Roundtable Discussion with Presenters

DR. McCABE: What I'd like to do is have all the speakers from the morning and the afternoon come to the table. We're going to run until about 5:30. The individuals who are making public comment are able to stay, and we only have three individuals making public comment.

The purpose of the discussion, I just want to make sure that the members of the Committee and the ex officios understand what the purpose of the discussion is now. It's to help begin us to focus on what our priorities are. That's our job, to look at the seven issues that were presented to us and try to determine where our priorities are as we begin our deliberations tomorrow. So I think Eric's questioning of Dr. Sung about is there anything to fix here is quite appropriate, since certainly that was one of the issues.

DR. LEONARD: I'd like to start off with a comment on Eric's talk, which is that he followed the first ego genomics slide of DNA cream with a slide on CLIA testing, as if those two things were equivalent, and they are not. So I think that's very important for this Committee to realize, that there are regulations that control and advise CLIA-certified laboratories that are not in place for these other types. To put those two slides next to each other is a little disturbing in my mind, because that's my practice.

DR. McCABE: But I would also point out that that's why they're very careful in their Internet information to say that this is for recreational use. Similarly --

DR. LEONARD: No, I understand that. But it was just that --

DR. McCABE: But I also like to point out that that has become the code for non-CLIA, outside of the CLIA perspective.

DR. LEONARD: And I'm very concerned about that.

DR. McCABE: Because we saw that some of the information that was provided to us, that a company that is supposedly doing gender testing is really doing pH testing of urine and says this is for recreational use. So we need to recognize that that's why they're saying this really has no medical validity so they can avoid CLIA oversight.

DR. LEONARD: Right, and I'd just like to put those into two categories -- they're very different things -- and not put them together.

I have a question following up on Eric's question. Should medical information, medically useful information, be protected for exclusive use or non-use by patents, since once you have a patent you can do anything you want with it? When you raised concerns, your concerns were on research and business, but there are definite health care concerns raised by patents that were not at all addressed in your summary. I think this is a focus that is essential to this Committee.

DR. SUNG: No, and I think that there's a distinction I'd like to start off with. There may be information that is in the form of databases that raises a concern about how databases are used, for example. There's not presently protection for databases within the United States patent system or copyright system. There is, however, something that lawyers refer to as a sui generis database initiative that the Europeans have adopted, for example, that allows exclusivity to extend over database compilations of information as well.

Beyond that, the uses that you're talking about, to the extent that they bore safety and health-related issues may block access by the public, it is certainly at least contemplated within the mechanism for access to that through a variety of mechanisms. One of them is, for example, the federal government can step in and because of the health and safety-related issues mandate public access to this.

An example of this you can point to is with the Cipro anthrax situation, where the government certainly had made initial indications that it may proceed to appropriate the technology to Cipro and allow its manufacture by other competitors to the extent the patent holder buyer was not capable of meeting the demand for this and at the right price.

So there are mechanisms for that. The only recompense that a patent holder has is under something called a 1498 action. They may sue the U.S. Government for reasonable compensation as a result of that appropriation. That really smells a lot like a compulsory license. Essentially, you are forcing the patent holder to accept the use of their technology without their permission but at a reasonable royalty, for example.

There are a variety of other mechanisms as well I'd be happy to share with you that can be used to allow public access to this. One other example is that again as an enforcement mechanism, a patent holder goes to court and asks for others to stop doing what they're doing without permission. So for example, if you had a pharmaceutical patent and decided for whatever reason you did not want to license this to anyone nor did you want to exploit it in any manner, the infringer can certainly have a voice at that hearing to say to the court this is inappropriate for an injunction. I should be allowed to continue to do this because it is of such great public health concerns, that the public be able to benefit from this, that you should not enjoin us, even though we're infringing, and again the mechanism for compensation is through damages in the form of a reasonable royalty, for example.

DR. LEONARD: True, but most of those infringing are in academic health centers and they don't have the money to be able to take a lawsuit to prove it in the courts.

DR. SUNG: No. Understood.

MS. BERRY: I have a question for Dr. Juengst.

I have a particular concern about preimplantation testing, and I wanted to ask you for some insights there because it's tricky. Really, regardless of what someone's views might be on elective termination or discarding embryos, I don't think it matters what their views are because I think in general, I have a sense but I would love your insights on, I think that the discomfort level increases as you get away from discovering a very, very serious disease problem, some defect where there's incompatibility with life and acting on that, and you move more towards personal preference, such as I want a child with certain eye color, or I want a boy, not a girl.

Do you have any insights to share about, really should people who are informed just be able to do whatever they want or should a line be drawn somewhere? If a line should be drawn, where do you draw it and who should draw it? The federal government, the physician or somebody else? It's a dicey one, but I would love to hear, based on your work, what your thoughts are.

DR. JUENGST: Sure. It's a good question. It's kind of the analog of that line between treatment and enhancement but in the selection world rather than in the treatment world.

I think you're right. The anxiety does increase as we move further away from trying to avoid serious disease and into selecting for traits that seem to have less relevance to the health of the prospective child and that's the line that I would focus on, is health and whether it's health-related or not.

Why do I focus there? Partly because that seems to me to be where the professions are focusing when they address these matters and the conversation that I'm most familiar with is a little further along in gestation but the question about the limits on prenatal diagnosis. What should we be willing to test for through amniocentesis or CVS at the patient's request?

One of the conversations that's moved the furthest has been the conversation about gender. Should we be willing to test prenatally for gender at the patient's request, and the argument of those who say no, that's a place we can draw a line as professionals has been we are health professionals. We're happy to help prospective parents make tough decisions that turn on the presence or absence of pathology in the fetus, but gender is not pathological one way or the other, therefore we can leave that off the menu. We don't have to offer that service. It's not part of our professional responsibility.

That answers another one of your questions. Who makes the decision? I think there is a role for the health professionals here to stand on their moral integrity and draw some lines based on the goals of their business which is the promotion of health and the cure of disease, even against the charge of paternalism in that case, but they are a profession that has a specific goal. That seems to me to be one place to draw the line.

The danger with drawing those lines in public policy is illustrated by a Scandinavian case. I think it was Sweden where they did draw up a list in public policy of the conditions for which it would be appropriate to test for prenatally because they were worried about this expansion of tests and what happened was that became the approved list of conditions to test for prenatally and pretty soon was the expected list of conditions to test for prenatally and everybody got tested for all of them.

DR. HOOK: I want to follow up a little bit on Cynthia's comment about PGD and your concerns well expressed about the difficulty of keeping away from the so-called germline manipulation because I think on a very practical level, what we're seeing is that as PGD expands and it is expanding rapidly in terms of various mutations being tested for, disease conditions being tested for, as we develop means of therapy beyond viral vectors, non-viral transmission, the therapeutic efficacy is going to be to treat that embryo when there are fewer cells and you can ensure that there's adequate transmission of the so-called normal gene.

The end result of that will be, of course, that you're treating the individual but you can't avoid then treating the germline, and so I'm concerned that that distinction where people have held the ground for eugenic reasons is not going to hold at all.

DR. JUENGST: Well, and it just underlines the need to begin to put in place the sorts of things that the AAAS was recommending, which is basically to studies to get a better sense of what the actual risks are involved in germline transmission, something we don't know much about in the human case.

DR. HOOK: Then my next was a broader question to all of the panelists and maybe this is opening something, a can of worms, but it's an important question to me, and that is, we have a number of very important pragmatic issues that you've laid on the table for us, and one of our jobs is to prioritize those, and yet it seems through the ELSI project and HGP and a lot of these discussions at no point have we really come back and said or looked at the question what would be the good use of genetic information for the good of society? What's sort of the larger target we're trying to achieve with all of this?

We have these specific questions here and there, but what's the larger picture? What do we want to see accomplished? I'm curious as to your response about the feasibility of that project and is that something that you would recommend we try to take some time to grapple with?

DR. McCABE: Who would like to take that on from our speakers? Francis?

DR. COLLINS: I'm not sure I completely grasp the full thrust of your question. I think it's almost maybe not verbalized because it's so internalized and so assumed that the goals of studying the genome and applying genetic technology to medicine are to develop better ways to prevent, treat and cure disease, that that is the expectation of where we're headed.

DR. HOOK: That's one world view, but there are others who would say no, we should genetically improve the race or that we should have a completely laissez faire libertarian type of approach to the use of genetic materials so that people can benefit themselves and their children, not just the elimination of disease, and so yes, that is the assumption, but I'm not sure that there's been sufficient public discussion of some of these other goals which are very much out there for the use of this material.

DR. COLLINS: I guess historically I can say that with regard at least to the Genome Project, the enthusiasm for the enterprise, the fact that it did happen, that the Congress decided to fund it was all directly related to the expectation of medical benefit, and I think a lot of the people who worked on it were attracted to it, myself included, because of that assumption, and the other applications that you refer to, such as "improving the race," assuming that we would know an improvement when we saw one, which is to my mind somewhat doubtful, really fall into the category of are these boundaries that we shouldn't cross?

I guess what I'm trying to say is I think we know the center of what this revolution is supposed to be about and it's a medical benefit area, and then there are these questions about, well, are there lines around the periphery where you start off in other directions that you really shouldn't be lurching across without a great deal of thought at the liberation, and our ELSI program has spent a lot of time thinking about those boundaries around the outside and not very much time worrying too much, I think, about the core because I think there's a lot less argument there about the benevolence of that enterprise to try to alleviate suffering and prevent disease.

We have a wealth of scholarship that focuses on some of the boundary questions, about enhancement, for instance, and including where the limits in terms of things like PGD, but that scholarship, that does not translate into policy deliberations. That's what this body is largely entrusted with.

In fact, just one more word of history and then I'll stop talking. One of the reasons that I think we have this Committee, if you sort of trace its origins back, is because in the first five years of the ELSI program, there was a working group which was internal to the Genome Center at that point which deliberated on many of the same issues that we're talking about today, but was located within the NIH, and was not perceived as having the kind of clout and credibility that it would take to actually get something to happen in terms of a policy deliberative body.

So one of the recommendations that was made back in, I think, 1995 by a group that looked at this was we need a higher level group that would be heard, that would have broad representation, would have the resources to study an issue in some detail and then make some recommendations of options that ought to be followed for cabinet member-level individuals to pay attention to and decide whether or not they agree they should be moved forward.

So in fact, this Committee, I think, is sort of third or fourth generation in that ELSI process, but it's probably the most mature and most potentially important generation yet because of the breadth of the charter and the challenge and the depth of expertise and the high level connection to the United States Government.

DR. McCABE: Any of the other speakers wish to comment on that?

(No response.)

MR. MARGUS: Yes, I've been wondering all day long if this Committee would have new ideas that could be generated that haven't already been generated by all the other previous generations. So that's one question. Maybe afterwards, any of you who have been on all these other predecessor Committees could come up with something of what you think, because the science has changed or because it was missed, maybe you think would be new today, I'd be really interested in hearing that.

What I wanted to talk about was Jack Rowe showed this slide that had the 40 percent, I think it was, or some number of people who were willing or eager to know information, even though it didn't have any value to them, or actionable things you could do.

So representing for a minute those 40 percent, I guess I want to ask Wylie for starters, you know, I see, especially with complex disease, people are going to start finding more and more of these genes that only account for a small fraction of the genetic variants but do ratchet up the risk a little bit.

So assuming that you have a good sensitive and reproducible test and assuming that a gateway for it were absolutely associated and everyone agreed on the statistics, assuming all that, that it's good science, are you saying that if there's nothing you can do about it as far as -- no way you can change a diet or change your life or take a drug, that people really shouldn't be -- a test that's made available to people now?

DR. BURKE: Let me answer that, but let me first make a comment to your previous comment as a former member of SACGT. My sense in that process which was one of the Committees in this line of Committees was that there was a lot of good discussion and there was a lot more discussion yet to be had, and as Francis said, this Committee has a much larger charter and, I think, better able as a result of that charter to talk at the periphery outside of the health care application. So I wouldn't see it as things having been resolved, what else new is there to do, but rather a sort of ongoing and important widening conversation.

In terms of the specific point you made, why shouldn't people get an Apo E4 test if they want it, I actually think that's a legitimate question, and I think it's a very important conversation to have as part of the discussion that needs to go forward, but I would stick by the claim that I made earlier, that it's not a good medical test. So I'm really thinking about it in terms of the health care setting.

From my responsibility as a health care provider, which includes taking action to improve health outcome as my primary mission and in doing so making prudent use of resources, putting those two responsibilities together, I find it hard to justify using the resources of the commons. That is, the money that goes into health care coverage, to pursue that information because a particular patient wants it, particularly with the vast number of tests of this sort that are going to be available when the same resources could be used in other ways to improve health outcomes.

Now, having said that, I certainly don't mean to say that there isn't a legitimate conversation to be had about whether validated information should be made available in the same way, for example, that we make cosmetic procedures available. So I think that's a conversation that needs to go forward and as it goes forward, I think we do need to be attentive to the health care resources common and what's appropriate to use, take out of health care insurance dollars, and also simultaneously, I think particularly in view of the Internet sites that we saw, how tests that we think are legitimate to be had because they're valid but yet not really good medical tests might be offered in a responsible and legitimate and safe way.

MR. MARGUS: I'm really glad to hear you say that very last thing because what I would hope is that the direct delivery of genetic information isn't always going to be thought of in terms of kind of wild, junk science things. You have to separate the two things, and hopefully, it may not come soon enough, I don't know about Francis's schedule, but hopefully some day there will be so much genetic information that maybe the only way to deliver it is through completely different channels than we do now, but so I like seeing it separated.

So you're saying if people pay for it themselves, maybe it wouldn't be so bad. Your biggest objection today would probably be that the resources shouldn't be spent on tests that don't have any use.

DR. BURKE: Well, medical use, I want to separate that. I really think it is the responsibility of the health care system to use information to improve health outcome, and it seems to me that's what health care dollars are for.

Now, if we agree that there's going to be a long list of tests that are potentially available that give information that some individuals might want and we want to give it responsibly, what that means is we don't yet have the system to do that, and so I think that's why I feel like it's a whole big discussion. How do we decide what information is legitimate enough to offer? Are the existing commercial channels the right way to offer it? Do we need to think about some other system? I think there are a lot of questions there. I didn't mean to say that I was dismissing those possibilities.

DR. LEONARD: Also, can I just add one comment, that the 50 percent number, we have the Huntington disease experience, that on polling people, 50 percent of people would say they would want that test. When it actually comes down to the genetic counseling and the actual utilization of the test, it is much lower than that. Once it's not just a question of theoretically would you use it, when it actually comes down to making that decision, it's much less than 50 percent.

MR. MARGUS: I'm not sure. Was the slide I was referring to the Huntington slide?

DR. LEONARD: No, but Huntington's is that similar --

MR. MARGUS: So it's got to make a difference. Maybe I'm wrong, but it seems like it's got to make a difference what the test is actually for, too. So it's an interesting thing about the twofold relative risk increase in Alzheimer's or if you're definitely going to get Huntington or something.

DR. BURKE: And I agree. I think people might be less afraid to get a test because it's just a twofold increase risk. They might be more receptive to that, but I would want the delivery system, whatever it is, to be one where people understand that they're getting risk information but that is not going to be followed by any medical recommendations.

MR. MARGUS: Well, the other thing is the population's going to disagree with you maybe on whether there is something you do about it or not. So while you might say there's nothing you can do about

Alzheimer's risk today, last time I checked, there are lots of articles every week, someone saying something might work with Alzheimer's and there might be people who want to make that decision on their own.

Somebody mentioned -- I think it was Eric earlier today that used the word "patronizing" and just whenever it starts to wreak what some physician acting as God deciding when it's time to be finding out this information always scares you a little bit.

DR. BURKE: I agree. I think you're raising very important issues, and at the same time, I want to say that I think health professionals have a responsibility and that responsibility includes making a distinction between stuff that's been published but hasn't yet been validated and information or therapeutic options that have passed some threshold, and I think that's part of the discussion. Part of the discussion is what are the criteria by which we decide a genetic test is now really a legitimate health care service.

DR. JUENGST: Or a recreational service.

DR. McCABE: Reed, Kay, and then I'm going to ask some questions.

DR, TUCKSON: I'm going to be real interested in our discussion tomorrow about this prioritization.

I am struck by this conversation now with one starting point, and that is, that genetic information is inevitably, as some of you have pointed out, essentially the core of what medicine will be, and so the idea that this is somehow different or distinct from the practice of medicine, that you can separate perhaps these issues out, I mean, it's just all going to be mixed together all as one gamut at some point and really we're close to being there now.

So the question I hear asked, and I'm curious to see what your comments are, is it our job to do one of three things: to support and facilitate the enhancement of good things that can and could be achieved through the molecular biological revolution, things that will do the things that Francis so articulately described? Are we sort of here to think about what are all the ways in which we can make these good things happen faster, better, more evenly distributed through the society and so forth and so on, more intelligently used as, Wylie, you have articulately said? Is our job also to frustrate or limit bad applications? Are we to try to slow those things down, to put them in a different context, to provide information that says this is not a good thing, we would advise against this or there should be availability of information for more informed decisionmaking, better counseling? Or third, is our job to also think about stopping things, stamping out things, ruling them out of bounds, making them impossible to be done?

We've had a couple of comments that made me wonder about that last thing because it just seems to me impossible to do. I mean, I don't know how you say to someone, you are not allowed to have a test that tells you the sex of your child. Now, it's not a good thing. It's not useful. It's a waste of money. You can't have it. Well, you can't stop that, and by the way, I guess at the same time, when you do the ultrasound, the physician is not allowed to tell you the little dangling thing there.

So you will not have this. I don't think you can do it, and I think one of these days, what we'll have to learn from experts is if you tried to have that kind of control, what would that mean to the society?

Wylie, I would say I really liked your points because they helped me to think about this question. I could tell you now from the point of view of what I do every day, the number of dumb stuff that people buy and the waste, the CT scans for the -- if you really loved her, you'd give her a whole body CT scan at the mall.

(Laughter.)

DR, TUCKSON: In Minneapolis at Christmastime. That is the dumbest thing in the world and it wastes gazillions of dollars and there's 41 million uninsured people who don't get access to aspirin, much less that, and it's immoral. However, there is no tool anywhere that allows you to stomp that out. So I don't know. Does anybody here think we should be stomping things out?

DR. McCABE: Any comments among the speakers? Reed was very shy on SACGT and I'm glad that he's overcome this in the interval.

(Laughter.)

DR. COLLINS: After that passionate speech, it's somewhat difficult to respond as I'm about to, that yes, I think there are some things, some boundaries, that we ought to be willing to say we should not cross that, and I think the public expects that, both in the scientific and the medical communities and in a body such as this, but we ought to choose them extremely carefully.

I will give you the example of reproductive cloning. We should not be pursuing reproductive cloning of human beings. That's my view. I think that's the view of the majority. I think in many ways, it's sort of a disgrace that we haven't figured out a way in this country how to implement that consensus at the legislative level, which is another story but we haven't, but okay, that's a pretty drastic example where the evidence, whether you come from a safety perspective or a more broader philosophical perspective, is overwhelming. But we better reserve our drawing sharp lines and boundaries for that kind of very egregious circumstance and not start applying them willy-nilly in other places.

Let me just say, I'm really glad that you had in your first list of things this Committee might do the effort to try to enable, to try to benefit, to try to speed up the advantages and what we all hope will come out of this because I think we have -- I'll even say this is maybe a bit of a problem for our own ELSI program. We focused more on the bad things that could happen than perhaps we should have on how to enable the good things to happen.

DR. McCABE: Nick, did you have a comment?

DR. DRACOPOLI: I would just add, I think there is one force that will in some sense get rid of the bad stuff and we hope that eventually would be the market. As long as this stuff is safe, I'm not sure the cosmetic issues you can get at Saks are really the issue that you need to be focusing on because they'll be on to metabonomic screening of urine next and then on to something else. I mean, how stable and longlasting that is, as long as what they're providing is essentially not hurting people, I would argue that the marketplace will eventually get rid of that. That's trivial. It's fluff. It gives us all a bad name, but it will go away eventually.

Really, I think the value of what you can do here is enabling the good and the important stuff that gets to the issues that Francis was talking about. We all believe as scientists that this can have an enormous impact on medicine and the way medicine is applied in the future and if you can enable the good stuff, this is really where you need to be focusing and not worrying about, I think, the things that don't harm people. I believe we would all agree on the bad use of genetic information.

DR. McCABE: Any other comments in response to Reed?

(No response.)

DR. FELIX-AARON: I'd like to connect points made in Wylie's presentation and Francis's presentation, and I'd like to focus my question on the middle of the spectrum, on diabetes, heart disease, these common conditions, and how genes and the environment interact, and so I've observed over time that conditions like diabetes, obesity and this seems to be rising in the majority population, but in low-income and minority populations, these conditions are very prevalent, and I'd also like to sort of place on top of that our interest in finding and intervening on the genetic level without a clear sense of how the environment reacts with the expression of these genes because I would like to hear your comments on that.

For example, in the communities where there seems to be some sort of genetic predisposition and that explains why some conditions are more prevalent today than they were, say, 30 or 40 years ago, the question I have is how much has the genetic background in these populations changed versus the environment? I mean, do we get a sense of the contributions to those patterns of disease versus how much is environmental and how much is genetic? Because I think we really need to understand, because I think that for the future, it may be that diseases that are prevalent now will be prevalent 20 and 50 years down the line as our environment continues to change.

So I think we have the opportunity now to understand the interface and the interaction between the environment and the genetics and not only on an individual level, sort of people's diet, but sort of their neighborhoods, how they live, their working environments, and how does that relate to sort of the diseases that we will see 50 years down the line.

DR. BURKE: Well, I agree with your comments, and I actually think that there are two ways in which genomic research, the kind of genomic research that I think we're all agreeing we'd like to see promoted might contribute. If you see a rising prevalence of a disease over 10, 20, 30 years, asthma for example, rising prevalence of asthma, I think we can be fairly certain that what's changing that's resulting in that changing prevalence is something in the environment. There's no reason to think genotypes are changing over that kind of time frame, and yet at the same time, we know that genetics makes a major contribution.

I think genomic studies will, Number 1, get us closer to understanding the disease biology and thus identify, for example, drug targets and potentially innovative therapies, but speaking more specifically to the environmental issues and why I think it's so important in these large data banks that both genes and environments are studied, I think understanding the underlying genetic susceptibilities may allow us to much more precisely understand which are the key environmental factors, may help us to identify them better, may help us to understand what environmental interventions may make the most difference, possibly different ones with different kids or understand at what age the critical interventions can occur.

So I think there are going to be many common diseases where our opportunities to intervene are going to remain environmental or drug-related, drug therapy-related, but where genomics will enable us to do a better job.

DR. McCABE: I think many people have commented that one of the fallouts of the Human Genome Project will be a heightened sensitivity about the environment because what we'll begin to realize is that reactions, disease that we thought was idiosyncratic, is really stratifying across certain genomic relationships and it will give us an appreciation that got lost in all of the noise before. So I think it's an intriguing situation, that this genetic determinism that we've been living with could end up actually giving us insight into environment that we would not have had without it.

What I want to ask the speakers is just if you have any ideas about how we ought to go about our task of prioritizing the issues that we need to raise. Are there issues that we -- this was dealt with a little bit before, but I'll come back to it -- should avoid, issues that we should definitely take up? Should we deal with the issues as they are today or should we be trying to anticipate issues that are on the horizon, emerging issues?

So really, how should we begin to shape our discussions in the Committee? Eric?

DR. JUENGST: In terms of your prioritization problem, one strategy would be to look for overlap between the presentations that you've heard today and see where people are bringing up the same or similar kinds of themes. Not that we're representative or authoritative, but at least it's some form of robustness. And then, I would also urge you to be anticipatory and be willing to look down the road, in addition to trying to address the immediate urgent problems.

DR. McCABE: Other comments? Francis?

DR. COLLINS: Well, I was probably already more directive than you expected in the brief presentation I made earlier this afternoon. I won't reiterate what those four suggested priorities might be, but I do think it's probably very important for this Committee to jump in on one or two topics early where you can make real headway. I noticed that in fact the charter for this Committee was signed in September of 2002, and it obviously takes awhile to get things up and going and at the present time it's a two-year charter, and then they'll consider again what happens next. So it would be really good if this Committee had some deliverables to put forward by the sort of fall of 2004, which isn't very far off.

So I think it would be good in your panoply of considerations to try to pick some topic or two for which there could be real forward motion in terms of a product, an output in that kind of time table, recognizing that's pretty challenging with this just being the first meeting here today.

I also think, and this is just obvious stuff, that it would be most appropriate to pick topics that are well within the charter of what the Committee is asked to do. Obviously it's a pretty broad charter, so maybe that won't be too hard, and also topics that are not currently being undertaken by another highly ranked group and there are a number of them that need to be sort of looked at to see what their intentions are at the moment.

Also, of course, you ought to pick things where the expertise that you need is well represented amongst the membership.

DR. McCABE: Other comments from others? Because this is what we will spend the bulk of tomorrow dealing with. Any guidance? Yes?

MS. WILLIS: I just had a question for Dr. Fraser. I was just fascinated by your talk and some of the issues that are there and following Dr. Collins and what he was saying about not trying to do repetitive efforts that other organizations are doing, and I was wondering, is there any organization or Committee or anyone who's devoted to maybe pointing pharmaceutical companies back toward making antibiotics or paying attention to issues of microbial genetics and uses and bioterrorism?

DR. FRASER: I'm certainly not aware of any Committees that are tapping that issue, but it's one of the things, in thinking about what I presented, that I find most disturbing. It's disturbing no matter what, but I think it's even more disturbing in the context of all the possibilities and all of the potential breakthroughs from having this new starting point as a result of the significant federal investment in microbial genomics.

I think that that's a very, very serious issue and it gets back to the issue of the need for the appropriate public/private partnerships.

This is certainly something that has been discussed now within the context of the biodefense arena, and I confess I don't necessarily understand all of what the bioshield initiative is, but that's certainly an example of trying to provide new vaccines, new drugs, new reagents, to increase our overall level of preparedness. I think that we should take a lesson from that and acknowledge that going forward, while those are the most definitely serious concerns, I really think what's going to be more important and deserves as much, if not more, attention is dealing with the issue of emerging infectious diseases and how we prepare ourselves for tackling those in the future.

DR, TUCKSON: Just the extraordinary experience with SARS, where the world was able to move so rapidly and so quickly to decode that genome, does that indicate to us that the infrastructure is in place and that this is an area that is pretty good, it's pretty okay, and it ain't broke, don't fix it? Do we need to sort of push for more in that direction?

DR. FRASER: I would agree that the infrastructure is very much in place and that there's a tremendous amount that could be done with the current infrastructure, and I think the message that I've been taking out to various groups is that if there's really a concern that we're not prepared at the appropriate level, and I think that is indeed the case, that someone needs to put their money where their mouth is and invest in the research, making use of available infrastructure, so that when the next SARS comes along, we're not reacting.

The one positive point is that we seem to be able to react more quickly now, but constantly being in a reactive mode I don't think is the most sensible way to go.

DR. McCABE: Thank you very much. Thank you to all of our speakers. Your input has been extremely valuable to us as we proceed with our deliberations. I know some of you are involved with the Committee. I hope others of you will continue to follow the efforts of this Committee and provide input to us, if you feel that it would be useful to us. So thank you very much for helping us with this inaugural Committee meeting. Thank you.