could do to intervene which would minimize the barriers to access.

For coverage and reimbursement, we all know that health insurance affects both the cost of the overall health care system and the quality that's delivered, and as a result the access to care. So coverage and reimbursement decisions, particularly for new technologies, new markers, are still very difficult in this country. We're a multiple payer system and we have multiple payer disparities in terms of what's covered, how it's covered, when it's covered, and that all has an impact on who actually is able to get testing done.

Some of the coverage and reimbursement decisions are not made because there's felt to be insufficient data to support that something really is medically relevant. There's some misunderstandings about the costs associated with genetic technologies, and there's some new challenges that genetic technologies pose in the paradigm of health insurance, that sometimes it's necessary to test family members in order to get a specific result for a proband, as well as the fact that we now will be potentially able to do testing for diseases that would develop much later in life but are currently asymptomatic.

So again, coverage and reimbursement. The policy questions are basically focused on is it a barrier to allowing people to get access to the genetic technologies, what specific actions would facilitate coverage and reimbursement decisions, and are there any unique characteristics that impact these coverage and reimbursement decisions, or are these really just like any new biomarker that comes out and has to establish itself on the basis of clinical utility.

We heard at a previous meeting about concerns in direct-to-consumer marketing, and this is basically focused on the marketing of medical services and products to consumers. It's common practice now with all the television and print advertisement for pharmaceuticals, so there's some concern that genetic testing might not be quite ready for that level of consumer interaction. So the risks really are who is regulating the claims that are made in a direct-to-consumer situation, and the potential harm that could be done to this field if the public's first interaction with these kind of tests is through sort of junk science.

The average consumer we felt doesn't really have the background and experience to judge for themselves what's good science and what's junk science, and there might be some need for "experts" to weigh in on that. Then there's the whole issue of how many results do you want going directly back to a consumer without the intervention of a health professional, and which kinds of tests might be okay to have results go directly back to a patient and which ones you would definitely want to have a health care professional and potentially a counselor involved with.

So the benefits of having some kind of intervention would be to enable the consumers to be better

informed and to participate more fully in their health care. We all know that the first thing anybody does today when they're diagnosed with Disease X is log on to the Internet and find out what Disease X is really all about. So in terms of being an informed consumer, that's a good thing. We do have oversight both from FDA and FTC to protect consumers from false and misleading advertisements, but unfortunately right now we've heard from both FDA and FTC that neither agency has the bandwidth on their staff to be actually monitoring this.

So the policy questions come down to basically do the risks of direct-to-consumer advertising outweigh its benefits? Does direct-to-consumer advertising in this particular field raise any greater concern or warrant more attention than any other area of medicine? And is there anything that this committee can do to sort of facilitate the right kind of consumer interaction with genetic testing?

The next area was genetic discrimination. We've talked about this a fair amount. We know that genetic technologies have been sold on the promise of the future of medicine being positively impacted. We have just completed a really huge publicly financed program to sequence the human genome, and now we're working on the next phase of understanding the variation among individuals in the human genome. But we're not at the point where it has yet been integrated into the practice of medicine in a routine way.

So what are the barriers? Is there a fear that patients would not either utilize genetic services or participate in the basic research that's needed to move from a research setting into a medical practice setting?

There's still a perception that genetic discrimination exists, although there are actually not that many documented cases, and the ones that have been documented are ones we trot out on a regular basis. So the question is is this a real fear based on facts, or is this a sort of fear of the unknown or fear of worst case scenario and we just haven't seen the worst case scenario?

The policy questions are will a federal law, such as the Senate bill that passed last fall, be effective in preventing discrimination? Are there other areas beyond health insurance and employment that we should also be thinking about? There is a moratorium in the U.K., for example, on life insurance, using genetics to make any risk assessment for the purpose of life insurance. But there are also areas, like adoption and immigration policy, that we really haven't discussed or gotten into at all yet. Then again, what further steps should this committee take to deal with this issue?

We also heard at the last meeting a lot about the status of genetic education and training. The goal, of course, is to make sure there's a better understanding of the role of genetics in health and disease. We are I think well acquainted with the fact that we need to involve a wide variety of health professionals and make sure that they have the right education and training to facilitate the integration of genetics, and I think currently there is still a perception that health professionals are not sufficiently trained and educated to meet the goals of having this just as a standard part of your medical care.

So what are the gaps and how can we fill those gaps? Is there a role that the federal government should play, or is this a role that should be played, for example, by the AMA and other professional groups? So that was the training and education section.

Genetic exceptionalism is sort of a philosophical issue. It basically comes down to do we believe that genetic information is different than any other medical information, so should it be treated

with some special additional considerations beyond the confidentiality and other things that are in place with which all medical information is treated.

The critics say that genetic information is just another part of your overall medical history and that there's no real compelling reason to separate it from other information in your history that might be just as damaging or difficult to deal with, such as HIV status or the fact that you'd had cancer five years ago, those kinds of things. The advocates say that genetic information is unique because it is a unique identifier. It does allow you to, with the exception of identical twins, a unique personal identifier. Because it's inherited, anything that you find out about an individual could have implications for family members, and it can be predictive, and therefore it can be used to stigmatize and discriminate.

So this is sort of one of those ongoing debates, whether we want to make it an issue, and what, if anything, this committee can do about coming down on one side or the other, whether we believe genetics is exceptional or not. Clearly, the fact that we have a committee focused on genetics says that we at least think we need to talk about this issue.

So in terms of policy questions, I think I already mentioned the issue of does the fact that genetic information is individually unique warrant special attention. Should our public policies be based on the premise of genetic exceptionalism, and is there an alternative concept that would allow the special features of genetic information to be acknowledged without necessarily creating a whole separate and parallel set of rules and regulations for genetics?

The next issue is large population studies. This basically is focused on the concept of translational research, that we need to understand better the genetic variability within populations and across populations and the impact that that has on the way individuals develop disease or react to drugs used to treat disease. The federal government has been funding a number of studies aimed at understanding the extent of variability and creating haplotype maps to help us with the research tools. I think we've been doing a good job of funding the research tools, but do we need to do the next step of actually initiating a large population-based study, such as is being done in some of the other countries?

One of the reasons to think about this is because for some of the kinds of genetic effects that we might look at in the broad practice of medicine, we are going to see effects that need a large number of people to actually get the statistical power just to properly power the clinical trial, and this might be beyond the realm of individual grant applications or clinical trials that might be funded by a company.

So the policy questions really are how important it is to mount large population cohort studies in the U.S., how would we deal with the heterogeneity of the U.S. population. Most genetic studies that have been done in the early phases went to very homogeneous populations to try and find effect. How do you extend that to heterogeneous populations? What should the role of the federal government be, and what obstacles might there be in order to be able to actually conduct a study in the United States where we're a mobile society, we don't have centralized health records? I mean, there's a lot of sort of logistical issues that would come into play that would have to be dealt with.

In oversight, we were looking at basically sort of a follow-up of what SACGT did a lot of work on, our predecessor committee, and that is what kind of oversight is needed at the federal level to make sure that the tests that are developed meet all the criteria for being put into medical practice. So basically the issue is have we done enough or are there still some gaps? Clearly, a number of

agencies are already actively involved in oversight of both genetic as well as other tests, and the question is is there a need to do more than what they're currently doing? So I guess that's really pretty much those things.

Patents and access. This was a pretty hot topic I'd say two years ago, and still I don't think has been completely resolved about what to do about the patent system. The pros, of course, are the basic premise under which the U.S. patent system was created, which was to promote innovation by granting exclusive rights for a limited period of time, basically so that you would invest in developing things and get some kind of assured reward, as market conditions permit.

The cons are that when patents are held in an exclusive manner and not promulgated across multiple sites, there's a perception that this can limit innovation or limit the ability to use innovation. Of course, the financial rewards that come from patents are basically through licensing fees. So those who need to take a license and pay fees almost always pass those extra costs directly on to the consumers of their products, including patients who are getting genetic tests.

The questions on a more basic level are is there any evidence that patents held in an exclusive manner have limited research or decrease the ability for tests to be out and utilized in terms of access to genetic testing services? So the policy question as it relates to genetics is is there really anything in the way U.S. patent law is interpreted and executed in the field of genetic diagnostics that is unique and requires some kind of special treatment or special consideration, and can we somehow balance the public good that comes from full dissemination of new innovative technologies with the financial rewards that are required to incentivize investors in actually developing those things to the point where they're commercially viable?

So again, a balancing act. Is there anything that this committee can or should do to sort of influence how that scale is tipped?

In the field of pharmacogenomics, I think it's fairly well recognized that there are individual differences in the way people respond to drugs or are susceptible to disease. There's some evidence that your genetic background also plays a role in your likelihood of developing an adverse event when treated with some drugs. So the question is how to make the best use of this sort of general knowledge and put it into the practice of medicine. So to what extent should we individualize the practice of medicine and use genetic determinants to target pharmaceutical interventions, or to what extent are we using genomics to identify new drug targets and evaluate them in the process of drug development through clinical trials?

So the relevant policy questions in pharmacogenomics are basically does the current evidence indicate that genomic technologies can improve health care outcomes? And the part that we haven't really dealt with too much as a society yet is the costs and quality issue. So do we need more health economic modeling of how a test might or might not benefit the overall practice of medicine? How will the clinical validity and utility of pharmacogenetic tests be established? How will pharmaceuticals already on the market be reassessed? We know that there are a number of drugs, for example, that already have in their labeling a statement that says, "By the way, this drug is metabolized by this enzyme, which we know to be polymorphic," but they don't really tell you what to do about that. So how do we develop that body of information that takes it to the next level? And then how will the integration of pharmacogenomics into clinical trials and drug marketing be optimized?

So the relevant policy questions in this area are basically what can the federal government do to

improve the chance that this technology will be integrated and used to improve patient care? Are there sufficient research studies in place? Is there a role there for the federal government? There's always the fear that if you genetically subdivide diseases into enough groups, that you end up with genetic subsets of disease that might then be sort of orphaned diseases on their own, and do they qualify then somehow for orphan drug status or orphan disease status? And finally, what's the most efficient way to integrate this technology into the health care system?

On public awareness, I think we also have identified this and discussed this to some extent at previous committee meetings. The question is just I think focused on how to make informed consumers, how to make sure that the public, and the public being kids in school through elderly on social security, how do we make sure that they have enough knowledge to make good, informed decisions when presented with an opportunity to integrate genetics into their health care, and how to make sure that the public education that occurs through the media is accurate and not misleading.

So I guess the key things in terms of what this committee might do is what is the role of the federal government in assuring or improving genetic literacy, and if we can identify what the role is, is there more that the federal government should be doing or could be doing to improve public awareness in the right way?

The vision statement issue is really not an issue, more a mechanism to help this committee formulate its framework, and we have a very, very broad charter and basically are given a wide range of things that we could work on. The thought was that if we could create a vision statement, it might help us to describe where we want to get. What is the goal ultimately of integration of genetics into health care and into society? Then once we identify what the ultimate vision is, then you can take a step back and do a gap analysis and say really where are the gaps, what are the most critical gaps, and which ones do we have the ability in this group to influence?

So I guess the main policy questions are beyond just giving this committee a chance to get more focused and get a better internal vision for what we want to do, is there some role that such a vision statement could play in becoming a broader Health and Human Services vision statement or a federal government and public vision statement so that we really sort of start with the seed at this committee level and move it up to speak with one voice about where we as a people of the United States want to take this whole area?

So that's the overview, and now what we're going to do is we have different committee members assigned to just give us a brief run-down on each of the areas.

DR. McCABE: Thank you, Emily.

We do have time now for a very brief discussion, probably about 15 minutes or so, before we take the straw vote right before the break. So if anybody would like -- Francis?

DR. COLLINS: Just a point of information. When it came to the discussion about patents and access, you may be interested in knowing the National Academy of Sciences has started a study on that, which met for the first time this past Friday, specifically looking at the impact of patents on genetics, genomics, biotechnology, and a distinguished panel, chaired by Shirley Tilghman, president of Princeton. This will be an 18-month study. They have a lot of expertise on that panel from both the public and the private sectors and will be collecting data in order to try to assess what the impact has been so far of patents in this arena, and then ultimately making recommendations about steps that might be taken to maximize the benefit to the public in the

future.

DR. McCABE: Thank you. That is important information because, as we've discussed before, there's no point in us taking on issues that are actively being engaged by other groups. There are a lot of things to do, and we shouldn't duplicate efforts. That would not be efficient, nor probably effective.

Other comments? Yes, Emily.

DR. WINN-DEEN: Francis, can you tell us who would be the right person to contact to maybe have somebody come and just give this committee a briefing when they get to the point of having something?

DR. COLLINS: I can get you the name of the chief staff person, and I'm sure they'd be glad to come and make a presentation. They're just getting started with the first meeting, but perhaps in two or three months. I can get you the name.

DR. McCABE: Good. Thank you.

Other comments? Questions?

Yes, Brad?

MR. MARGUS: Just on the same lines, I remember at the last meeting someone mentioned that the IOM is looking at the population study idea. I was wondering how much redundancy there would be if we made that an important thing here.

DR. McCABE: Francis, can you help us?

DR. COLLINS: That has not gotten underway. It's been discussed. Actually, at the present time we're sort of deciding between whether that kind of analysis would be best done in a fashion organized by some of the HHS agencies -- NIH, CDC, and so on -- or whether the IOM would be a useful contributor. We're sort of leaning in the direction of doing that internally. But certainly from my perspective, having the input of this distinguished panel on the value of such a study would be quite helpful.

DR. McCABE: Is the IOM still pursuing it, or is the discussion moving toward the agencies?

DR. COLLINS: Well, you may be aware, the IOM pursues studies when somebody identifies a budget to support that. So they're looking to the NIH for whether there are funds available. Things are very tight right now, so at the present time the IOM has no plans to initiate such a study.

DR. McCABE: Thank you.

Other comments or questions? Point of clarification of anything that Emily raised?

(No response.)

DR. McCABE: Any thoughts about some of the discrepancies between the two lists, the list from the members versus from the ex officios?

Yes, Francis?

DR. COLLINS: I'm sorry to talk so much, but I'm curious, in the deliberations of the groups that met in-between meetings of SACGHS, there is this apparent potential for overlap between the topic called access and the topic called reimbursement. In fact, reimbursement appears as a subtopic under access. So how did you all come to grips with that in terms of deciding whether these are really different or whether these are two topics where the federal role in terms of what could be done as far as a policy decision is actually fairly similar?

DR. McCABE: Emily?

DR. WINN-DEEN: It was clear to us that among these 12 topics that you could easily create some subgroups that had common threads, such as access and coverage and reimbursement, whereas you say one of the key issues surrounding coverage and reimbursement is whether it does limit access. But we decided that since they had been ranked as important by enough individuals on their own that we would keep them for now as separate topics. But it is absolutely clear that -- I mean, you could put patents in there as patenting, limit access. So there are subgroups that one could construct and make a sort of coherent subset that might fit together.

DR. McCABE: Debra, did you want to make a comment?

DR. LEONARD: Well, in fact, there are four of the topics that are subsumed in access. There's discrimination, patents, coverage and reimbursement, and there's a fourth one. I forget what it is.

MS. HARRISON: There's large population studies and also --

DR. LEONARD: Education. That's the other one that was specifically included in access.

DR. McCABE: On one of the conference calls there was some discussion about one of the things that might be done is some lumping, though we wouldn't want to be so creative in our lumping that we ended up not narrowing the field at all, which given the creativity on this committee I'm sure we could probably do. But that would not be effective given the purpose of the process.

Barbara?

MS. HARRISON: I don't want to get too ahead of myself as the point person for discussion on access, as well as reimbursements. As I was going through information last night, I was trying to separate my thoughts, and it was becoming very difficult.

One of the propositions I have for the committee is a topic that was brought up before, if I'm not mistaken by Emily, to use access as a framework for whether or not a topic is worth our consideration or not. It's my bias that in serving the public, to make sure that people can even access these kinds of services, that maybe those are the kind of topics that we need to expand upon, the ones that fit under access. So maybe not identify access as a separate issue but really set it up as a framework in setting these subtopics and these are the ones that we're going to try to address in the next year, couple of years.

Again, it may be premature to bring that up, but I wanted to let the others outside of the committee know that that's a thought that's out there.

DR. McCABE: I think that was actually Cindy's idea, but thank you for reminding us of that.

Suzanne?

DR. FEETHAM: Just as a point of clarification, due to a communication in how HRSA scored it, their rankings were not added in, and as the access agency, that may have affected it also. So just to get that on the table.

DR. McCABE: As I looked at the discrepancies between the rankings by the members and the ex officios, and this is only my interpretation, but it looked like perhaps what we were seeing was the members just looking and ranking by their feeling of importance, but perhaps the agencies were looking at what could actually be accomplished by the agencies. I don't know if the ex officios would comment on that.

Francis?

DR. COLLINS: Yes, I think there is some truth to that summary, although that in no way should either imply that the agencies know what they're doing or that the members don't. It's just a different perspective.

(Laughter.)

DR. McCABE: Yes, Hunt, then Cindy.

DR. WILLARD: For the purposes at this point in the conversation, it may be useful to get some guidance before people go into the straw vote, because clearly there are issues of how people read this, or even react to what Emily presented, that we also saw in the task force. So genetic discrimination is a perfect example. Some people rated it number 1 because it's a critical issue. Some people rated it number 12 because it's a critical issue, but we already dealt with it because we wrote to the Secretary. So everyone meant the same thing, but the votes were completely opposite, and probably there are six other examples like that. So I don't know how you want to address that from the standpoint of either the first or the second straw vote.

DR. McCABE: Well, I think to some extent that will probably come up in the discussion between the first and the second straw vote. But I think it is important to recognize that that probably did influence -- I mean, genetic discrimination was the obvious one that everybody feels is important in the public to SACGT. You know, my first communication as chair of SACGT to both administrations, and our first communication as I was directed by this committee was on genetic discrimination. Clearly, everybody feels it's important.

There's the issue of how rampant is it, but the perception is that it's a concern to the public. But I think that will come out. What more can be done about it? If there is more, then that would influence the ranking. But that will probably be a matter of discussion between the first and the second straw votes.

Cindy?

MS. BERRY: And also, I'd put the genetic exceptionalism in that same category, because you'll remember when we first ranked it and then we looked at it and had a discussion on our conference call, we were all in the same boat in terms of our thinking, but we interpreted our duty to rank it in a different way. So it's the same exact thing, and that one might also merit some

pretty intense discussion because it actually has the potential to dramatically affect how we rank our priorities overall and what the committee does.

DR. McCABE: Kaytura?

DR. FELIX-AARON: Thanks. I just wanted to comment on the apparent discrepancy between the members and ex officios' rankings. It appears that, at least from my perspective, I interpreted the mandate to be, one, what was uniquely the Department's role. So getting clarity and focusing on using that as a priority. So ranking, topics where I thought the Department had a unique role; and two, where action could be taken in the short term. So where there were opportunities for the Department to intervene on a short-term basis. Those were the two things that drove my ranking of the items, and not that the others weren't important. I recognized the importance of others, but I was driven by those two factors.

DR. McCABE: Thank you.

And I think it's also important to recognize the second point that you made about all of these being important issues. Certainly these are the 12 most important issues that the committee identified. So we recognize in our ranking that we're making some difficult calls, but we also recognize that if we're to be effective we have to have some prioritization. So I don't think we should consider that we don't think that the other points are important. We just have to identify what is the most important where we can be effective.

We will also be discussing process, and to the extent that we can come to some closure on one or more of these within this meeting and possibly the next meeting, then we can move on in the prioritization list. But the purpose of this was so that we didn't flounder around not getting our arms around anything, but trying to identify at least three items or three to begin with, and then move on.

Debra?

DR. LEONARD: There are also things the committee can do that are rather rapid, such as recommending an NIH/CDC study on how we would do a large population cohort that this committee wouldn't necessarily do, and then there are things that this committee would need to do work on. So doing the relative ranking of those types of things is also difficult.

DR. McCABE: Thank you.

Emily? And I think this will be the last comment, and then we'll take our straw vote and our break.

Oh, I'm sorry.

MS. MASNY: I was going to say something very similar to what Debra said, that I think if we could clarify what are the important priority issues that we have to address versus those areas where we could make more quick recommendations, because we would want to be able to focus most of our time on those areas where we want to set the priorities rather than spending time where we just need to make a quick recommendation.

DR. McCABE: Thank you.

Emily?

DR. WINN-DEEN: Well, I think we seem to be coming to a little bit of a consensus here in terms of what we might want to do, so I'm just going to try to reiterate for a moment what I think I've heard in this discussion. That is, when we vote this time on priorities, I think we should try and consider what issues are sort of burning issues, what issues the committee can actually do something about in the time frame that we have to work with it, and what are the issues that we believe are important but are either already dealt with or someone else is dealing with them in sort of an active mode. I mean, the goal of this exercise is to focus on getting to a small subset, and we'll say three just as a guiding number, of things that we're actually going to specifically work on and push to take action, not that all of these things aren't important but to try and have some guidance on priority, sort of the "so what?" rule.

So if we do something with it, so what? That's just sort of my comment on maybe how we could think about prioritization.

DR. McCABE: Okay. So with that, we will vote. It is the blue sheet in your folder. The green is for the second straw vote. Please vote. Recognize that there was a lot of discussion about this on the conference call in terms of prioritization. They're just alphabetical here. That's the way they are listed here. There is no priority intended. It is merely alphabetical on the blue sheet.

Please vote, and then Sarah and the staff will pick up your votes and tally them during the break. We will resume at five after 10:00. For members, ex officios and presenters, there are refreshments here. For the members of the public, there is a gift shop out in the lobby of the hotel for refreshments.

We'll resume at five after 10:00. Thank you.