U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NATIONAL INSTITUTE OF MENTAL HEALTH

INTERAGENCY AUTISM COORDINATING COMMITTEE

STRATEGIC PLANNING WORKGROUP MEETING

MONDAY, APRIL 21, 2008

The meeting convened at 11:00 a.m. in Conference Room D, Neuroscience Center Building, 6001 Executive Boulevard, Rockville, Maryland, Steve Hyman, M.D., Workgroup Chair, presiding.

PARTICIPANTS:

STEVE HYMAN, M.D., *Chair*, Harvard University

DAVID AMARAL, Ph.D., University of California, Davis

PETER BELL, Executive Vice President, Autism Speaks

MARK BLAXILL, M.B.A., Coalition for SafeMinds

JUDITH COOPER, Ph.D., National Institute on Deafness and Other Communication Disorders (NIDCD)

GERALDINE DAWSON, Ph.D., Autism Speaks (attended by phone)

STEVE EIKEN, M.A., Thomson Reuters Healthcare (attended by phone)

MARTHA HERBERT, M.D., Ph.D., Harvard Medical School

PARTICIPANTS (continued):

ALICE KAU, Ph.D., Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

DAVID MANDELL, Sc.D., University of Pennsylvania

PRISCA MARVIN, J.D., National Institute of Neurological Disorders and Stroke (NINDS)

SAM ODOM, Ph.D., University of North Carolina, Chapel Hill

ISAAC PESSAH, Ph.D., University of California, Davis

LYN REDWOOD, R.N., M.S.N., Coalition for SafeMinds

DENISE RESNIK, Southwest Autism Research and Resource Center (SARRC)

STEPHEN SHORE, Ed.D., Autism Spectrum Consulting

FAN TAIT, M.D., American Academy of Pediatrics (attended by phone)

EDWIN TREVATHAN, M.D., M.P.H., Center for Disease Control and Prevention (CDC)

LUCILLE ZEPH, Ed.D., University of Maine

ANDREW ZIMMERMAN, M.D., Johns Hopkins University

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PROCEEDINGS:

Dr. Steve Hyman: Okay. Welcome, everybody. We have a very full day, and I'm going to try to be a ruthless chair so that we actually get through our work. But what I'd like to do is just start–I suspect a lot of people here know each other, but I think it would be very useful to start with some introductions. I'll introduce myself, Steve Hyman from Harvard University, and I'm going to chair today's session. And why don't we just go around in a circle, so, Joyce?

Dr. Joyce Chung: Okay. Hello. My name is Joyce Chung. I am the Autism Coordinator for the IACC.

Dr. Lucille Zeph: My name is Lu Zeph and I am the Director of the University Center for Excellence and Developmental Disabilities at the University of Maine.

Dr. Steven Shore: I am Stephen Shore, Board of Directors of the Autism Society of America, and I am my own autistic child.

Dr. Ed Trevathan: Ed Trevathan. I'm a pediatric neurologist and Director of the National Center on Birth Defects and Developmental Disabilities at CDC.

Dr. Sam Odom: Sam Odom. I'm the Director of the Frank Porter Graham Child Development Institute at The University of North Carolina at Chapel Hill and also the Director of the National Professional Development Center on Autism Spectrum Disorders.

Mr. Mark Blaxill: Mark Blaxill with SafeMinds and the father of a 12-year-old girl diagnosed with autism.

Ms. Prisca Marvin: I'm Prisca Marvin. I sit on the Council for NINDS, and I also have a 15-year-old autistic daughter.

Dr. Isaac Pessah: I'm Isaac Pessah. I'm at UC Davis, Director of the Center for Children's Environmental Health and Disease Prevention.

Dr. Andrew Zimmerman: I'm Andy Zimmerman, pediatric neurologist, Kennedy Krieger Institute and Johns Hopkins.

Dr. Alice Kau: I'm Alice Kau. I'm an extramural program official from the Eunice Kennedy Shriver National Institute of Child Health and Human Development.

Dr. Judith Cooper: Good morning. I'm Judith Cooper. I'm Deputy Director of the National Institute on Deafness and Other Communication Disorders here at the NIH.

Dr. Martha Herbert: I'm Martha Herbert. I'm a pediatric neurologist at Mass General Hospital.

Ms. Denise Resnik: I'm Denise Resnik, cofounder of the Southwest Autism Research and Resource Center and the mother of a 16-year-old boy with autism.

Dr. David Mandell: Good morning. I'm David Mandell. I'm a psychiatric epidemiologist and health services researcher at the University of Pennsylvania.

Mr. Peter Bell: Good morning. I'm Peter Bell. I'm Executive Vice President for Autism Speaks and also the parent of a 15-year-old boy with autism.

Dr. David Amaral: Good morning. I'm David Amaral, Professor of Psychiatry and Research Director of the MIND Institute at UC Davis, and I was one of the workgroup chairs.

Dr. Hyman: Very good. Thank you. So what I want to do just for a few minutes is talk about what the purpose of this meeting is, and it is a very ambitious agenda to get in by 5:30.

The Interagency Autism Coordinating Committee or the IACC, in essence, has charged this workgroup with a priority-setting exercise. And what we are going to do is to begin so that you have the background within which to understand priorities in current budgets with a portfolio analysis of the current NIH autism portfolio. And I think that's really critical, so that you can see where the gaps are, where investments have been made and so forth. And I think it'll also give you information as to how things are classified as autism relevant.

The core of the meeting will be to look

at the 41 sets of plans, projects, ideas that –

(inaudible comments)

Okay, here, now it's on. It's on again. So the core is going to be to prioritize.

Now you've gotten this list of 41, and this is a result of prior workshops that have had an extensive set of processes, and Joyce is going to talk about this in a minute. It was not meant to derive all of the important sets of outstanding goals for autism research. But it was done in such a way that it was very difficult to give relative weight to any of them.

Now one of the things, if you look at the 41, you'll notice it's divided into 6 clusters, and one of the reasons for that is that – my understanding is that the workgroups believe that some areas might end up being orphans in terms of investment and attention. And a good example of an area that has been neglected and could get neglected are interventions for adults with autism. And so the notion of dividing these 41 concepts into 6 groups was to make sure that we didn't ignore or leave out some critical areas that, for one reason or another, have less caught the imagination of either the advocacy community or the scientific community. And we're going to try within each of these 6 groups to say what is more important than the next.

And then finally, we are going to try to talk about budget priorities. Now here, looking at the existing autism portfolio will be very, very useful, because you'll have a sense of where investments have already been made and at what size. Frankly, we can't – and in fact, it would be almost foolhardy in an hour – to try to put numbers on the priorities. But I think it is critical that this group try to stake out those areas that they think are of the highest importance.

Now one thing that I also think – if we're going to really get through this day – one thing that I think we really have to do is to work through the existing priorities that are the output of the current workshops. Now it may be that we will see that there is an important idea missing, and I think what we ought to do since we are, in essence, tasked by the IACC, is make sure that we have recorded any potential missing ideas, but not discuss them extensively or try to fit them into the priorities.

Recognize also that there's going to be an open townhall meeting that also may come up with new ideas, and we should forward anything we feel has been missed in here to the IACC for further discussion, because, as hard as the workgroups have worked, it may be that there are some additional ideas that we will want to bring forward. But I think we want to try to do this in a disciplined way so we actually return to the IACC what they've asked for, which is a set of priorities and a sense of which ones should have the greatest budgetary weight.

Let me ask if there are any questions. I may not actually be the best person to answer all of them, but Joyce Chung, who has worked closely with the IACC, is at the microphone and can answer any questions that I can't. Yes?

Ms. Marvin: So I have a question. Are we supposed to take into consideration the work of the do-ability of the project?

Dr. Hyman: Okay. So that's something I was going to talk about when it gets to priority setting, but clearly, this is true across all of NIH. Right? There are two major pulls of deciding what is a priority. One is clearly what we might call the public health need based on, you know, unmet medical need, disease burden, possibility of prevention, whatever, but the sort of the public health need.

But the other pull is feasibility. That is to take something – let's leave autism out of this – you know, we desperately need a cure for glioblastoma, but if we really don't know how to go about it, setting something that we don't have the prior information to do might be a poor use of funds. On the other hand, you might think about the steps that are needed to get us into that position.

I don't know whether, Judith, you want to say something from your position? But I think sensibly weighing those things is what this group, in some sense, is tasked to do, and we'll come back to this. Mark?

Mr. Blaxill: I guess, Steve, one question would be, to what extent – well, let me express an opinion and –

Dr. Hyman: Okay. Yes, sure.

Mr. Blaxill: – then ask whether that's out of order or not. But I think there are quite a number of us who have opinions about the task that we've been assigned and the process itself and have some suggestions for how that process might be improved. And, you know, I think that's inevitably intertwined with the objective of being compliant with what's being asked of us. And I know we should try to be task focused, but I think there may also be – I would encourage us to take the opportunity to provide some commentary and advice on how to improve the process, because I know there are some issues with it and concerns in the advocacy community.

Dr. Hyman: So, Mark, the good news is that in order to stay on schedule, we still have 15 minutes, and so I think if you have concerns about what we've been tasked with by the IACC, you might raise them. And I think, clearly, these concerns and issues have to be carried back to the IACC. But why don't you raise your concerns.

Mr. Blaxill: Well, I'll raise a few. I'm not – I don't think I'm alone in having some concerns but, you know, I think if we think about strategic planning as an exercise, it's something I've done for a fair amount of time. I've spent 25 years doing it in a different context. The science is a challenge, and what you all have to do at NIH is a very different exercise than most people have to deal with in strategic planning, and so I recognize that, and that's a real issue and a challenge.

And I think there are a lot of things about the process that have been interesting and valuable, particularly the outreach, you know, the townhall meetings and the extension of the outreach to a lot of the scientists, to involve them in coming up with ideas.

But I guess I would raise the point that a lot of what's going on is backward, that I think one of the things that CAA, the Combating Autism Act, charged the NIH with was, not simply a bottom-up generation of cool ideas and neat projects, but actually with the assignment to figure out what's the size of the problem, what's the scale of the issue, what's the magnitude of the funding that needs to go on. We have that on the agenda, I know, but it's last, which is backward.

We ought to think – most strategic planning processes start out with the idea of the external environment, how big is the problem, how big is the market, you know, what kinds of economic issues are we facing. So I think there's a budgeting question that shouldn't be last. Simply bubbling up from the bottom lots of fun ideas for science projects, you know, is not the way that most quality strategic plans would be organized, and so that's a concern.

And I guess the other thing is, while I think it's terrific that we have parent and community representatives here, and that weight is moving, I think the weight has been more supplier driven than customer driven, and most strategic plans need – ought to be market driven and look to the customer.

And so I think what we're presented with is the output of a lot of scientists getting together with a selected group of parents. But I think a lot of the advocacy community would, you know, look to the representation and the process that we've been through and the task that's been placed before us as, you know, moderately informed by advocacy and parent input but not well informed. And so to the extent that we can make this more customer driven rather than supplier driven, that would be an observation.

And then the final point I would say, is, you know, we ought to take the time that's required to do this right, and we – there is no rush. I mean I'm not sure – there is a calendar, a pace that's been proposed, but if it's going to take longer than that, there's no reason that we should hurry. And I think this is a great group. We're convened for one meeting. You know, I don't know why we need to jam it all into a single meeting, and so I would urge us to consider the idea of what's really required to do this in a high-quality way as proposed to the way that's been presented to us.

Dr. Hyman: Mark, let me ask Joyce just to comment on – first of all, I think your comments should be carried back to the IACC, because in some sense, we didn't create our charge, and it's really important that the parent body that created the charge hear these comments.

Mr. Blaxill: I think some of it comes from the parent body of the IACC. I think–

Dr. Hyman: Well, but –

Mr. Blaxill: – I don't want to speak for them, but I'm not speaking in isolation.

Dr. Hyman: Okay. And let me ask Joyce, in particular, to address, I think, the very important issue of the engagement of parents in the formulation of what we have to work on today, our grist.

Dr. Chung: Yes. I agree with many of your points, and I think one of the things that I would like to emphasize – I'm going to through the steps of the process to date. One of the things is that this is our first time doing this, and it's an annual process, so the good news is we'll learn, we'll get better at this, and I expect that each year, when we have to go back and write a new plan essentially or update our plan, we'll have an opportunity to do it better. I think it is very difficult to know what you're – all the moving parts are when you start off.

But that said, I think, for instance, the townhall meeting is a great idea. It will happen on May 3rd. And we also, if you listen to my talk, have tried to include stakeholders in every step of the process. And stakeholders include not just parents and consumers but also a lot of organizations. We've had a lot of interest from health care organizations, state health organizations. We've had interest from researchers and clinicians and schools, so there are many, many people who are interested in what we're doing.

So I would say that the consumer focus part as well is quite important, and the main reason why the six areas that we're looking at start off with a question is, those are the questions that many consumers have in their minds when they're facing issues related to autism. And so we wanted to start with the consumer question and then build from there. So, again, we are trying to be responsive to that, but I think we can always do it better.

Dr. Hyman: So I think, you know, we'll

see as Joyce goes through her presentation. I think one thing we might talk about a bit from the point of view of strategic planning is, at one time I did work for NIH, and one gets to see the complex intersection between top-down planning starting with the public health need or starting with the budget and then the bottom-up planning, that is, what the scientific community can do in terms of having well-trained scientists who want to work on a set of problems and the tools. And in some sense, I always think of these exercises, in part, as luring the very best scientists to work on problems such as autism.

And so the plan is somewhat different from a top-down corporate plan. But I'm wondering if you had any reflections on that. That is, if you tell the scientific community what we want them to do, they tend not to do it. That's –

Mr. Blaxill: Steve, this is a much longer conversation. I don't want to monopolize the floor, but I'll just say briefly, obviously, as a parent and a customer of the research, we're desperate for quality science. We're asking for it. We're campaigning. We're passing bills in Congress.

Dr. Hyman: Right, yes.

Mr. Blaxill: We are the advocates for quality science. The issue we have is that we have an emergency in our country. We have an explosion in the rates of this problem, and there are all sorts of irrational behaviors: stubborn, obstinate reactions and political problems in the organization of the constituencies that are involved. And again, I don't want to get too far into it–

Dr. Hyman: Okay. All right.

Mr. Blaxill: – but the problem, as a parent, we want to attract scientists. We also want to stop repelling them. We want to make it safe to conduct quality science. We want to make it safe to confront controversial questions, and there are a lot of controversies swirling around this, and we've got to deal with those. And we've got to make an open and transparent process so that people aren't punished for, you know, taking on difficult questions. And that's so much of the larger issue. I won't even expand, but that's the point.

Dr. Hyman: Fair enough. David Amaral has a comment.

Dr. Amaral: So, Mark, I just want to say that I was at all of the workshop meetings, and I think that the sense of the scientists there and the advocates were exactly in line with your thinking that there is a sense of urgency; there is a sense that we have to do the very best science, that we have to confront controversial issues. So my take on it – and, you know, again, it was a very rapid process, and I agree with you there, too. You can probably spend months going through this process, but I think it was, in essence, very effective and very open in terms of the discussion. So, you know, not to say that there couldn't be more added, but I didn't get a sense that anybody was champion of the discussion.

Mr. Blaxill: I heard good things about your workshop, David, so I think yours was one of the best.

Dr. Hyman: Okay. Well, if we can keep it that collegial, we will make a lot of progress. Unless there's another comment in this vein – yes, go ahead.

Dr. Odom: I have one question. Given the interagency nature of what we're doing, this – I've heard us talk about NIH funding – are we focusing on –

Dr. Hyman: And CDC.

Dr. Odom: –and CDC – but other agencies that fund research in autism?

Dr. Hyman: There are.

Dr. Odom: I didn't see them represented in any of the materials.

Dr. Hyman: The Department of Education. Go ahead.

Dr. Cooper: I was going to say Department of Education and perhaps DoD. Where is Diane? Okay. Diane says that DoD and Simons are in our packet of materials you reviewed, but Department of Ed didn't respond or–because they do have autism research.

Dr. Hyman: Joyce, let me make an observation about that, which is that the IACC is within HHS Committee –

Dr. Chung: Yes.

Dr. Hyman: – but the legislation does include–I read the bill again–does include mention of the Department of Education sending a representative. And I'm just wondering, historically, has the Department of Education sent a representative to the IACC and have they been engaged in this priority-setting process?

Dr. Chung: Yes, they have. Gail Houle is the representative from the Department of Education on the Committee. She's expected to come here today. She's been quite involved and, really, provided information that is relevant to any step of this process.

Dr. Hyman: Okay.

Dr. Trevathan: I might just add, there

have also been representatives at meetings from SAMHSA and HRSA, FDA.

Dr. Hyman: Good.

Dr. Trevathan: I may be leaving out some others, so there has been quite a lot of participation in some of the other Federal agencies.

Mr. Bell: If I could just add from a clarification standpoint, the task at hand is to create a Strategic Plan for research and not a Strategic Plan for the IACC.

Dr. Hyman: Correct.

Mr. Bell: So it's entirely possible that there will be other aspects of what the IACC does that will go beyond what we're here to do.

Dr. Hyman: Absolutely.

Mr. Bell: But I think there has been some confusion or perhaps time spent on trying to be as comprehensive as possible, but really, we're here today to talk about research.

Dr. Hyman: And set priorities.

Mr. Bell: Yes, exactly.

Dr. Hyman: Joyce?

Dr. Cooper: Okay. So one of the things that we neglected to do so far, before I begin, is to remind people that we are casting this meeting on a Web base and a phone line to the general public, and so we need to be mindful that if we can introduce ourselves, I think, before we speak, it will be helpful for people's orientation–that's not too awkward.

We also have some workgroup members who are on this group and who aren't able to be here in the room. I don't know if they're able – they have a special call-in number in which they can speak, and I don't know if that's something they can do now and just introduce themselves if they're on. So is anyone on the line now who is a workgroup member who could state their name and their affiliation?

Dr. Tait: Yes. Can you hear me?

Dr. Chung: Yes.

Dr. Tait: Good morning, everyone. This is Fan Tait. And thank you, Joyce. I was trying to figure when I could jump in here. I'm Fan

Tait. I'm one of the Associate Executive Directors at the American Academy of Pediatrics and over the Department of the Community and Specialty Pediatrics, which houses the autism initiative. So thank you. I'm so sorry that I couldn't be there. I will be on the call off and on most of the day. Thank you.

Dr. Chung: Thank you very much. Geri Dawson, are you there?

Dr. Dawson: Yes, I am.

Dr. Chung: Can you speak up a little bit?

Dr. Dawson: Sure. Pardon me.

Dr. Chung: Okay. We can hear you now.

Dr. Dawson: Okay. Yes, I'm here, and I've been listening, so I can hear all that you're saying, and I'm happy to be part of it.

Dr. Chung: Okay. Do you want to just introduce yourself very quickly?

Dr. Dawson: Sure. I am Geri Dawson and former director of the Autism Center at the University of Washington and currently Chief Science Officer at Autism Speaks.

Dr. Chung: Thank you. And Geri was one of our workshop chairs.

Dr. Dawson: Yes, that's right. I chaired the treatment workshop.

Dr. Chung: She and David Amaral will be helping with questions about those initiatives later on. And then there may be one more person. Steve, are you there?

Mr. Eiken: Yes, I am. Thanks, Joyce. My name is Steve Eiken from Thomson Reuters. We're a policy-oriented research and consulting group. At least that's my task within Thomson Reuters. A lot of our customers are the state agencies that, you know, develop or fund–Federal or state agencies that fund the programs that serve especially adults with autism spectrum disorders but also children to a certain degree. So I'm kind of coming at this more from a more policy-oriented perspective.

Dr. Chung: Okay. Thank you very much. Now there may be other – Steve?

Mr. Eiken: Yes?

Dr. Hyman: Just one other bit of housekeeping that I recognize we didn’t do is these conflict sheets. Do you want to mention this now or at the end?

Dr. Chung: Yes, I was going to do that. There are some conflict of interest forms that everyone participating in an official capacity in this meeting needs to review and sign. There are some – there's language in there that might be important to work through very carefully in terms of any potential conflicts. And anyone who has a question can–Ann Wagner over there, could you raise your hand? Ann Wagner is our Federal official at the meeting, so everyone should be turning in their forms in to Ann. And if there are any questions about portions of the form, please raise them with her.

Okay. So one other thing is I'm not going to have people from the IACC introduce themselves. They all have the option to either be in the room or be on the phone. But we have an IACC member comment period near the end of the day. And at that time, I'd like to people to introduce themselves and speak. So we're going to move on if we can.

Of course, the general public will be listening. They can't be heard but they can hear. So they're going to be listening to what goes on in the room.

Okay. So my job here is to take you, rather quickly, through the steps of the planning process that we've already completed, again, as background for those of you who may not be as familiar with what we've done so far and also to help you orient to the task today.

So we began this process back in November 2007 when the IACC was reformed according to the Combating Autism Act. The only difference between the old IACC and the new one, really, is a few – more public representation on this new Committee and that this Committee is now what we call a Federal Advisory Committee, so it has more authority to make recommendations. Again, it was something that was reformed, and the first meeting of this Committee was back in November. So all of these things flow from that date forward.

So the parent Committee's the IACC and underneath, in a diagram, is a box with a workgroup. So this is you. This is this Committee. There was another workgroup that met for one meeting, and I'll go into that later. But the workgroup basically is a group of individuals who are gathered to help provide input, recommendations to the parent Committee, the IACC, and really brings additional expertise to the table that might not be present on this federally appointed Committee.

So there's a lot of information on the IACC Website about the roster of the Committee and so forth, but the workgroup here today would be working for the IACC, and as such, must report their recommendations directly to the IACC and not to the public.

Underneath this in the diagram are the four workshops we implied. We had four scientific workshops that were held in January and that really were – these were inputs again that you're looking at today through the initiatives. And as I said, all these steps involved stakeholders of various types and the team that I help run here at NIMH. We staff the IACC and all these meetings.

So the summary here is that the completed steps are as follows. We had the planning process we presented to the Committee back at their first meeting in November, which they approved. We had, at that time, suggested an ambitious 6-month timeframe, and we're pushed back a little bit, maybe a couple of months, but we're mostly on target with our timeline.

In order to do this, we started to do something practically every month – we had a stakeholder RFI, a Request for Information, which we sent out in late December and collected responses through the beginning of January. And these were important inputs to the workshops that we just described in January of `08. We had a workgroup meeting in February, and then a new workgroup, which is all of you, was formed this past month in March.

To say a few words about these steps, I wanted to say that the stakeholder RFI was an important first step. So we began with the idea that before we did anything else at the beginning stages, we needed to have very broad input about what people out there in the general community felt were important research priorities And so we cast that net very broadly, and we sent out this RFI electronically to many organizations and got a tremendous response.

In terms of the responses, I'm not going into any detail here, but we received 542 responses in a short window of time over the holidays, and we received them from practically every state in the U.S., from military families serving here and abroad in foreign countries. And the stakeholder groups were broad. Many parents, obviously, relatives, individuals self-identified, but lots of organizations, researchers, advocacy organizations, and foundations. So the number of different kinds of stakeholder groups vary quite a bit, and we were very happy with the diversity of responses that we received.

So back to the scientific workshops. We divided the ASD research endeavor into four large domains – biology, treatment, diagnosis, and risk factors. And we had these workshops held on consecutive days in January. And we managed to not have a blizzard happen during that 4-day period, so we were very happy about that.

And then we deliberately did them consecutively so that there was some opportunity for individuals and participants to, if they were on a workshop panel, they could stay and observe another panel. Some people served on a couple of panels if they really did work in the margins between groups. It was very useful in terms of a continuing and ongoing iterative process of making sure ideas were discussed and that the process was refined, even over the 4 days.

Importantly, these workshop members were given the RFI responses in the summarized form. We also provided a lot of information from the different agencies and organizations that do autism research in terms of what they had recently found through their research funding, what kind of accomplishments and resources they had and supported. And you might notice in the initiative format you got that there's sort of an outline or structure to it, and that's because we asked these workshops to use a template when they generated the research initiative so that the information was relatively well formed and complete.

Now moving on to the workgroup meeting. This is the workgroup that preceded the current workgroup. We should have named it Workgroup 1 and 2, but the previous workgroup met in February, and that included the four workshop chairs. And at that time, the group discussed the 41 initiatives that came out of the four workshops, so approximately 10 per workshop, not exactly 10, but overall 41.

And what they did is they looked at them to make sure they understood the content of them and that they clarified kind of what questions they were addressing. Then they began to talk about what kind of guiding principles or values would be useful to apply when formulating a Strategic Plan, and I'm going to share those with you in a moment. So they came up with a set of values for the IACC.

And they also discussed and proposed a framework for organizing the initiatives that was consumer oriented. And here the idea of having questions that parents or stakeholders ask when addressing autism was really important.

And the last thing they did was discuss ideas that might be missing – again, this idea that not all ideas might have come up at a workshop, so there was an opportunity to think about what was missing.

And again here, we've been talking about the framework, the six bins or the six sorts of categories of what we use to organize our thinking here. We have six questions, which I'm not going to read to you, but I think if you read through them, you'll see that they're general questions that are often asked and are relevant to people who are dealing with autism on a daily basis or thinking ahead to what is at stake. The numbers next to the initiative questions–the question is simply the number of research initiatives that are in each bin, so they have a different level of distribution. But if you add them all up, that adds up to 41.

And I want to be careful to emphasize what values – these values were presented at the IACC meeting in March, and the IACC approved these. They thought these were really great principles to guide what we do here. So these would be principles then that this group today should also be thinking about as you move forward. So the first is a sense of urgency. The second is the spirit of collaboration. The third is consumer focus. The fourth is excellence, fifth is partnerships and action, and the last is accountability. And we'll come back to these slides later if we need to, but I wanted to make sure you understood that these were the principles that IACC wants you to apply in thinking about your work today.

There were a few interim steps that we took between the last IACC meeting in March and the meeting today in April. We went back to the workshop participants in those four workshops and made sure that they had a chance to look again at the RFI responses from the general public against the initiatives that were generated to make sure that ideas were included. And if there were new ideas or things that we could modify, we definitely modified some of the RFIs based on feedback from those workshop participants. But we did not end up writing any new initiatives. There are still only 41.

And then we also spent a lot of time –

and Diane Buckley will take you through this – getting a lot of information pulled together at the behest of the IACC and, I think, at the public on what our current ASD research funding portfolio looks like, both Federal and private.

So I'm going to end with a slide that sort of describes what's in your agenda for the day, but there are three major things, topic areas we're going to cover. The first is to have this group review the 2007 ASD research-funding portfolio. The second task will be to prioritize research initiatives within the six-question framework. And lastly, we'd like you to discuss the budgetary requirements of the Strategic Plan.

Dr. Hyman: Thank you for being so crisp and direct. Do we have any questions about this discussion, any clarifications? Peter?

Mr. Bell: I have a question.

Dr. Hyman: Yes.

Mr. Bell: Peter Bell. Who ultimately will be drafting the Strategic Plan?

Dr. Chung: The writing of the plan you're saying?

Mr. Bell: Yes.

Dr. Hyman: That is what comes out of today.

Dr. Chung: Well, I think what's – the plan is that we would like to be able to provide prioritization and information on the budgetary discussion back to the Committee meeting, which is going to be May 12th, the next IACC meeting. And then what we're going to try to do is have a draft plan by July. So the idea is that internally, the team that I run, along with the science writer, will be writing these priorities up. We're going to use that question framework, and we'd like to include the summary of advances that's also required by the Combating Autism Act as part of that document. But I think we're going to take–we're going to ask the Committee in May to provide us with input on the form it will take. Is that what you're asking?

Mr. Bell: It is, and I guess if I could

just take a moment to share, I guess, some of the frustration that, having been a part of this process, that is very challenging for us. Because I think really what you're asking us to do is to prioritize what essentially are a number of different tactics. And you know, many of us have been a part of strategic planning before for different enterprises, and typically, that is framed in having a good idea of what your goals are and what are the important things to accomplish and so forth. And so in the absence of that, this is a very challenging position to be in to look at 41 things and try to assign some level of prioritization.

And so it's been a little unclear, from our perspective, what role we're supposed to be playing. Quite honestly, when we were initially invited to be on the Strategic Plan working group, I think there was a sense of we were going to be working on a Strategic Plan that would then go through the IACC. But it became obvious at the last meeting that that was not our charge. And then, obviously, we got invited back to help prioritize that.

So I share that just to give you a sense of, you know, we can go through this process, but it's very challenging to do this in the absence of really trying to figure out what is it that we're trying to accomplish as a group. And I think that's really what the intention was of having a strategic plan in the original Combating Autism Act was to create a guide map of sorts for not only the NIH but the whole research community. You know, we're fortunate that we now have significantly more funds than we did, still probably not quite enough, never will be enough, but, you know, I think that there are a lot of really good things that are happening here.

We're all at the table and, you know, when they went through this process 5 or 6 years ago for the matrix, the community was not involved in that. So there are a lot of really wonderful things going on, so I don't want to discredit any of that. And I think, to your point, Joyce, you know, we will learn from this. And I think if we had an opportunity to sit down and create a framework of some kind, this could actually be quite effective, because I think we have all the right players at the table to have a really meaningful and productive conversation.

Dr. Hyman: Yes.

Ms. Marvin: This is Prisca Marvin. Joyce, can you just tell me again what the T in SMART was for?

Dr. Chung: Diane, what was the T? Go back. Time-bound.

Ms. Marvin: Time-bound.

Dr. Chung: Back to the values. So Peter, you know, you're absolutely right, and we can use all the help we can get.

Dr. Hyman: One other thing – David Amaral and I were having a little side discussion before, and not only do we not have a top-down framework, but if you look at the 41 components, each of them, you know, doesn't really fully specify what it's after, which also increases the degree of difficulty on this dive, as it were. I think it really is very important that these concerns about the time – I mean on the one hand, we want to make sure we have an initial product. On the other hand, I think what we would want to recommend is that the IACC undertake, in the future, a strategic planning process that gives people more tools to actually formulate a plan.

Dr. Chung: Okay.

Dr. Hyman: Okay. Any other questions for Joyce or comments? If not, Diane Buckley is now going to provide information on the portfolio, and everyone, of course, received this portfolio ahead of time. I have a great deal of sympathy. It's very hard to read something like this and really know, with adequate information, what all of the components are. Diane, I think you probably have a lot of material you want to get through, but I think it's very important that the group be able to ask questions if they feel mystified about certain titles or certain areas so that they stay appropriately engaged. Because I think this is the critical platform against which a strategic has to be developed.

Ms. Buckley: Certainly. Thank you, Steve. So again, my name is Diane Buckley, a member of the Autism Team. And so I'm here today, as you all know very well now, to provide you with an overview of some information about research funding in autism. In fiscal year 2007, as Steve indicated, there are many parameters and caveats that go to any kind of exercise like this. And one we've also talked about is the pace that we've all been working under, and really, what you're going to see here is a reflection of what we were able to gather and accomplish in the timeframe we had since that last IACC meeting in March.

So you're not going to see comprehensive data that covers the full landscape of autism research, but it's a first step in, I hope, a meaningful insight and gives you useful background for your task today.

So the key topics I want to go over just to once again reiterate – the charge from the IACC, specifically with respect to reviewing the portfolio information, to provide you an overview of the NIH portfolio from fiscal year 2007, to speak to other investments in autism research through other Federal and private funders and talk about what's here and what's still not here in the materials we have today, and to leave you with a picture of overall funding by broad research topic areas.

So last month at the IACC meeting, the members were very clear that they wanted to see a detailed listing of the NIH autism research grants, projects funded in FY 2007, and the understanding that I came away with from that discussion was one of wanting the information to be presented in a way that was meaningful, that was transparent. It was clear that the list that we would provide would actually add up to the total that we report and that it would be done in such a way they could help perform these proceedings. I'm hopeful that you'll think that we delivered on that. We certainly delivered a product by our deadline of March 31st, and we'll take a look at that today.

And so the charge to this newly formed workgroup is for you to consider current investments in autism research when recommending priorities to the Committee.

So for NIH, in FY 2007, invested $172 million dollars, and that includes grants, contracts, and intramural research projects. Those are dollars that were paid in FY 2007, so some of those grants or contracts may be in their first year. They may be in some other year. It could be an ongoing project. So what you have is a slice in time of what happened in 2007 and where the funding that we were appropriated went in terms of all kinds of autism research.

In addition to that $127 million, NIH also invested $3.9 million in the further development of NDAR, the National Database for Autism Research. So to again try to meet not just the letter but the spirit of the IACC request, the NIH Autism Coordinating Committee, which is a group of extramural program staff who work with grantees on a regular basis from several NIH Institutes, who work together regularly regarding coordinating autism research. They came together and developed a coding system so that we could turn our diverse portfolio into something that could make sense by assigning each research activity and its associated funding to one of five broad research areas and subcategories based on its primary aims and objectives.

Certainly, many research activities have addressed more than one aim, but we what really tried to do for this task is to be tough about it and to say when we're looking at something, really, what is the primary focus of this, which category would that fall into. And so, really, the lion's share of the work that's represented here was done by that group on the Autism Coordinating Committee, which was led by Ann Wagner, who's in the room. You were introduced to her earlier. And so these research areas–

Dr. Hyman: Diane?

Ms. Buckley: Yes, sir?

Dr. Hyman: Let me just stop you. What you said is actually very important, because whenever looking at a disorder-relevant portfolio, there's often a lot of disagreement about where something fits. So in reading through this, I think actually you did a remarkably good job. Let me just ask you a question, which is as you get to more basic science, what sort of processes did you use to – you know, what was the threshold for saying that it was autism relevant?

Ms. Buckley: Well, I can tell you a little bit about the process that I was involved in, and then perhaps if that doesn't fully answer the question, I'll ask my colleague, Anne, to supplement the answer. Because really, I came in at a simpler point in the process and that is after the Institutes had already determined if a grant should be coded as autism or not and it had already been included in the number that NIH reports in its total funding for autism research.

So the coding system that I'm talking about now is something that we applied for the planning purposes of the IACC and this workgroup after the actual portfolio of NIH grants, contracts, and intramural research projects had already been termed or coded as autism. Now, as you know, and many of the folks here may be familiar, the Institutes have differing processes for making those determinations. And so if you'd like to hear more about it at the Institute level, it would need to go to other folks.

But so you understand what we did here, we took that pool of already-defined autism grants, and we applied a coding system to meet the needs of the IACC.

Dr. Hyman: I think Mark has a question. It wouldn't be bad, Judith, maybe – you know, I don't want to put you on the spot, but I think just for the point of view of transparency, this is actually an important point. Mark, do you want ask?

Mr. Blaxill: Yes, I just have a process question, which is, this is a very important document. I've been through it very thoroughly, and I have lots and lots of questions. How much can we ask questions about this?

Dr. Hyman: Well, let me–I hope you can ask a lot. How much time did you need on the slides?

Ms. Buckley: I think we're – just a few more minutes on the slides just to, again, give the full picture. The slides, I just have the overview information, and then what you have in your folders are the detailed grant–

Dr. Hyman: Okay. So let me then hold my question, and let's all hold our questions. Let's let you get through the slides, and then we can ask you but also other people in the room questions.

Ms. Buckley: I think that's perfect because the slides are really a little bit more just about process and just hitting the highlights.

So again, the research areas, you're familiar with these – biology, treatment, diagnosis, and risk factors that corresponded to the – well, the inspiration we got from Autism Speaks and the way that they present their information and also the four scientific workshops we held in January. This was the first time where we really defined subcategories within those four areas – again, they're very still broad strokes – and also realized a need for another category, for lack of a better term. And in there, you see things like research capacity building, training, dissemination of information, and research infrastructure, data systems, things that would pertain to more than one content area and, really, it was not appropriate to force into one topic area.

So you have in your folder a stapled packet for NIH that gives you an overall chart that shows you how the dollars fell out once we applied this coding system to the portfolio. And you can see the numbers here. They're basically exceeding $36 million in biology, exceeding $18 million in treatment, approaching, what, $21 million in diagnosis, and exceeding $28 million in risk factors and approaching $23 million in other, which is kind of the infrastructure-type things I mentioned. Maybe in an easier way–which this pie chart is not in your packet–but just a way to just kind of see, okay, so it's the pool of money and how is it divided up, and so here you see the diversity the portfolio reflected. And you have these numbers in your packet. You just don't have the graph.

All right. So just to take a minute to speak about other investments, and this already came up in the discussion earlier, we did encourage other major Federal and private funders of autism research to provide portfolio data. A couple of things I would say in response to the discussion earlier, as Joyce indicated, before our workshops in

January, we did a very broad call to 19 agencies, Federal and private agencies involved in autism research and asked for research accomplishments and initiatives in the last 12 months. And that was a great resource to the workshops.

In that, some of the organizations we contacted didn't have anything to report. One, for example, was the Department of Education. In that particular call, we didn't receive anything. So in terms of, again, working within our constraints in the last month and deciding where to focus this current effort, we contacted just four organizations, and they're the ones that you see listed here. So perhaps that's a point of discussion. If there are others that are major contributors on a research aspect that we need to follow up with, you know, maybe that needs to be considered.

But in terms of Federal partners, we see CDC and Department of Defense, and on the private side, we contacted Autism Speaks and the Simons Foundation.

Lovely interactions with everyone. Everyone very excited and willing to cooperate. We shared our coding approach. Several of these folks even went way out of their way, applying the system that they don't use on a regular basis, but perhaps they will in the future. We were able, in a timeframe, to receive data from three of the four. Autism Speaks, just for time constraints, I believe, wasn't able to provide it, so it's not in your packets, but I think when I finish this part of the discussion, Peter Bell of Autism Speaks might be able to talk a little bit about where things stand for their organization.

Again, in your packet, you have a chart that shows you then where the dollars fall by organization in the broad research areas. You also have detailed listings for CDC. The CDC and the NIH listings are public documents and are final. The DoD listing that you have, many of those awards are not final yet, and so those pages are marked not for distribution.

So they're provided here for your use, but we just ask that when you leave that you're not disseminating those, because, again, several of those awards aren't named yet.

And so even the Department of Defense numbers, I believe, will come up somewhat, because in some places, they just have awards that they don't even have an estimate on yet, and I think those numbers will be even higher than what you see reflected here.

And then Simons also provided a detailed listing that they asked that I distribute at the meeting and then pull back and collect after you're done working on it, so I'll pass those out now. It's just a single-page document, if you can pass those around.

Dr. Hyman: Okay. So everybody will be giving those pages back at the end of the meeting?

Ms. Buckley: Yes. And so, again, this is a pie chart that displays the percentage of total autism funding – with a very large caveat. The total here means that this just reflects the data we have from the NIH, CDC, DoD, and Simons. And you see the diversity of the portfolio – 28% to biology, 13% to treatment, 20% to diagnosis, 24% to risk factors, and 15% to other. And again, the coding was done independently at these different organizations. So that's where we are.

Dr. Hyman: So let me just start by saying that given the time constraints, that's a terrific effort and a really good approach. Ideally, the IACC can, again, this being the first year, can sort of pursue this with more leadtime. And the other thing about nomenclature, which was behind some of my question before, I realize you can get into fruitless bureaucratic niggling over what you call what. But by the same token, insofar as all of these groups can generally share some coding or nomenclature system, these portfolio analyses will be maximally useful to the various communities here in the future, but really, very well begun.

Ms. Buckley: Thank you. I would like to offer Peter the opportunity if you had anything you wanted to share from Autism Speaks.

Mr. Bell: Sure, and I apologize – I think we have a document that is being printed and copied, so we will have an inventory of grants that are currently active that we're pursuing at Autism Speaks. Part of the problem that we had is that when we make a commitment to fund a grant, typically, it's multi-years, and so we were looking at it from a full commitment standpoint. And when we got your analysis, it was obvious that you had done it just for a single year, and so we had to go back, and that's one of the reasons why we weren't able to produce something in advance today.

I can just give you a rough sense, in 2007, how our portfolio was divided just in terms of total spending. We spent roughly $22.5 million dollars on grants or research resources, as you defined earlier here. About a third or 33 percent of that figure was in biology, in the biology area that we've discussed. About 32 percent was in etiology, which, of course, includes both genetics and the environment. Twenty-four percent was in treatment, and 11 percent was in diagnosis. So that'll just give you a rough sense, and then when the document does appear, you'll see specifically the individual investigators and the types of grants that have been funded in the last roughly 2 to 3 years.

Dr. Hyman: Great. Thank you. Okay. So now we have a half hour for questions and discussion. Judith, did you want to make any comments ahead of time about–

Dr. Cooper: Just to reiterate, I think, what you said–or maybe it was Diane – that each Institute does, in fact, code its autism portfolio in a unique way. And so when the grants came to the group to then fit into these four categories, we had already made some decisions about what we considered autism within our Institute. And so that information – I mean if that's something you're really interested in–we'd have to have each of the Institutes sort of say what kind of guidance they used to so characterize their grants, because I think it does vary by Institute a bit.

Dr. Kau: This is Alice Kau from NICHD. I may add that NIH, as a whole, is in the process of standardizing coding of each autism grant, so I can't remember exactly if it's 2007 or 2008 that is the piloting year. So these are really transitional difficulties, but eventually things will be more standardized across Institutes.

Mr. Blaxill: I have several short questions, points of information. To what extent, Diane, is this a public document, or what portions of it are public or will be made public?

Ms. Buckley: All of the slides are public. The NIH portfolio is public. The CDC information is public. It's only the detailed listing from Simons that they asked that we take back, but I'm not sure perhaps what's on their Website. I don't know. And the Department of Defense has also asked not to share at this time. And you'll see, their list doesn't even have full information yet, because those awards just aren't all complete.

Mr. Blaxill: And on the amount, was this reverse – I'm a little confused as to how you went about the process of aligning the reported amounts with the actual audit that you did. Was the amount a given and all of the projects that had received the coding a given? Or did you go in and inspect the grants and then sort of magically come up with the same end number? I'm curious what the reconciliation is between the total $126 million NIH number and the specific projects.

Ms. Buckley: Right. So perhaps Judith would want to talk about the first step of actually determining the grant and the pool, and then I can talk about the coding.

Dr. Cooper: Okay. It really wasn't a reconciliation that had to be made. I mean, each Institute had provided their listing to the NIH Director of this is what we've supported in this particular year. And so then we took the list and those listings and came up with the overall dollar amount, whatever it was.

Ms. Buckley: Right.

Dr. Cooper: And so then we took the grants that made up for each one of us the amount that we reported to the Office of the Director, and those are the grants we coded. So there was no question that they wouldn't add up to the same thing. Is that your question?

Ms. Buckley: Yes.

Dr. Hyman: So you're saying it's from a bottom-up budget?

Mr. Blaxill: Well, it was already coded, so there's no original work in this other than the sorting into categories.

Dr. Cooper: Right. This was – yes, we didn't go back and look for other grants. I mean we had already reported that–

Mr. Blaxill: So why just 1 year? Why

can't we see a trend? If it's not that hard, if they're already coded and you're reporting the numbers on a regular basis, why can't we see the breakdown over time?

Ms. Buckley: Well, if I could just speak to the part that is new and why it's happening now–it's really in response to the IACC and this particular strategic planning process. So in prior years, the Institutes and the way that they award grants and all of that, they – we weren't using these four or five research topic areas kind of approach. I mean these are the steps that you're seeing reflect the fruits that have come out of the strategic planning process already.

Dr. Hyman: Well, let me see if I can help. Mark, I think that the total autism research investment for the NIH is in the public domain for every year. It just hasn't been collected here in a bar graph.

Ms. Buckley: Right.

Dr. Hyman: I think a separate issue, which I think is very important and I'm glad to hear it's being addressed, is to make sure that everybody is calling it the same thing so that you have a sense of what is “under the hood” when you look at the detail.

Mr. Blaxill: Yes, and that – the total number is public. I guess the reason I asked the question, and I'll just – you know, I think from the perspective of an autism parent, we look at these numbers. We have a sense of urgency, and we'd like to know whether we're getting our money's worth from our Federal tax dollars that are allocated to autism.

And we'd also like to see, if we're asking – thinking about priorities and where the money has gone, you know, not just a single-year snapshot but a 5-year snapshot, because a lot of the science is very long lead-time. And so it's not just a single snapshot. It's the cumulative investment and the cumulative investment by categories, because, you know, there may be deficits to – I believe there are deficits to make up. I believe that there have been long sustained investments in other areas, and just looking at a single year's picture doesn't give us that.

And then I would also say, you know, reading through the list, I'm not convinced that they're all autism. I mean just to be, you know, have a “green eyeshade” offense allowed, right – you know, we want to have the sense that these are valid research projects and the numbers that are being reported are actually going to projects that will help our children.

And, you know, I can tell you that I've gone through 350 some odd grants, and about a third of them don't show up when you code in to the CRISP database – autism, PDD, Asperger's, you know, the range of things. And as I've looked through, there are all sorts of difficulties in the coding process in the CRISP database. But, you know, it's not obvious that this is $126 million dollars that's really going to autism research.

And then, you know, actually understanding what patterns are reflected in these choices is harder still. So I applaud the effort to do it. I know the IACC has been asking for it. You know, Lee, I gather you've been asking for this for many years. It's really important that we have this, and this is a step in the right direction.

But I can't say, you know, as a strategic planner, that I have a lot of confidence that this is the kind of information we really need to make, you know, quality decisions. And I think there's more of this, and more depth and more elaboration is really, really important.

Mr. Bell: So is it safe to assume that there are going to be grants in here that apply to more than just a disorder called autism–

Ms. Buckley: Yes.

Mr. Bell: – and that perhaps maybe it's being counted in other places as well, so for example, if something is applicable to a certain region of the brain and that brain has been identified to affect people with autism and fragile X and schizophrenia and Parkinson's and so forth that it's going to apply to a number of different disorders, and just because it doesn't have autism in the title doesn't mean that there may not be some relevance to this disorder. And so I think you're exactly right, Mark.

Ms. Buckley: That's correct.

Mr. Bell: And, you know, it's not going to be a perfect science where every grant that they give at the NIH is going to have 100-percent relevance just to autism. That being said, I think that, you know, we as a community, have to be cognizant of the fact that there are going to be some discoveries that are going to be made in other areas that are going to be absolutely relevant for autism. In fact, maybe when you guys figure out autism, it's going to open up a whole avenue of other areas as well.

Dr. Hyman: I think David has a comment.

Dr. Amaral: I just want to echo what

Peter's saying, because I think the difficulty is it’s hard to predict what science – I mean all in favor of a goal-directed approach, but it's hard to predict sometimes what science is going to lead to the answer. So one example is the fact that Carla Schatz has shown now that immune markers are fundamental to synaptic elimination, a study that she published in 2000. I'm sure that that work, which is probably on plasticity in the visual system, wasn't coded as autism-related work. But that's given enormous credibility to the whole area of immune factors in autism. So I mean, it's a daunting challenge to try and figure out what is related and what's not.

Mr. Eiken: This is Steve Eiken. I don't really have a strong opinion on this but just a suggestion for the future, because I've developed similar typologies in other areas. Just to kind of state, I think, the Institutes within NIH, maybe there should be an umbrella of criteria of what is autism-relevant research so that everybody consuming this information can know what NIH considers autism relevant. And then the Institutes can characterize their grants autism relevant or not. I think that would be more useful in the future. This is really useful info, but it would be more useful if we knew where the numbers were coming – you know, how folks made that tough decision between autism relevant and not autism relevant.

Ms. Buckley: And I think that's the point Alice raised earlier about at least the direction NIH is moving toward trying to have a standard approach that would be applied across Institutes.

Mr. Eiken: That's great.

Dr. Herbert: This is Martha Herbert. I think that it's terrific that this work has been done, and I also think it's going to be very useful to have the standardization going forward. I think it would be, from the point of view of strategic planning in the future, a good investment to do a longer term evaluation of the work that's been done up until now, and it would be something you would only have to do once, and then you would have it, and then also to include in the evaluation, after appropriate reflection, also a tracking of deliverables over time. When you decide about what's relevant to autism, that part of that is, again, not only that it has the word autism but that it has domains that are pertinent. But I think that a thorough, comprehensive tracking and deliverables would be worthwhile for this strategic planning process in future years.

Mr. Blaxill: I just wanted to – David, on your point, you're absolutely right. I mean, the problem with this kind of exercise is it's difficult to do, you know, full allocation accounting on science. Science is connected. Some projects, you know, cover multiple things, and you should commission the projects to be successful, not to meet some artificial target. So, you know, it's naive – I mean it's tough to evaluate this output because it is a naive output. It doesn't embrace any of that.

I can tell you I've done a search on the CRISP database myself and have a good friend in the autism community who knows crawlers and screen scrapers, and you can take all this public information and download it. I can tell you you've missed some projects that at least show up as being autism coded, you know, if you use the CRISP database.

The issue is this is much more than–to do this right requires much more than simply, you know, totaling up to the $126 million that gets reported. It requires a sophisticated management of complex interrelationships, but at the same time, you know, a clear eye view of how much emphasis is going to autism and how much is being coded in the name of something else. That's where all the dirt – you know, the – what's the – devil’s in the details on all of this. And this is detailed at a level, but it's also – it doesn't embrace the true complexity of science and the difficulty of doing this. It doesn't have trend. It doesn't have connectivity. It's missing a bunch of projects.

And so if we're really going to have, you know, a view of what's going on with autism funding, where have we been getting results, where has the money been spent, and what can we expect in the future from a bunch of decisions we're going to try to make today, you know, we're not well informed right now. It's a good step. It's a first step. But, you know, if we really want a high-quality set of decisions coming out, we need, you know, a higher bar for the kind of information that we're operating with.

I don't say that to be unpleasant. I just think there's an issue of the degree of resource commitment that's required instead of just taking, you know, okay, I got $126 million and some coding and I'll distribute 350 projects in four categories. That can be hard to do, but there's a lot more that needs to be done that requires, you know, real intelligence and real hard work, you know, and I think that's still ahead of us.

Mr. Bell: I was just going to say – again, it's Peter Bell – this is not a problem that is specific to autism. I think every disease state goes through the same challenge, and you know, we participate in some consortiums with other disease states and so forth and so – cancer, Parkinson's, seizure disorders or whatever – they're all experiencing the same problem. And we are working, and certainly Geri can add on here after I'm finished, but we are working on developing a system where we can assess the success or the lack thereof of various granting mechanisms and grants that we award at Autism Speaks. And we're working with a lot of different groups trying to figure out what is the best way to do that, and I think it's something that we, as a community, should perhaps try to share.

I think, you know, this is a great start. It's a great way to start systematizing and looking at how we can divide up the kind of work that's being done in this community. I think the next step of the process is what are the measures of success? How do you calculate a return on investment for a grant? Is it because it gets published? Is it because it actually leads to something that then adds on to something else? Does it, you know – in the case of where we're doing pilot grants within a private organization, does it lead to public funding at a higher level and so forth?

There are a lot of different ways in which you can measure success, and I think that this is something that we have to work on together as a community. And I think the guiding principles are very well stated in that, you know, we need to have accountability. We need to have transparency. We need to have a spirit of collaboration. And I think this is a good demonstration of the fact that we're started on those things, and now it's just a matter of taking it to the net level.

Dr. Dawson: So this is Geri Dawson. Could I make a quick comment?

Dr. Hyman: Geri, sure, yes.

Dr. Dawson: Just to make sure I stay awake here in Seattle – so just a couple of comments. It does seem like we're talking about two different things, although they are related. One has to do with the distribution of funds across the different categories in the portfolio. And then the other has to do with impact analysis and planning.

But with respect to the first one, even though this is not perfect, I think one question is whether it still is a roughly accurate snapshot of the different priorities in spending. So for example – I guess I just lost my pie chart there–so for example, is it relevant that there is a lot more work being put into risk factors and biology than there is treatment? Or for example, if we did a rough coding, even if you disagree with some of the details of how much work is spent on Alzheimer's versus autism relative to the prevalence of the disease and the burden of the disease, do they match, and the burden of the disease.

So I mean, I think that the systems are not going to be perfect, but the question is whether we can get a rough but accurate enough picture to make some informed decisions.

Dr. Hyman: I think that's a really great point, and let me say to Mark and Peter, I mean, these are not at all unpleasant comments. These go exactly to the heart of strategic planning. I guess I would ask those here who are at NIH about two of the fundamental bases, at least of reporting spending, because impact, again, would require an enormous intellectual effort. But what is the timing – I mean, are there difficulties across the Institutes, of course who have their own trajectories, in coming to a shared definition? You mentioned the pilot year was 2007-2008?

Dr. Kau: Yes, just around this time–

Dr. Hyman: And what will be the tests of success besides agreement, and can the criteria be transparent?

Dr. Kau: I would think so. Lisa Gilotty and I were on a task force for autism grant coding, and we said it's a data you know, I'm not an expert in this area–what they do is they have computer software that reads the abstracts and maybe the specific end pages of the grants, and they pick up certain vocabularies, and that's the basis of grant coding. At least we will get a standardization of coding across Institutes, but is it going to be 100 percent, I don't think so. Because, you know, like – but we will have that. Hopefully, it will hit us at a high–I think when we did the pilot, we hit 99-percent correspondence, you know, between two of our codings. But we were told by the NIH that the coding standard can be modified always.

Mr. Blaxill: Alice, how does it compare to the CRISP coding standard?–because you do a search in CRISP, and it gives you a score. Is there any relationship to that?

Dr. Kau: I can't say that with absolute certainty, but the CRISP vocabulary base is where –

Dr. Hyman: So here's our deus ex machina, Dr. Hann, who's going to answer some of these questions.

DR. HANN: Thank you. Just to sort of pick up a couple of things. Yes, the coding that Alice was just describing is fundamentally different than what goes on at CRISP. The CRISP system will go away. In 2008, it will disappear. The new system that she's talking about will come online. We euphemistically refer to it as RCDC. Everything in the government, you know, has to have an acronym. And it will roll out. Alice and Lisa were instrumental in developing – in RCDC language, they refer to it as a fingerprint rather than a definition, because what you do is you identify key terms by which–and then the computerized will then use those key terms to identify grants that match. And it will only look at the title, the abstract, and the specific aims of the grant.

Mr. Blaxill: Will it do it

retrospectively? Will you reprobe your history–

DR. HANN: No.

Mr. Blaxill: – so you're –

DR. HANN: It will be going forward.

Mr. Blaxill: Oh, man.

DR. HANN: It will be going forward, so it will not be doing it retrospectively. Part of that has to do with our grant database begins to loosen integrity, shall we say, as one looks at the electronic database. All of those pieces are supposed to be together, and the information will be produced for reporting out the FY 08 information, which probably will become public around January of `09.

Dr. Hyman: So I think there is the answer of where NIH is going. I guess the issue is that it's prospective, not retrospective. Okay. Other questions? Peter?

Mr. Bell: Just to clarify. So we just have distributed the document that I was referring to earlier. This also falls into the same category as the Simons and the DoD. This is something that needs to be handed back at the end of the day. All the information is publicly available, but it's just how we look at it that we'd like to keep it within this group.

Dr. Hyman: A little lunchtime reading. Any other comments or issues? What–yes, Denise?

Ms. Resnik: I'd like to bring one up, and that is guiding principles, and that was the best way that the last sub-workgroup tried to organize ourselves in the absence of specific and measurable goals and objectives. And wrestling with ordering the 41 initiatives, it seems that perhaps some discussion about those guiding principles could be very helpful to get us on the same page in terms of how they're interpreted and how we can apply to setting our priorities.

Dr. Hyman: That's a good point. Shall we – do you want to hold that discussion for the beginning of the priorities piece? Now with all of the flaws of this being an early effort, just getting off the ground and having been done relatively quickly, I guess the question for when we get to the priority-setting exercise after lunch is what pieces of this are going to be most useful? Is it the pie chart? I mean, what is it that we should have in front of us, again, understanding that this is early? Ideally – I know Mark is disappointed – but prospective – I mean this will get better over time. What's going to be the most – is it the pie chart? I mean, what has the greatest utility for priority setting? Did you want to –

Mr. Foote: This is Steve Foote. I'll be leading the discussion about prioritization. What we had intended to do was devote the first 15-20 minutes of the time we have set aside for prioritization to getting the group's input about what criteria are important for determining priorities so that – for example, Prisca raised the issue – is it important, is feasibility important, is innovation important, is – you know, some of these other issues and dimensions of these initiatives.

So we will have a discussion about that issue if that helps you in this current discussion that you're having right now. And we could start with the principles, and we could then try to, if you wish, to move to things that are a little more concrete. For example, the issue of feasibility is at a little bit different level than the guiding principles are pitched at. So we are intending to have time to have a little discussion about this, of what should we have in front of us and what should we have in mind as we have that discussion, so at least we may not all be using the same set of criteria, but we will have a feel for where other people are coming from and why they might be developing opinions about priorities.

Ms. Resnik: This is Denise Resnik. And perhaps some of those concepts would be very helpful for IACC in establishing our objectives, because we need to create some aim. And our hope – my hope – would be that perhaps this input and what we discuss today on these criteria could ultimately see its way into specific objectives.

Dr. Hyman: I think we'll take that as a promissory note. We are actually on time, so the instructions for getting lunch, I take it, are to go and buy some and bring it back. Is that –

Dr. Chung: For those of you who would like to purchase lunch from our back counter here, Steve Foote is the bank, so you need to pay him. There's also a cafeteria on this floor if you'd like and restrooms as well.

Dr. Hyman: And we will reconvene at 1:00 o'clock.

(Whereupon, the Committee broke for lunch at 12:29 p.m. and re-convened at 1:02 p.m.)

Dr. Hyman: Now we get to the even more challenging part, and that's why we're beginning with you, David, to talk about the research initiatives that have come out of the workshops.

Dr. Amaral: Good. Thanks, Steve. Before I get started, I want to say that there is – there were several other people here who were at those workshops, so David was at a workshop and Martha and Isaac. I'm sorry? Sam was there as well and Geri, who we have to all look up to see Geri, was there as well. So all of you, please, as we go through this, just review, chime in if I misrepresent something or forget something, which I'm likely to do.

So just to get started, I think, again, the process was that each one of the workgroups had to struggle through lots of different initiatives, and then when the biology workgroup that I chaired, we had at one point in the meeting, more than 40 topics that we were initially going to consider. And that got winnowed down to 8 or 9 or 10 or something like that, and our initiatives came out of that. So there has already been a winnowing process.

Before I get into the framework for initiatives, the kinds of things that seem to me to be changing or the emphasis across all of the different workgroups are some of the following, and maybe others might have recollection of other global topics that they think were addressed. So one of them, for example, was community assessment, and community assessment was something that came across in different sessions. So the geneticists wanted to have an easier sampling tool to be able to do very large studies of samples out in the community, and there were questions about the validity of current diagnostic tools and how we might be able to get streamlined diagnostic tools. That will come up.

Biological markers came up across several of the different workgroups – again, biological markers as an etiologic tool. Biological markers as a tool for earlier diagnosis to get intervention started earlier was another thing.

Another thing that I was impressed by was lifespan. There was emphasis both on very early research–because some of the biological markers or some of the biological consequences of autism seemed to be happening, things like exorbitant brain growth, during the period 6 months, 24 months or so. On the other hand, there was an emphasis that we don't know enough about autism in adolescence and adults, both from what's taking place in the biology and the psychology of autism as well as, you know, how do you intervene, how do you treat, how do you support those individuals?

Another thing that came up was special populations – over and over again. This related, for example, to male-female. We don't understand the four-to-one ratio, and there's, you know, questions of, if we understood the male-to-female ratio, maybe we'd understand something about the biology, but also we may understand something about risk. Is there something protective about being female and not getting autism? We simply don't know. And so, again, through several workgroups, the emphasis was placed on putting more support and doing studies with female subjects, female patients.

But there are other special populations – underserved populations–issues about diagnostic tests being translatable and valid across different populations and making better use of populations that are purported to have lower or higher incidents of autism. Defining phenotypes or endophenotypes in autism came up. Both in biology it came up and genetics as well.

And then I think the last two things that are a big change from 2003 were that the whole issue of environmental factors, which was hardly mentioned in 2003, became a big topic, and it was one-half of the risk factors workgroup. Genetics was one, and the environment was the other. And then I think both in that workgroup and the risk factors as well as in the biology, the issue of immune factors in autism, again, was one that was heavily endorsed. And I think, in a sense, there was a sort of a lack of controversy but an understanding that this is an area that's important but we need to do a lot more research in it.

So, again, you know, in terms of prioritizing within these 41, I think it's going to be a difficult task. But those encompassing issues were ones that I think, you know, might help us think about this.

Dr. Hyman: So Martha?

Dr. Herbert: Thanks a lot. I have a process question, which is that, in reading over these 41 items, there's a great deal of redundancy or partial redundancy.

Dr. Amaral: Right.

Dr. Herbert: And so is there going to be a process–and there are also different categories of things. There are things that are more infrastructure related and things that are more substantive. So what's the process for consolidating and categorizing?

Dr. Hyman: So I think as was mentioned earlier, I mean, there's not only a certain amount of overlap, but there is also a certain amount of–let's say, fuzziness is a pejorative term, but you know, a lot of the priorities are, you know, not as sharp as they might be, which I think reflects an early stage of priority setting when you have a community get together, because by saying what's important, you're also saying what's not important.

And I think that, realistically, within the 2 hours that we have right now, which is clearly, as Mark pointed out earlier, hardly enough time to really come up with a Strategic Plan, I think we shouldn't – my suggestion to the group, unless you disagree – is that we shouldn't work to sharpen all of the 41 and eliminate overlaps, because I think then we'll spend all of our time on those tasks but rather against the background of the kinds of principles we're going to discuss, against the background of the pie chart, against your own knowledge that you carry with you, to see whether within categories some things are more important than others.

Now one of the things you said, however, is a category that I think we all have to take very seriously, which is not one of the six, and that's infrastructure. Maybe that's in the other, but it's really infrastructure and platforms, because I've asserted, without much discussion, and maybe there should be some discussion, that one of the goals has to be to get the most talented scientists into this field. And the reason people come into fields are not only because there is money and not only because there's a public health problem but also because they can successfully do their work. And so one of the things I think we should keep in mind is to have some sense of how important research platforms are and, in particular, whether there are good ones that would serve the autism community or not.

So that would be my advice. David, is that fair?

Dr. Amaral: Yes, I think that that's fair. And I think we'll see that infrastructure is actually built into a couple of these as we go along. So what I'd like to do is just, first of all, in the last workgroup meeting that was, I guess, the last meeting of the last workgroup, we were struggling to try and bring order to these 41 different initiatives. And I think it was Alison Singer who came up with this very lovely way of conceptualizing, framing the 41, and so I think these stand without much comment.

There was one issue that came up in the meeting that didn't get reflected in these questions as they are, and that's the issue of prevention. And it doesn't show up anywhere, and I think we might just–I would propose that we amend number three – what caused this to happen and how could it have been avoided or how could it have been prevented – and just send that along. Any questions about that or is that all right with people?

(No response)

Dr. Amaral: Okay, so Joyce, I think what we can do is, why don't we, in order to make this as efficient as possible, let's not go through the individual questions. Maybe we can go to the next slide.

So these are the kinds of background questions that go into each of the different sections. So this, for example, when should I be concerned about my child's development; what are the early warning signs; are there typical characteristics that are part of the ASD diagnosis; how much variation is there? So this is a human-speak way of talking about the topics that are itemized in the initiatives. But I think what we can do is just maybe fast-forward to the initiatives and then make sure that–and then as I understand – so now this would be the first initiative–when should I be concerned about my child's development, which was broken down into three subsections.

And again, I think you've all read these, but just to remind you of these, we'll just pace through them unless there's a question about this process.

Ms. Marvin: I just have a question about these categories. Are they sacrosanct? Do we have to take one out of each category? Am I drilling down too far? Is that a later question?

Dr. Amaral: Yes, so I've been told by Steve that the task of the group will be within each one of these groups to prioritize which are more or less important, not across the categories. So you're not going to pick category one or category two. There would be components of category one and category two that would go forward, and the goal of this group is to say within category one, these topics here, which ones do you think are the most important? So in this category, under number 1, there's, I think, 10 different initiatives.

So these three all are under the general category of streamlining screening and diagnostic approaches. And Geri, are you back on the line?

Dr. Dawson: Yes, I'm here.

Dr. Amaral: Okay. So Geri, please chime in, you know, if you have any comments as well. But again, I think the general issue here was that people know that there are “gold standard” diagnostic procedures, particularly within research universities. But there was the notion that we have to do things faster in order to get large population studies being done, and then we have to ensure that the diagnostic approaches, which I think is (b), that they actually can be ported to the community with efficacy.

And then (c), then this component of it, the issue of looking for quantitative diagnostic procedures that could actually be associated with biology, things like looking at genetics or other biological markers. So the current diagnostic instruments being non-quantitative, it's hard to correlate severity, for example, of any of the symptom classes with a biological marker. And again, there was a lot of discussion around having better and more quantitative diagnostic procedures. Any –

Dr. Dawson: Just a comment there. I think the other point with –

Dr. Amaral: Geri, you have to talk a little louder. Don't hang up. Sorry about that.

(Dr. Dawson disconnected)

Dr. Amaral: Anybody else have comments about this particular or remembrances about this particular item?

Mr. Bell: I have a question. Prior to the last time the original strategic planning workgroup got together, there was a ranking that was done by that group. Is it at all helpful to revisit and see where those rankings came out?

Dr. Chung: Let me speak to that, Peter. This is Joyce. That was really when we thought we were going to prioritize there. We didn't have a framework like this then.

Mr. Bell: Right.

Dr. Chung: And what we noticed without, you know, really going into the details was that certain things really didn't get very highly ranked but were very important, and so like a whole group of something in a question domain here might have been on the very bottom. So we thought that, to get better coverage, it would be just sort of ranked within these areas.

Mr. Bell: Look at it again with this –

Dr. Hyman: Yes –

Dr. Chung: We're not using them –

Dr. Hyman: – as we talked about it this morning, this is the orphans issue, so treatments for adults with autism kept, apparently, falling off the radar, even though there's very little research. And so I think that was the logic for why you divided things up this way.

Dr. Chung: Right.

Dr. Amaral: So there are a lot of issues then within diagnosis, streamlining, community validity, community measures, quantitative aspects of it. And again, each one of those is important in their own right.

So why don't we move on to number two. So these – and I should say – the other thing I forgot to say was that these did not come out strictly from each of the four workgroups. So there are six topics. And what's happened is that oftentimes, as I mentioned, biological markers came up in several workgroups. So then they were just put under one of these topics. So in a sense, sometimes when there are redundancies because there was just slightly different emphasis on a particular topic coming out of two workgroups, they've still managed to find their way into the five or six topics per question.

So in terms of biology, again, there was a strong emphasis on studying very young infants to try and get at the etiology, birth to 3 years. But then there were also issues about studying fetal life as well. That came up through the discussions.

I'm not sure – if I give a little summary of each one of these, it's going to take a long time, so Joyce – I mean how much input do you want at this point?

Dr. Chung: Well, I think if we go through this quickly – people should have read over this.

Dr. Amaral: Yes.

Dr. Chung: And maybe there are questions about individual initiatives that don't make sense or they don't understand. So maybe we could move through this a little more quickly.

Dr. Amaral: I think that that would be good. So in terms of biology and risk factors, are there any issues or any vagaries or–here, again, gender differences have come up. And here's an example, if you just go back one, Joyce, an infrastructure issue was the post mortem brain and tissue acquisition. That was really an issue to do a national or international database of post mortem brain material.

Dr. Hyman: Mark has a question.

Mr. Blaxill: I have a process question, which is – let me phrase the problem and then ask for guidance–we have information cut a number of ways. We have some 41 proposals that we're being asked to prioritize. We're being given a framework within which to vote. I guess there's some kind of voting mechanism in which we would register preference. We have information on the past year's spending, which is a portfolio question that doesn't match–we have dueling frameworks. We have different frameworks for the portfolio investments and the prioritization of the future investments. And it's not obvious that we have a mechanism for registering an opinion across categories in terms of, you know, the portfolio distribution, not just which projects.

So I'm pretty confused about what the decision we're being asked to make – the decisions we're being asked to make. I know which ones I'd like to make, but I'm not sure we'll – I'm curious how the mechanics will work.

Mr. Foote: We will have a discussion of that, obviously. So let me suggest that we finish this part, and then we'll launch directly into answering those – discussing those questions.

Mr. Blaxill: So the framework is going to guide – this framework will guide decisions that we make? Will we be making –

Mr. Foote: Yes.

Mr. Blaxill: and prioritizing within the six areas?

Mr. Foote: Yes.

Dr. Amaral: No. Is that right?

Mr. Foote: Within, yes.

Dr. Amaral: Within each of the six areas, not across the six areas.

Mr. Foote: Right, that's what his question was. He said, within the six areas, and I said, yes. I said, we'll be within the six areas.

Dr. Amaral: Okay.

Dr. Hyman: I think one useful – outside of the prioritization, and I think part of the utility of showing at least the prior year's investment would be for the group to say, just as an advisory matter, “x” looks woefully unfunded given the opportunity as a large category. And you can take that information back. Right? That seems fair?

Mr. Foote: Yes. Part of the process would be then to discuss the process also, so, and that's the question you're raising–is one of what the paradigm is for arriving at these priorities and what your comments then are about that paradigm. That will be part of what we do.

Dr. Hyman: Any other questions? Yes.

Dr. Pessah: Isaac Pessah. We also should keep in mind that some of these questions – for example, streamline screening and diagnostic approaches seems to be not at odds but inconsistent with developing better phenotyping so that you can then take it back to the geneticist and substratify. So we need to keep in mind that we have to have a more integrated approach amongst these.

Dr. Amaral: Well, I think that's a good point and, actually, I think it comes out of all the initiatives that streamlined screening has one purpose, but it actually leads then to genotyping that might actually find more homogeneous subtypes of autism. Then that should be subjected to more extensive phenotyping and more extensive diagnosis. So in a sense, yes, you can't take just streamline screening and diagnostic approaches and leave off detailed phenotyping, I guess. It'll come up later on, so your point's well taken. It's – and again, in two hours, it'll be difficult to try and deal comprehensively with all those potential conflicts.

Dr. Dawson: I'm back on the line. Just a comment about that last comment. This is Geri. I think that what you see there is that in the area of genetics, there are many different strategies for gene discovery, some of which might involve very large samples and form lighter phenotyping and another strategy that would involve smaller samples of very deep phenotyping. And we don't actually know which strategy is going to be the one that's most successful, or even more likely, we'll need both strategies. So I think that what you're seeing there is a reflection of the fact that we're still at a pretty early stage in understanding the best way for gene discovery, and so people want to do both.

Dr. Amaral: Right. Thanks, Geri. Okay. So why don't we just quickly go through. So we were in the first, and then here's the issue of heterogeneity. Again, there were a couple of guiding features of autism that we started right from the very beginning of the workgroups. One was trajectory, changes over time. And the other one was heterogeneity. So out of the biology workgroup, issues of heterogeneity came up over and over again.

Numbers three and four there, I think there was an appreciation that genetics or the tools that we have for genetic analysis have gotten faster and cheaper so that doing things like array base, array CGH in order to find known genetic malformations that are predisposing to autism, something that 5 years ago was just too costly to do, but now the notion that every child diagnosed with autism could have an array CGH in a reasonably cost-effective manner.

So the idea, number three, for example, was that you could do that with all children with autism, find that group that has 16 key deletions, and then do extensive phenotyping of that particular genetic phenotype.

So number three and number four were two that are linked, the doing more extensive genetic screening initially and then doing extensive cognitive analysis only on those subgroups that come out of the genetic analysis. Let's move on.

Okay. So what caused this to happen and how could it be prevented – this came out of the risk factors. And so, again, as Geri was saying, many of these initiatives are that there are a variety of different ways of finding genes that are associated with autism. Some of them are actually trying to take advantage of existing large surveys of individuals, not necessarily with autism, but samples, for example, through the National Children's Health Initiative and so to dovetail with those.

And number five, for example – so these are all more related to environmental factors. Isaac, do you have any global, generalizing comment about these five factors, or do we have to leave them as they stand?

Dr. Pessah: Only what I suggested at the workshop that any epidemiology-based study, even gene-environment interaction, is, by virtue, an extremely expensive endeavor, and typically ends up with a lot of samples that are underutilized by the biologists, the toxicologists, and the chemists, and so there needs to be more effort on doing things with the samples in a timely fashion, analyzing them.

Dr. Amaral: Thanks. Let's move on. Okay then, practical issues not in terms of treatments of children that have autism or individuals that have autism – and again, lifespan issues were very important. Again, all of those reflect the fact that we need to be dealing with intervention at different ages. Go on to the next one, please.

And, you know, I mean my sense of this was that we're really at the very beginnings of trying to understand treatment, biomedical treatments, at least for the core features of autism. Here's an issue where animal models were discussed primarily in the biology section, but looking, for example, at genes associated with autism, plugging them into animals and looking at the phenotype, and using those as targets for treatment was something that was highlighted. And then fast-track mechanisms – again, this, I think, needs a little bit of–this is – even anecdotal findings could actually be brought into more rigorous scientific evaluation and brought back to the clinic as quickly as possible. One thing that didn't get put into the verbiage is single-case studies and how single-case studies can actually influence thinking about possible treatment outcomes. And I think that all got subsumed under fast-track mechanisms. Next?

And again, biomarkers, peer biomarkers,

meaning why do some treatments work in some children or individuals and don't work in others; how can we be more predictive; how can we be predictive before treatment is even started? And again, it gets back to the whole issue of developing better biological markers. In novel treatment for core symptoms, there was, in a number of these initiatives, the sense that we can treat some of the comorbid features – anxiety, gastrointestinal problems – and actually more effort should be put into that, but there's really still not a lot that is available for treatment of the core symptoms.

Services, Sam, I don't know, maybe it would be better for you to just look at these and see if you can capsulize them if you don't mind?

Dr. Odom: Thanks. Lu may be a better person to–

Dr. Chung: David Mandell did a lot of these, so maybe –

Dr. Amaral: Okay.

Dr. Odom: I was actually on a different Committee, but I will make a pitch since I have the microphone.

Dr. Amaral: Sorry, sorry.

Dr. Odom: I think there is a considerable interest in the field about how to move science into service in an emerging field, both in education science and mental health, of implementation science as a legitimate area of inquiry. I think these may reflect that to some extent, how one moves into the community, out of the laboratory, out of the clinic.

Dr. Amaral: David or Lu?

Dr. Mandell: I thought that was a good summary. I think the only thing I would add is, I guess, Denise, I appreciate your suggesting we put the values in front of us, because it also gets to the issue of urgency and in thinking about how we split our resources to think both how things get developed in a lab but also how they both get developed and implemented in a community. And I think the treatment group, sometimes we might have referred to ourselves as the "everything else group," because there was a lot of stuff thrown in about services and policy, but the idea was to think about that along a continuum and make sure that we didn't leave out any of the parts that would ultimately lead to treatments and appropriate educational interventions getting implemented quickly.

Dr. Dawson: Yes. I think part of what we were trying to do with this section is to provide something for research that would allow for better policy formation, for better advocacy, for insurance coverage and just, in general, to take treatments that have known efficacy in research-based settings and to translate them into wider community settings.

Mr. Eiken: This is Steve Eiken from Thomson Reuters, and I'm not sure I'm saying this at the right point, but I figure I'll throw this in at some point. But when I look at this section in particular, I think about what's happened with other disability groups with the Medicaid program where a research funding source in one or more states can work in partnership with CMS in terms of having a practical research-based model. The one that did this most vividly is the Cash and Counseling Demonstration for self-directed care for people with physical disability. We had double-blind tests and people enrolling, and it was Medicaid funded, so it serviced the treatment for the – the funding for the actual services came from state and Federal sources.

So I mention that mostly as a way of stretching this part of the dollars. You know, there's an opp to stretch these dollars further. And also, a lot of the adult services are provided through Medicaid. I think some children’s services are as well, but this is especially true for adults. So it would also facilitate getting that research into practice, because the states tend to talk to each other. So getting one state on board can facilitate this.

Dr. Zeph: Yes. Just having been involved with the original IACC group, we did a lot of work through a services Subcommittee there and generated what we though was a matrix for looking at services, and I'm wondering, as I look at this, how those things relate to one another and whether or not what we're looking at here might also have – some of the answers may go back to some of the work that was done earlier. It seems like 5 years of work teasing out some of these questions and having some of these discussions might have some solutions that have been a little bit more thoughtful than us having to do this kind of in a vacuum at this point.

So I'm wondering if there would be a way to look at some of the findings there and to draw some correlation here that could provide some guidance, not at this very moment but as the decisions are being made.

Dr. Amaral: No, I think that's a very good point, and, you know, I gather that for this whole Strategic Plan, we're going to have to pull from other resources as well.

So there's one more group, and that's "what does the future hold?" And again, just to put on the table that this stressed the idea that there's a lot of uncertainty in the community about what's going to happen to children with autism as they grow older, not only in terms of their issues, their medical problems, but services that are going to be provided to them. And there just isn't a lot of data at the moment on what families can expect. And so a lot of the issues here are following individuals throughout the whole lifespan, and again, you know, here's again a sort of a – it's a conflict, because if you're trying to understand the etiology of the disorder in order to get to prevention, early intervention, you want to put resources early on in life. But there are a lot of individuals who have autism. You want to deal with them as well, and you want their best quality of life to be foremost as well.

You know, where do you apportion resources to both of these? And there was a lot of discussion about this during this session. And again, I think the issue is that the workgroups didn't want to leave anybody out. There can be complete lack of support for areas, and I guess the challenge will be to try and decide where a limited amount of resources is going to go to the entire effort. Anyway, so that was a little philosophy there.

And then, again, the last thing that if we're trying to understand what's going to happen to these individuals in the future, there is a lot of information, state databases, databases like IAN, CDC/NIH registries, and we need to take advantage of that data right now and see what it gives us and then try and figure out how to best capitalize on data input that's going to be happening over the next 10 to 20 years to be able to answer some of these questions. So again, there was a real sense that we have to pay attention to individuals with autism throughout their lifespan.

Dr. Hyman: Lu, you had a comment?

Dr. Zeph: Just going back again to that services piece, one of the things that I thought was most helpful in that process in terms of giving us framework and answering some of these very difficult questions related to using some kind of a sorting system that looked at things from a more universal design perspective in terms of what was going on. And that is what is going on; we know that is true of all people, all children, all adults who are in need of lifelong supports; what do we know about specific disability populations; and then what do we know about specifically for kids with autism throughout their lifespan? And by doing that, it allows us to look at some of the interplay and overlap that happen, and what already is out there that may be successfully supporting and serving the population throughout the lifespan but may be being delivered under different names.

So the earlier comment around CMS, for example, CMS does provide a lot of supports to individuals that require lifelong supports.

Many of those have proved to be successful and cost-effective over time. They are, in some cases, being applied to individuals with autism, but we haven't been able to really kind of find out what is out there and working in a way that, because it's integrated into other subpopulations.

So I'm wondering if, again, going back and looking at that framework and looking at how some of those questions were asked and begun to be sorted out, I think gives us a more universal perspective of what is out there for services support and quote, treatments that will benefit or are currently benefiting individuals with autism and their families throughout the lifespan. So I feel like we've got a piece of the picture but not the whole thing, and we tried to grapple with the whole big picture at that point to answer some of the questions that I don't think we'll be able to answer otherwise in this time period.

Dr. Dawson: This is Geri, and as chair of the treatment section, I just want to say it would be wonderful to look at that document and to benefit from it. And I'm sure that there is a way to take advantage of that in this process.

Dr. Hyman: Denise?

Ms. Resnik: David, I had a comment–this is Denise Resnik – something that you said in terms of, you know, what end of the lifespan do we deal with and, you know, do we really have conflicting interests. But truly, when we look at the adult population with autism and the comorbid issues that seem to arise later in life, obviously, it's empowering other areas of study further. I think it could be incredible for our enrollment in the autism that, you know, when you have a child, you're not always thinking in those terms but as an adult. So truly, it will empower, you know, research that will help the other end of that spectrum.

Dr. Amaral: So I agree with you, absolutely. I wasn't trying to pit one against the other, but you know, in terms of resources, you know, there's a rationale for why you might bias your effort toward one end versus the other. But I agree with you – there are benefits along the entire lifespan.

Dr. Zimmerman: Andy Zimmerman. Will there be an opportunity to expand on some of these portions here in the next session, or should we do it now?

Mr. Foote: This is Steve Foote. I think the general strategy is that as we go along through these, rather than trying to rewrite or edit initiatives as we go through the process; we have a transcriptionist. We're keeping track of all this. And your comments about what could be altered within initiatives or generating a new initiative, we will keep track of. That's part of the feedback to the IACC, and we will do that. So your comments are welcome, yes. But I think we won't try to incorporate them on the fly right now.

Dr. Shore: I'm just thinking back to the four-to-one ratio back in the genetics area.

And the question I have is, is it really four-to-one, or is there some way to identify, at least what I perceive and many other people perceive, as females that are flying under the radar?

Dr. Amaral: Maybe, Geri, can you address that or answer that question?

Dr. Dawson: Well, I am not aware of, you know, any systematic bias in, you know, acquiring samples, but I do think that there has been–you know, as we have new populations of kids being served, that we have to be very careful about documenting the ratio, and there has actually been some discussion of late of whether the ratio might be changing. Maybe even more importantly is whether, as we identify different subtypes of autism–because I think we'll all agree, you know, autism isn't one thing, but it's probably many, many different diseases with different etiologies and will require different treatment, that kind of understanding in a careful way how to track the differential male-female ratio, I think, will be really important to understanding mechanism.

The only other point is that I do think there has been some tendency, not necessarily in, say, large diagnostic screening epidemiology studies, but rather in targeted studies, to sometimes exclude females, because there are, you know, few of them, and so it makes analyses complex. So for example, in brain-imaging studies, because there are male and female differences, you often have small numbers of females, and the subgroup is not large enough to do meaningful statistical analyses. And so I think that is kind of a serious problem that we could be strategic about so that we don't really miss a really important piece of what might be a clue to mechanism and treatment.

Dr. Amaral: So just to finalize on that. So in the initiative, to look at the underlying basis for the four-to-one ratio, it actually discussed screening procedures to make sure that we're not missing girls that have autism but may have a different phenotype or, you know, for whatever, personality issues or whatever else, we're missing diagnosing them as well as looking at all the biological features. So that's a comprehensive approach to trying to understand that population.

Dr. Herbert: Just one other thing on that list is that's also an infrastructure or platform issue in order to facilitate collaboration across centers.

Mr. Foote: Okay. Thank you. So let's try to develop a little bit of context here and a little bankruptcy trustee of discussion about the process.

So in undertaking this exercise, we've gone through this framework that we've built for these initiatives. I think, harkening back to Peter's comment earlier today about, well, what is it that we are doing and if we had a vision and a large framework that we were kind of working toward that would help us determine where pieces might go if we know what the groundwork was, well, I think for the time being, it's reasonable to treat this framework that we've been using of when do I need to be concerned about my child; why did this happen to my child; what can I do to keep it from happening again in the future, that these are our goals–is to be able to answer those questions. Those are the big overarching themes that we're working toward.

Then we have, as you'll notice in your materials, we have sub-questions under each one of those overarching themes that lend an additional layer of specificity to the initiatives and kind of cluster the initiatives within even smaller groups than the six themes. And we have also, kind of on a parallel track almost if you will, what you have in hard copy in front of you, which are the principles for the Strategic Plan. So those are kind of along a different dimension – urgency, spirit of collaboration, consumer focused, excellence, partnerships in action, and accountability.

So we have this big Roman numeral outline of big chunks, slightly smaller chunks, and so on. Then we have these motivating and guiding principles to help us in inserting things. Now we're going to undertake step one of the specific prioritization process, which is to discuss and develop criteria for prioritization at a little bit finer grain level. And we've already had some discussion of what those criteria might be, and we'll have some added discussion now so that you can express your opinions about what's most important. I mean, for example, we've discussed the issue of cost. That's one thing that helps decide these things. Prior funding history for the area might be – or current funding for the area – might be another kind of criteria to consider. Feasibility is another issue – those kinds of issues. I think if we talk a little bit about those issues and how important they are, or non-important they are, that will help also people's thought processes as they prioritize here.

Then we're going to prioritize within

each of these six domains. One at a time, we'll march through them. The purpose of doing it that way – there are several purposes – but the major one is our goal, is to provide feedback to the Interagency Autism Coordinating Committee. And by kind of chunking these within this framework, which the IACC has adopted and approved – this question framework, the IACC has said that looks good, that's the way we ought to do it – so we'll chunk under each one of those, and that will allow us to focus on five, six, seven of these things at a time and make relative priority judgments among that subset.

Now that doesn't mean necessarily that that's the only thing the IACC is going to do with that information, but we will be able to provide them then with that information all the way across all 41 initiatives when they're considered in smaller groups.

The way we're going to do that is each of you will have a ballot for question number one that lists the initiatives, and you will make two decisions. So let's take group number one. You will pick three initiatives out of there that you think are, relatively speaking, deserving of a little more emphasis than the other initiatives in that group. So that's one decision, kind of a binary decision, a go, no-go decision.

And then you'll make a qualitative decision – I mean a more quantitative decision, which will reflect the degree of your enthusiasm. You'll have 100 points, and you can distribute those 100 points among those three that you've picked. And you can do 50, 25, 25. You can do 98, 1, 1, whatever it is in terms of how you view the relative importance once you've picked those three. And we'll do that for each group.

There's one additional step that we'll undertake if we have time before we get to number four here, because I think this has come up a couple of times, and we really want to do this, that is, after we finish this voting process. I think it would be a good thing to get people's opinion about what the strengths and weaknesses are of doing it that way so that we can communicate that to the IACC if you have reservations or if you have comments that you want to make about the kind of information that's being produced by this protocol.

Then we're going to go off and do our other major item of business, which is to discuss budget issues. And while we're discussing budget issue, we will also be tallying the results of this scoring process so that then, after we finish the budget discussion, we can come back and give you what the results of the scoring exercise were, and we can have a little bit of further discussion about how those looked to you and what you think those mean.

And then, of course, all of this information will be forwarded to the IACC for their May meeting so that then they can take this substantial amount of information and try to further digest it and give us their instructions about incorporating this into a Strategic Plan.

So, this is our colleague, LeRoy Thomson, who's our strategic planning consultant, and he's going to be doing some scribing here. You all have this, and you have your initiatives and the titles and so on in hard copy in front of you and the budget material. And right now, let's do talk some about criteria and what people think are important factors to keep in mind when doing your scoring. So the floor is open. Denise?

Ms. Resnik: This is Denise Resnik, and I have one, and it follows on what Mark was sharing with us earlier and some of those concerns. And that's the return on investment in terms of prioritizing and funding infrastructure and capacity-building initiatives, those that will have direct impacts on individuals and their families and ultimately lead, of course, to effective treatment and approaches. But the idea would be that, you know, since significant dollars are already being spent and have been spent, that having that kind of information to know where we can build and get that much farther because we are leveraging an existing investment could be very beneficial to the prioritization. Does that make sense?

Mr. Foote: It makes sense to me. Mark?

Mr. Blaxill: I have just two things I'd like to throw in, and I'll apologize in advance for mixing up item number five a little bit, because it's sort of tough to talk about criteria without, you know, offering a little bit of a critical assessment of, you know, the way we're being asked to prioritize. Two things. One is on the spirit of the sense of urgency and the guiding principles.

I think, and again, I don't speak for everybody, but there is a widespread sense among many in the autism community that we need change, to pick up on the theme of the Presidential campaign, we need change and we need it rapidly.

Mr. Foote: But it would be interesting to know what you mean by that.

Mr. Blaxill: Personally, I think we ought to have, and I feel bound by the obligation to support investments, you know, in a status quo sense across all the buckets, because the six categories are basically diagnosis, biology, risk, treatment one, treatment two, and then a new category which is the future. So you basically adapted, you know, the workshop frameworks in a consumer-friendly language, but it's not that much different. And so what we're being asked to do is sort of support the status quo in four broad areas.

Personally, I don't support the status quo. I think we need a rapid change in order to achieve a different result. It's important to note that, you know, we're 15 years into the epidemic problem, we're dealing with a tsunami, and we don't know anything. We're not making any progress is my view. I think I speak for a lot of parents who are unsatisfied with the rate of progress that we're making, and I know that's overly harsh in some respects. There's a lot of progress in some ways, but there's a degree of dissatisfaction with the progress, and in particular, dissatisfaction with the degree of investment that's going into some urgent areas. And I would emphasize, too – you know, the environment and treatment, and a lot of us would like to see much more investment.

And in order to affect that change, to affect a meaningful investment in those categories in light of all of the past, you know, commitments, recognize that whatever decision gets made in 2008 is going to affect a minority of the research portfolio. So if we effect change rapidly, we've got to make huge change. It's like turning a tanker. You've got to crank, you know, the steering wheel enormously and even then, you're going to move slowly.

So if we're going to have a sense or urgency, we need to recognize, you know, the degree of leverage we have in any calendar period to drive change. And it's relatively small. And so in order to drive a large amount of change, you have to drive–and even, you know, a disproportionate amount of change in a short period of time. And so on the point of the sense of urgency, I think that's a concern, particularly if you believe that we ought to have reprioritization across the items. That's point one.

Mr. Foote: Okay. So let me make two comments before you move on. So I didn't hear anything new about criteria, but I did hear because urgency is one of the points –

Mr. Blaxill: I'm going to move to criteria next.

Mr. Foote: Okay, now, but you made remarks that I would say are relevant to two issues. You talked about risk factors, so now when we have our vote within the risk factors category, there will be a chance for you to express your priorities within that category. That's one issue you raised.

Now the other issue you raised, I think, is really going to be relevant to the budget discussion, because what you were talking about was how resources are distributed across these big categories. And one opinion you are expressing is that there ought to be a relative shift in how the priorities are distributed across those categories. And so that, to me anyway, is an issue that is an issue that is relevant for the budget discussion that we're going to have right after we finish this.

Mr. Blaxill: It's relevant there, and I confess that I am jumping to question five. But I also think there's a larger issue, which is we not only need prioritization, we need a reconceptualization of the problem to deal with the external reality. And the way that we're framing this discussion is we're sticking ourselves into old conceptualizations. And I just want to register that point, and I don't think that's a sufficient degree of urgency to address the problem that we face.

The second point I want to make is just

coming back to return on investment. You know, it's very difficult to have a discussion about return on investment, because we want to make high return on investment choices, when we're censoring information about the productivity of past investments. And again, past investments don't always predict the productivity of future investments, but for example, we have had an extended investment over a period of years, hundreds of millions of dollars most likely, into, you know, a particular area of research revolving genetics and genomics. I would suggest that that has not been a high return on investment, that we don't have – we don't know much more.

And I'm not saying these were wrong decisions to make given what we knew at the time, but if we reflect carefully on what we've learned and what progress we've made, there's very little in the way of results. And if we even ask the question if we learned something, what would we do about it – Would we help children? Would we get a return on investment for the populations that we're talking about? I don't know. I have a hard time understanding the path from here to there.

And so as a parent, you have a shorter time horizon, I guess I'd say, for the return on investment. And I would think the return on investment ought to be an important thing. We ought to critically evaluate the performance of research areas, and we ought to consider in the return on investment the discount rate, which is, you know, what's our time horizon for when we get a result? And I think that ought to be a criterion. So, enough said.

Mr. Foote: Okay. Are there contributions to the criteria discussion here? Prisca?

Ms. Marvin: Okay. So this is my own personal bias, but I think these longitudinal studies are just – I know they're very valuable, but I think we're just not a good country for them. And I think they're better in small nations with compliant populations who don't move around a lot. And so as a rule, I'm not a big fan, so I'll let you guys know that.

And the other thing that I like is I like potential initiatives that can attract or that just – that do not impact just autism, and I say that in the context of the fiscal realities of the NIH or nightmare of the NIH at this point. So those are my two priorities.

Mr. Foote: So generalizability of results to other –

Ms. Marvin: I'm thinking in terms of the attractiveness of, you know, getting other organizations to help do a collaborative type of effort.

Mr. Foote: Okay. Martha?

Dr. Herbert: It's interesting the way the point system is set up. It allows you to say the things you like but not the things you don't like in that you say nothing. And this may be a bit complex, but you could, in theory, have a point system that you have 100 points in absolute value, and then you put in pluses and minuses, and so long as the absolute adds up to 100 percent, you're then prioritizing. It's probably too complicated, but I just want to point out that we really only have one way of registering it at this point.

Mr. Foote: Yes, we're aware of that. Okay. Other comments? Andy?

Dr. Zimmerman: I'd like to make a picture of studying human beings. There seems to be very little emphasis here in the initiatives on actually studying children from a medical, neurological perspective, particularly intensive studies early on as well as in the baby sib studies. I think that that's important and hasn't been given adequate strength.

The other area is looking at cells from the patients and setting out cell studies where you look at different cell types from the same individual and compare them with the idea of having an infrastructure to have cell banks available, because a cell can represent many different aspects of the organism and could lead more directly to, I think, an understanding and treatment initiatives that you're talking about.

Mr. Foote: So in -- David do you want to say something? I was just going to say so are you–is your position that that enhances clinical relevance?

Dr. Zimmerman: Indeed.

Mr. Foote: Okay.

Dr. Amaral: So I agree with you, Andy, that looking at human patients or subjects is – but I just want to emphasize that it did come out in the–yes, so, you know, for example, this multidisciplinary longitudinal study of infants with autism before age three was really looking at, you know, kids at earliest diagnosis and following them on. And I guess I would take – and I understand your concern about longitudinal studies, although families with children with autism are incredibly motivated to participate in these longitudinal studies both at, I know, a number of sites around the country. So we're dealing with a unique community, a very highly motivated community.

And I would hate to slow the momentum of these longitudinal studies where we're finding the trajectory of changes in, for example, brain growth, probably the most clear-cut diagnostic marker that we have at this point in time. To say we're not going to emphasize that and sort of port that off, you know, to some other country.

Mr. Foote: Ed?

Dr. Trevathan: Yes, I echo Andy's interest in studying humans and also fully acknowledge Prisca's concern about the difficulties of in-out migration for longitudinal core studies in our society. Just to make the point, though, and I certainly agree with David, too; I think this is an unusually motivated population. I think most of us realize this. That said, one of the things that we're all interested with longitudinal core studies is also to have a representative sample of people who are really representative of the general population, including some of those who may take a lot of work to be motivated, some of the underserved folks. And so I fully acknowledge it's a lot of work, and it's expensive.

On the infrastructure issue that's been raised, however, it's worth pointing out that some of these longitudinal studies can provide the infrastructure under which many of these other human studies can be subsumed that are on the list. And so from an infrastructure point of view, some of these cohort studies can be very valuable for doing a lot of things other than just what the cohort study says.

Mr. Foote: Great.

Dr. Hyman: I just wanted to say one thing. I wasn't going to – I'm not going to say much about content, but in talking about return on investment, there's one risk that I saw as an Institute director for a long time, which is the issue of high-risk/high-return research. I mean there's also a way of thinking, with part of the portfolio, like a venture capitalist where you actually expect most of the things you invest in to fail. And I'm particularly worried about it because when money is dear, as it really is at the NIH now, feasibility, which is important – we don't want to reach for things that are clearly not feasible – but feasibility tends to dominate impact and certainly tends to dominate risk-taking in these study sections. And in some ways, this dovetails with a point Mark was making.

But I just think we’ve got to be careful about return on investment dominating thinking in such a way that we're not going to incentivize risks.

Mr. Foote: All right. Sam?

Dr. Odom: I wanted to just make a comment on leveraging initial investments and also a comment on the values that are part of the IACC. Even though the Combating Autism Act focused specifically on NIH, it seems like there are a couple of these initiatives that also happened in other parts of the

Government, particularly the one around service. So if one thinks about leveraging initial investments, it might be a nice strategy to think about how one might leverage those investments with other organizations, too. And I know it's maybe not the most common thing to do, but there are precedents of having interagency competitions and supports that may address those, so just wanted to get that into the record.

Dr. Tait: This is Fan Tait on the phone, please? Hello?

Mr. Foote: Go right ahead.

Dr. Tait: Okay. Thank you. I just wanted to agree with what was just said. As I was making my notes, I was thinking in terms of the core values and one of them being the collaboration, and I think, though, we've just received recently and we now know more about the funding for different grants already. If you look at, particularly at the Federal level, a lot through HHS, of course, and Education, but also, I'm just thinking in terms of some of the maternal and child health grants that could be leveraged. So I think as we're thinking about the criteria, I think it is important to know what's already been funded and key off of those. What you don't want is for us to be repeating efforts, particularly at the Federal level but also at the state levels. And I would agree with the concern about generalizability of results whenever possible. Thanks.

Mr. Foote: Thank you. Yes, Denise?

Ms. Resnik: Two or maybe three comments. So we've just heard about leveraging resources. Also, David, you spoke earlier about the diversity of the population. I want to make sure that's reflected in the criteria. I don't see it up there right now – diversity of population in terms of age as well as heterogeneity of the disorder. And then when you were talking about risk, Steve, absolutely to assess this not only according to our six questions and the diversification of the portfolio but also risk. And that at this point, where other areas maybe haven't produced in the past, we, I believe, need to be taking some risks in some new areas. But that needs to be balanced in terms of how we look at the portfolio of investments.

Mr. Foote: Martha?

Dr. Herbert: One issue in terms of leveraging is platforms and infrastructure and with a greater interest in environment and treatment than in the past. In particular, we have a genetic repository. We don't have a tissue repository. Of course, it raises the issues that Isaac brought up of you can collect these samples, but if you don't have the money to analyze them, that's a problem, too. But I think that we should be marking, as we go through, these areas that are of particular importance and that would be amplified across multiple proposals if they were in place and would allow other proposals to be more efficient and cost-effective and effective and productive.

Mr. Foote: Right. So you're talking about a gap in resources –

Dr. Herbert: I am.

Mr. Foote: – that can be highly leveraged in the future.

Dr. Herbert: That's right.

Mr. Foote: Mark?

Mr. Blaxill: I just want to pick up on something Steve said, and it doesn't necessarily fall into the criteria bucket, but it doesn't fall into any bucket, and it's worth saying. It's important to recognize that the way autism and all scientific research funding is organized, there are relatively small number of buyers who spend all the money. In economic parlance, I think you call that an oligopsonistic market structure, and one of the things that happens is you don't get venture capital behavior. You don't get risk-taking. In fact, you get a reversion to the mean and the politically correct, which I would argue is a big part of our problem.

And you also don't get, often, sophisticated thinking. And one of the things that we've heard a lot from – I mean the parent community hears a lot from scientists who are interested in risky investments – is that, you know, the NIH review process can stifle innovation and can shut down, you know, some of the more risky ideas – and so mechanisms to, you know, encourage innovation and risk-taking in appropriate ways, like special interest panels – I mean there are a whole range of things that we hear about that operationally could be a big part of a better execution, a better return on investment regardless of where the money's spent.

I think this notion of risk – different ways to review grants, all sorts of horror stories about wonderful grants that haven't gotten funded that all of us would look at and say, boy, that's a really important thing and that really needs to get done. I've heard a number of those. And so the oligopsonistic behavior should not be stimulated. It should be inhibited as much as possible.

Mr. Foote: So that issue has arisen in

other discussions as well, and just a note, it's also relevant to some of the previous points. So our vision right now and Tom Insel's vision right now is that when we get a wrap, even on the first substantial draft of the Strategic Plan, we have to think about implementation and that among the various funders and so on, we are going to have to figure out a way to have this strategic plan have impact.

And part of it – I think part of the consideration–is addressing these kinds of issues where we do have the advantage of having multiple funding sources, each of which has its strengths and weaknesses where we could have considerably more flexibility about mechanism than we currently have. And the Strategic Plan can add some push to exactly the kind of issue you are raising, I think. Martha?

Dr. Herbert: One of the problems in autism is that there are so many dimensions to it. There can be gene, brain, immune, and so on and so forth, but that funding mechanisms really don't give you a chance to cover that many of the dimensions. And some people are doing something like phenomics, but within the limits of most funding mechanisms, you really can't integrate across dimensions very well.

So in the implementation of the strategic plan, one thing that would fall upon what you were just saying, Steve, is figure out ways, and maybe they would be initiatives where there are virtual languages or virtual consortia of some kind so that the fragments of research that are what's feasible to be produced within any one funding mechanism can actually have a more efficacious and efficient linkage to the other pieces that they need in order to make full sense.

Mr. Foote: Yes. So at NIH, there have been examples of glue grants or things like that, that is grants–network grants would be a better way to say it–that facilitate interaction and so on that aren't structured the same way as our typical grant mechanisms have been very effective sometimes at stimulating new research efforts that are at the interfaces between expertise, different types of expertise and so on and so forth. That can be very helpful.

So is there anybody who hasn't spoken yet who –

Dr. Dawson: This is Geri. I'd like to make one comment. Is that okay?

Mr. Foote: Yes, we'll let you.

Dr. Dawson: Okay. I just want–with respect to the issue of setting priorities, I think it's really important to balance both short- and long-term impact, because I think there is low-hanging fruit, so to speak, of things that we know could be addressed and are not as difficult to address that could have huge impact on individuals’ lives within the near future. And there are other things – so for example, the role of environment that we're almost sure that we're going to be looking at gene-environment interactions. Those are very complex problems, and genetics has very complex problems where the progress may be slower or at least more complex.

So an example would be the recent ACE network that was funded to look at environmental factors and infant sib samples of 1,000 infants from conception. That study will take between 5 and 7 years to gather those 1,000 from conception and to study all the range of potential environmental factors that could be contributing to autism. So, you know, that may take a while to be able to have health impact where there are other things where I think we could have a fairly immediate impact. So I would just like us to consider both of those priorities and having some initiatives that address short-term and others that tack these more complex problems that will take longer.

Mr. Foote: Thank you, Geri. Your point's very well taken. So, unless I see some strong request to speak, I'd suggest we move on now and tackle voting on the first category and have people start filling out their ballots so that we can kind of see how long that takes and so on and so forth. So are we distributing the ballots now? Do people have the ballots? I actually don't know. You're sending them around right now? Okay.

Dr. Dawson: What about on the phone?

Mr. Foote: We're thinking about it.

Dr. Dawson: Thank you.

Mr. Foote: Okay. We're going to send the ballots out to you electronically, and you're going to send them back.

Dr. Dawson: Thank you.

Mr. Foote: But in order to move forward, Geri and others, if you have the attachment that we sent out that has the titles of the six areas and then lists the initiative titles underneath them, you can use that to type in your points after – so for the first category – you're supposed to pick 3 and distribute your 100 points.

Dr. Hyman: If people have questions of clarification, do we have – we have the local expertise in the room?

Mr. Foote: Yes, we do. Between David and Geri and others who were at the workshops, I think we could answer questions about the individual initiatives, yes. Dave?

Dr. Mandell: I hate to bring this up, but mathematically, if an area has fewer questions, it's advantaged.

Mr. Foote: But we are not – this is within-category voting.

Dr. Mandell: Exactly. So within–

Mr. Foote: This is within-category voting.

Dr. Mandell: Right, so within each category, if a particular category has fewer items, that is if the people –

Mr. Foote: Yes, comparisons of total number of points across categories are not valid. We see that. We know that.

Dr. Mandell: Okay. That's not exactly the point, but I'll just leave it at that and we can – I mean –

Mr. Foote: Well, and on those – on the last two categories, you're only going to pick two. You're going to distribute your points between two when we get there. So let's start voting on number one, and we'll see if there are any questions or anything. So, David, there isn't any attempt to equilibrate points to make points across categories comparable. So you're taking 100 points, and you're distributing them only within category one across three.

Mr. Bell: And you have to do three.

Mr. Foote: And you have to do three. You can only – you can pick one and only give it one, but what we want to do is kind of force people to distribute their points a little bit, because there are two types of information – how many people picked a given initiative and how many points it got. Those are two different kinds of information.

Mr. Eiken: Excuse me, this is Steve Eiken from Thomson Reuters. For those of us on the phone, I've not seen a ballot. Is there something we can fax in or send through email?

Mr. Foote: We're in the process of

sending you ballots right now.

(inaudible comments.)

(Pause.)

Dr. Dawson: Excuse me, on the phone, it's a little bit difficult to hear. Are we–I thought I heard you mention we might be moving on, or are we still on the first one?

Mr. Bell: Hold on, Steve's coming.

Dr. Dawson: Okay. Thank you.

Mr. Foote: So it seems that everybody's comfortable undertaking the task now, and they're working away on it, and so people are just – we are now moving ahead. We've decided that what we're going to do is we're going to go ahead and score all of the categories, which I'm assuming will take at least 15 minutes. It may well take longer than that. Then we're going to come back to a general discussion of what people think about the voting and so on and so forth. Okay?

Dr. Dawson: Thank you.

Mr. Foote: So for those of you who are listening from home, right now there's going to be a fairly lengthy period of silence and so on, so that's because people are busy doing their balloting, and then we will probably pick up the discussion again in 20 minutes or a half hour.

(Whereupon, the above-entitled matter went off the record at 2:28 p.m. and back on the record at 2:59 p.m.)

Dr. Hyman: Okay. We are going to come to order, and my understanding is that the results are currently being tallied and that we're going to begin our discussion of budgetary requirements, but Steve, you're – no, we're not–you have information for us. All right.

Mr. Foote: Okay. So we're ready to resume our discussions here, and there are a couple of points that have emerged already that I think we ought to spend a little time discussing. And then I want to see whether the group has any more issues they want to raise before we move on to the budget requirements discussion.

So one is this – a few of us were talking at the break, there was the sentiment expressed that perhaps we are doing the prioritization here prematurely, I think, is one way to phrase it, that perhaps what is needed is some more intensive deliberation in order to prioritize within categories. That was the discussion that I was listening to. I guess that would also pertain to the issue of prioritizing across categories as well.

But–so are there – having now done this exercise, we ought to get the sense of people in the group about whether they feel that–I mean the IACC will have its own opinions about this, but we ought to also have a sense of the group to communicate back to the IACC and that the IACC members who are here can listen to and are online can listen to about what your thoughts are about that issue. So opinions? David?

Dr. Amaral: I was talking to several people, and the bottom line is that we're going to be producing a product, you know, a prioritization that people are going to have to feel comfortable with, and my sense of it was that a lot of people are uncomfortable with the process thus far and the amount of discussions, the issue of looking into existing information and actually using that as part of the basis for your decision. So, you know, just like when you publish a paper, you want to get it to the point where you feel comfortable with it before it goes into posterity. I think my sense of it is we're not quite at the point where we're ready to allow these determinations to go into posterity. And I certainly would like to see more deliberation on each one of these items.

Mr. Foote: Okay. Other opinions? Martha?

Ms. Resnik: Denise Resnik – oh –

Mr. Foote: Oh, Denise, go ahead.

Ms. Resnik: I think also if the IACC could empower us with some more specific goals and objectives, that would make our job much easier and, hopefully, more valuable.

Mr. Foote: And what do you mean by goals and objectives?

Ms. Resnik: I think measurable goals and objectives that give us greater specificity beyond the guiding principles. That gave us a framework, but if there were some specific aims that could be articulated and goals and objectives that are a part of –

Mr. Foote: I guess I meant the question this way: Do you mean scientific goals and objectives or process goals and objectives?

Ms. Resnik: Goals and objectives for the research component of this Strategic Plan.

Mr. Bell: This is Peter Bell. I would maybe go so far as to say that I think this group is fully capable of doing that if we are given the power from the IACC. I think we have all the players here at this table that can really do a thoughtful job of creating what I'll call more of a Strategic Plan that is then populated with some very specific initiatives and tactical types of things, which is essentially what we've been doing in the absence of any strategic thought.

Ms. Resnik: But we need permission.

Mr. Bell: So we need permission from the IACC.

Dr. Hyman: Well, I think we – you need – Martha, go ahead.

Dr. Herbert: It sort of progressed beyond what I wanted to say, but I feel I agree, and I also think that there are certain issues that are – would motivate a strategic plan, and even if they don't motivate the whole Strategic Plan, they would motivate some of the Strategic Plan. And this, in particular, has to do with, you know, if there are significant environmental factors going on, and if there are any kind of time trends, then it's then how you mobilize around figuring out what's going on so that we can deal with it is a public health issue of some kind.

So I mean there are certain substantive issues in prioritizing or contributing to some portion of the prioritization, and a lot of the redundancy and the way that the thing is set up make it hard to have that discussion.

Peter, when you say we need permission from IACC to do that, is that something we have to sort of wait until they have their next meeting? What does that mean because we're sitting here, you know?

Dr. Hyman: In fairness, even if Peter can answer that, unless we're going to sort of pull an all-nighter and have some more information, I think we've done what we've done today.

Mr. Blaxill: I was about to say, could we get a–

Dr. Hyman: Yes, incomplete. Let me–David?

Dr. Mandell: So I would fully endorse having a thoughtful Strategic Plan. I would also endorse, before the afternoon is over, having a tactical plan; that is, it seems like these are the questions. The way these potential initiatives were put into baskets was based on a series of questions. It seemed like very thoughtful questions, but asked slightly different ways, would have ended up with different questions in different baskets.

The way that–so we could sort of accept as an initial premise, as uncomfortable as it might make us, that these are the baskets that we have. And then within each basket, we were asked to prioritize, but as you go through, you could see, as Martha was saying, there are some considerable redundancies and remarkable variation in the level of specificity of the proposed initiatives within each basket.

And while I could, I think, listen to an intelligent conversation about genomics, I certainly couldn't lead one. And I'd be – and so here I am now asked to prioritize those things without necessarily having that background. It might be that if we through the–I mean we could see – maybe, you know, we're going to look at the scores, and it's going to turn out that everybody's scores were exactly the same and we can all go home and pat each other on the back.

But if they weren't – I mean maybe that's sort of a point for initial conversation, and then we can continue the conversation to see about whether there are initiatives that fit together within sort of a broader scheme, and so they become, if you think about these ultimately as that which becomes the PA or the RFA, that they get tied together in a meaningful way. Is that already part of the process, or is there a way to do that?

Dr. Hyman: Let me try a hypothesis because, again, this–I think it's important – I mean, I'm a complete outsider to this, but it looks like we're all learning as a community, right, about how to best use these processes. And it would be a shame, even if the votes come out right, whatever that means, to put a weight on them that is more than they deserve. And I think that we should consider this a good draft but that – I could–let me try a few hypotheses.

One is maybe these are or are not the six categories that we ought to have in terms of content, but I think a number of us, including me, have argued that there also ought to be some crosscutting thoughts about what we've called platform for the community and debate about genomic resources or longitudinal studies all the way up to venture capital and launching young investigators and attracting people in the field. And somebody said it very well, and I apologize for not remembering who, but that different funding agencies have different strengths and weaknesses in terms of what they can do.

It may be that in order to have a really good Strategic Plan, there needs to be, in the spirit of the Coordinating Committee, even though it is chaired by HHS, a certain amount of buy-in from the private foundations, you know, through the various agencies and Education, which hasn't managed to be represented here, with different groups not necessarily taking responsibility for different subject matters but for different parts of the sort of more nimble voluntary organizations, might be better able to be venture capitalists, although I would hate to give up on NIH being a venture capitalist, and others might be much better at creating sustained platforms.

So I think we should think both in terms of subject matter but also in terms of crosscutting goals. And I wonder whether – you know, I mean that clearly takes a different kind of process, and this may be the ideal group because, actually, the fact that you're not an expert in genomics means that maybe if there's the right representation, people can look at the sort of whole panoply of things the way an NIH Institute council does and basically says, okay, I've heard the arguments, and we want to put different things in different baskets.

So it may be that some body, maybe this one, maybe another one, really has to spend maybe a couple of days at a retreat or something and really dig into these various different both subject matter-based and mechanism-based ways of seeing things with a set of goals and then – and develop a Strategic Plan in that way that can then – but this is going to be a fine first iteration.

But I think whether this is too difficult, what I'm talking about, I don't know, but it seems like as the Interagency Coordinating Committee thinks about moving forward for next year, I think something more elaborate and more deliberative than this process may be the right way to go. I mean, that's – I don't know if that encapsulates the discussion.

Mr. Foote: So let me take a stab at something here. So there – well, there's a whole spectrum of possibilities, but we've got at one extreme of the possibilities we've got, this vote is premature; we ought to put this on hold; we ought to get guidance from the IACC before moving forward; and that should be our primary message back to the IACC.

We've got kind of the middle road, if you will, which is what Steve was just suggesting, if I heard him correctly, which is that we communicate clearly that the outcome today is viewed as preliminary, subject to substantial modification and that this group, however, we need to adjust it because of people's availability and willingness to serve longer and so on, but that this group is willing to take on the job of doing some intensive deliberation about this rough draft and fleshing it out and making some further recommendations to the IACC.

And then at the other end, we've got a point of view that I haven't heard expressed yet, but somebody may want to express it now, which is yes, moving ahead is very important; we've made our votes; here's what the vote is; the IACC can mull this over and do their adjustments to it and then move forward.

Okay. So those – does that sound to people like kind of the spectrum of things we're talking about? Okay. So my suggestion now is we do a little straw vote, and we just say where do people stand, and then we try to consolidate what we're trying to say so that we can send a clear message of whichever one it is to the IACC. Is that a reasonable way to proceed?

Okay. So let's start in the middle. Today's vote was a rough draft. It establishes some preliminary possible priorities within categories. The group would like to take that rough draft and do some intensive work to shape it up. What's the feedback from the IACC, and do they want to take advantage of that generous offer? It's up to them. Okay. So just as a straw vote now, how many people are sitting in that space?

Mr. Foote: A couple.

Dr. Hyman: Your right hand.

Mr. Foote: Then there is the point of view expressed by a few people, so I'll just take that, because that's been expressed by a few people – the very end is –

Dr. Hyman: Binding.

Mr. Foote: – there's been a substantial process to this point; the workshop's generated proposed initiatives; we had a bunch of material; we looked at that; we sat down today; we gave it our best shot; we voted;

here are the results of our deliberations. I think it's even fair to say we're willing to serve further, but really, we view this as being a substantive rough draft of what the – how the initiative should be arrayed. Okay. Now how many are sitting at that space?

Dr. Hyman: Six, I count.

Mr. Foote: Six. Okay. So now the point of view with which we started the discussion was this is premature; there are many, many details here that haven't been dealt with yet, and until we dig into these some more, we are not comfortable having this be the product of our deliberations, so we want a chance to just have this be revisited in a much more intensive way before we even consider it being really a substantive draft.

Ms. Resnik: And can you include in that an amendment of establishing or helping to establish some objectives that would go along with it?

Mr. Foote: Right, yes, of course. That was part of the discussion. Okay. So how many people are sitting at that place right now?

Mr. Foote: Peter, did you vote twice?

Mr. Bell: Oh, I thought you – No.

Mr. Foote: No.

Mr. Bell: – because of your clarification, that's why I–

Mr. Foote: Oh, he wants to – Peter gets a hundred votes. Okay. Now it looks like just barely that's a plurality of the votes. So in fact, we're sitting seven at one end, six at the other, and four in the middle.

Dr. Amaral: Steve, could I make an – so the middle ground, I think, is a good middle ground, potentially, if it's stressed that it's a preliminary draft. And the worry that I have and the reason I was more on the right side were that if it's taken too seriously, it may be well, okay, they've done their job and we can move on. I would hate to, you know, see that happen. I really think that the message you're getting is that we need to do more deliberation in some way, and the IACC can, you know, provide guidance in how to do that.

But that's, you know – so I think you might be able to condense the middle ground and the right-hand side if you just make it very, very clear that it's a preliminary draft.

Mr. Foote: Okay, rough draft is the term. This is a rough, all caps, rough draft.

Dr. Dawson: This is Geri Dawson. Could I weigh in?

Mr. Foote: Yes. You might even get a vote.

Dr. Dawson: I was wondering if you were going to ask that. So I think one thing that we're seeing here is that what we're trying to do here is a very, very complex process. Defining the research agenda for autism across, you know, all ages, across all etiologies and types of treatments and so forth, it's a very daunting and big task. And at the same time, we're all learning how to work with each other as well, a lot of different stakeholders and agencies.

And it's one of the first times that there's been a lot of people at the table from a lot of different perspectives trying to work on a document like this. I think it's pretty typical in a process like this that when you do your first stab at it that it helps you to clarify what the issues are and what the strategy should be and where the weaknesses in your approach are. So I guess I see this as very much a part of the process that is the first year that this has been attempted.

I think everybody has approached this task in good faith with a very kind of inclusive attitude about perspective, and this is what we came up with. I think it does fall short by a lot of different metrics. For example, it doesn't have that overarching sort of strategic plan that does identify, well, what are our goals and objectives are and how do these initiatives fit into those.

So I think if we cast it as simply what it is and it was an attempt to brainstorm on a set of research initiatives and to prioritize those in terms of their relative importance, it really isn't a strategic plan, but it probably is helpful in forming, in the long range, a real Strategic Plan. So I think if we just talk about it for what it is, it has been a useful exercise, and I would hate to see it just, you know, thrown out after all these hours of work, especially since there's been so much input from so many groups along the way.

Mr. Foote: I don't think anybody's suggesting throwing it out. I may have overstated the case.

Dr. Dawson: Well – or, you know, not, I guess, being able to produce something out of the work that's been done that we can bring back to the Committee for them to react to, i only, you know, to be able to say, okay, well, here's the start and here are the things that, when we do this again or when whoever does it again, that really need to be added to it, and this is what we've learned from the process.

Dr. Trevathan: Yes. I appreciate Geri's comments. As someone who's on the IACC, and I know there are several IACC members in the room – it might be good for them to speak up, too, to make sure I'm correctly expressing some of the sentiment. But I know that – and Joyce will also have some perspective – but I think that, you know, as Mark has stated, there's been an ongoing impression of urgency, you know, that we really do need to stick to a timeline, that this is really critically important, and that this is a process that's going to be going on every year, and you know, there's a balance, obviously, between meeting deadlines, moving forward with that sense of urgency, and not slowing this down very much. And at the same time, you know, feeling like we all have a product that we feel good about or can support.

And I guess the question I have is if there's a feeling that we need to essentially call this a very rough draft, that we want to then continue working on this document as a workgroup, then are we going to sort of set up a timeline for – so how long is this going to take for us to do this additional work? What's this going to do to the timeline that Joyce has been doing a really great job helping us stick to? And there's a tradeoff between just how comfortable everyone may be with the final product and adhering to this sense of urgency and responding to it.

Dr. Hyman: Can I pose a question to you, which is that it's not clear that the IACC has to accept any of the offers that this group makes, and I think one of the reasons I tried to propose a middle ground is I think we do have to make progress. We can't throw our hands up, and maybe that particular middle ground wasn't the way to proceed. But I think the message back to you and your colleagues on the IACC is that there does need to be a more deliberative, probably unfortunately, time-intensive process that takes other factors into account. Is that reasonable?

Mr. Foote: Yes. Is this a good time to get comments from the other IACC members in the room if they wish to make any? I think it is, so any other IACC comments? Alison?

Mr. Bell: As Alison's making her way up, if I could just offer up a comparison. There are a couple of other people in the room, I think, that also serve on the integration's panel for the Department of Defense, and we essentially went through a vision-setting exercise that literally took us no more than a half a day to do. And I think it really served as a great model and framework for us as we were making the decisions in terms of grants and things like that.

Now I think what is required for purposes of creating a Strategic Plan for research within the IACC is probably more complex and deeper than what we did there. But it can be done, and when you have a professional facilitator, it goes very smoothly. And I know that those of us that I think participated in that felt very good about that process, so.

Ms. Singer: I think one of the reasons that at the IACC we adopted this structure and wanted to create a Strategic Workgroup was because we realized that the expertise for creating a Strategic Plan really required broader input than what was available at the table of the existing IACC members, because the responsibilities of the IACC are much broader than simply creating the research Strategic Plan. And so the membership of the IACC is, therefore, much broader than the expertise we need for the strategic plan. So we created this group, and sitting at this table is really the expertise that's needed for the plan.

So I think the idea of this group going back to the IACC and saying, you know, we need more input from you – I'm not sure what additional input we can give to this group. I think the IACC is looking to this group to provide input and to say these are the priorities. So I would hope that we would not come out of this day saying we've not made much progress, we need more input from the IACC, because I don't see that as moving us forward.

Mr. Foote: Okay. Other IACC comments?

Mr. Grossman: Okay. This is Lee Grossman. I–the strategic planning process that we've been going through is unlike any other strategic planning process I've ever experienced, and I was in business for 25 years and went through many of these processes. Our organization has been going through one over the last 3 years, and this is just not like anything I've seen before. And the reason why I'm saying this is that I'm still wondering what the objective is here. I don't see it. It's not clear to me at all.

And considering the urgency of this matter, considering the pandemic proportions of this condition and those of us that advocated for the Combating Autism Act to get passed, we felt that a strategic plan was going to put us in a position that we can finally address the urgent need.

With that said, I would challenge us, all of us, to be very bold in our objectives, to put objectives out there that in 10 years we will accomplish X. I think what has happened through the various workgroups is very productive and within the context of the information and the research that's been designed that we can reframe the discussion along very, very strategic and very bold objectives.

For example, just to frame this discussion, for me, as a parent and as an advocate, if I had an objective that I could take to my community for further advocacy that stated, for example, by 2015, every child with ASD diagnosis, when they graduate high school, will be able to be employed or be eligible for higher education. What a tremendous goal that we could work toward. And again, I see the scientific information that's in here fitting well into designing itself around such models. Right now, I see us just struggling to find our legs and how we're going to move forward, and if it's going to just be an exchange of ideas and pursuit of various research goals without a clear objective that's bold and transformational, then I think that the IACC

Committee is going to have a hard time dealing with this.

Ms. Redwood: I would just have to say I agree with everything that's been said so far. There's been a lot of effort, and when we first started this, it sounded like a wonderful idea and we were moving forward quickly and we had a sense of urgency, but I think we started in the middle. And we came up with this list of 41 initiatives, but we really had no overall goal or mission to be able to really say what it was we wanted to accomplish.

And so I really think – it's my opinion that we need to start this whole process over, because if we had a different mission and goal, we would come up with a completely different 41 initiatives than we have right now. So I think we really need to rethink this. I think we need to gather additional information. We need to look at research inventories. We need to identify gaps. We need to create new mechanisms for funding. We need special emphasis panels. We need to incorporate the sense of urgency. We've got an epidemic. We have 1 in every 150 children. We've got to do more to help treat them now.

It was so disturbing to see the amount of money that was spent on treatment in that portfolio. It was minuscule. There was one study on biomedical intervention. That was it. So we really need to rethink this.

Mr. Foote: So, Lynn, and just for a point of clarity, your point of view is that that should be done for the first version of the Strategic Plan, the first annual Strategic Plan?

Ms. Redwood: Yes.

Mr. Foote: Okay. Yes. David Amaral?

Dr. Amaral: I think I'd like to go back to what Geri Dawson had said and then speak to what Alison had said as well and Lyn as well – that I think the product at this point is the definition of these 41 initiatives. That took, you know, 4 days. It was a deliberative process. It actually identified areas where there are gaps in research at the moment.

Where I take exception to this process is now trying-so in a sense, all of those are important, you know, to some substantial extent. And what we're trying to do now is to prioritize within those, I think, without adequate deliberation of how to prioritize. So the message back to IACC is that I think we've made a lot of progress. We've identified 41 areas. There may be more areas, but I think, actually, a lot of the areas that are within the 41 address exactly the issues that you're raising, Lyn, in terms of treatment and, you know, lifespan issues and a variety of things that people are sensitive to.

So I think we have made progress. I think that could be reported back. My sense is that if we report back, you know, to the IACC that we've prioritized them and here's the top three in each one of these categories, that's where we're going to be doing a disservice to IACC, because we're not going to be providing very good advice potentially. And that's where we could take these 41, you know, consider them more and actually come up with a thoughtful way of prioritizing them.

And then, again, the product that I'd like to see IACC have is say, okay, well, these guys have done the best possible job they could, so to figure out where we should be investing our money in terms of all the priorities, you know, return on the dollar, you know, long-term versus short-term benefits, I mean all of those things, we haven't had a chance to talk about those things today. And it was, in a sense, too much data in too short of a time to come up with a vote that may be the most meaningful vote.

So I think Steve's suggestion that this would be sort of a draft, but you know, make the point that more work needs to be done. And, you know, that shows progress, but we're not at the end point at this point.

Mr. Foote: Lucille?

Dr. Zeph: Just – this is a comment that Peg Giannini asked me to share with the group because she had to leave. She is an IACC member and just asked me to bring up the whole idea of how this work, again, relates to the earlier work of the IACC and the old roadmap and whether or not the current IACC should be looking at linking some of the 5-year work that that had been done that could provide some of the direction for the Strategic Plan – not that you would accept it lock, stock, and barrel – but because time and circumstances change. But that it seemed to her as though she was coming into a situation where a lot of work had been done, but it wasn't on the table. And so that in an effort to move things in a more rapid manner, that that be a starting point to look and see how that gets rethought rather than having to start from scratch and how that might advise this work. So I told her I would share that with the group.

Mr. Foote: Thank you. Point well taken. Mark?

Mr. Blaxill: Yes. I would just, in terms of where I've come out on this, I'm with Steve's middle ground, with David's, you know, caution that, you know, it really is a rough draft because we do need to be productive and not punt. But we do need to say that this is a bigger job than the time we're allotted and we should take the time to do it right.

I guess I'd make one other point, which is, you know, there are times to do things – we all feel the sense of urgency. There are times to do things fast, and then there are times to do them right. And I would say this is a time in which we want to do this right and take the time it needs, recognizing there may be some calendar constraints that we need to, you know, support, which is, you know, in the spirit of the whole exercise of strategy, you know; there's a difference, in the business sense at least, from having a Strategic Plan that is often a document that serves a role in a budgeting process – there's a difference between a Strategic Plan and having a strategy.

And what we really need for autism is a strategy for science so that we can get results faster. And a Strategic Plan – some kinds of documents may be instruments along the path there, but I – what we're talking about here is, you know, let's get something on the table. Let's not wait for the perfect thing, but let's recognize that there's a lot of work to do and that this is a good – there is a vehicle that is established here that, you know, we've invested some time in. Let's take advantage of that and offer it to the IACC and say, you know, what we really need is a quality strategy for autism that really makes a difference.

Dr. Hyman: I just want to pick – I think it's important that we not, in some sense, negate the work of the four working groups. I mean that would be – in the end, it wouldn't be helpful. I understand the frustration, but to sort of demoralize the community wouldn't be such a good thing, but to say we've learned from this process – and, you know, again, I agree entirely with your point about treatment. I mean, the issue is how do you get treatment development–I mean if the strategy is to do – if a major new strategic goal is to have new treatments, then, you know, you have a whole set of how do you discover what they are, what kind of infrastructure do you have to do clinical trials at different age groups? I mean, a lot follows, but that doesn't mean that these 41 are not very good and important things and they actually set a stage, but maybe there's something bolder and more strategic beyond that.

Dr. Shore: I think what we're looking at is a work in progress, and we've done a lot of good work, and there's more to go. If we go empty-handed back to the IACC, as you said, that's bad news. But it's not the end-all and be – all either.

Ms. Blackwell: Hello? Can anyone hear me?

Dr. Hyman: Yes.

Ms. Blackwell: Oh, great. This is Ellen Blackwell. I'm one of the IACC members as well, and there may be others on the line. I'm not sure.

Mr. Foote: Yes.

Ms. Blackwell: But I agree with my colleagues, especially what Alison had to say. You know, we've come a long way, and I think that we've all learned a lot in this laborious process and that we should hang on to the good work that we have so far. And we would really welcome, you know, this group convening today and moving ahead to make its recommendations.

Mr. Foote: So, we need to get closure. Yes, you may say one word.

Dr. Herbert: All I wanted to say is one nuance, which is, yes, but we can't really postpone the strategic thing because it will keep haunting us until we deal with it, so that's – we need – we can't postpone doing the deeper thinking, just because we have a product that we've produced that we need to honor. Because until we sit down and do that strategically –

Mr. Foote: Last and final comment just

because you're an IACC –

Ms. Redwood: I just wanted to make a clarification about the 41 initiatives. It wasn't to scrap them, but I really think they need some work. When we received these back from the IACC, each workgroup was allowed 10 items, and so there's a lot of overlap. There's a lot of work where we could really develop these into something great, but the way they are right now, there's too much overlap, there are not any priorities. So, yes, take those, but please refine them and meld them into something, because that work has yet to be done and that's critical. So I didn't mean to scrap them all. I just meant that they really still need a lot of work.

Ms. Singer: I just wanted to clarify also, and I totally agree with Martha that there needs to be more discussion of strategy. But I also want to add that I think the discussion of strategy needs to happen within this group as opposed to happening at the IACC, because again, the IACC has broad responsibility. Only one of its responsibilities is production of the research Strategic Plan, whereas this group has the responsibility for the research Strategic Plan.

Mr. Foote: Okay. So here are three points. Let's – he's Chair and he –

Dr. Hyman: No, no. I've delegated to you this section because you have the Kevlar on.

Mr. Foote: Yes.

Mr. Foote: Okay. So here on the flip chart are what I thought I heard emerging – three major points that we could consolidate into a formal motion as our recommendation back to the IACC. And I want to see if we can get some agreement on this. So, that this is a rough draft of priorities, and what I have in smaller letters down there is both in terms of content and in terms of their ordering of priorities, that this is information; it's a work in progress, but it is rough; and both of those dimensions of the priorities may need further work.

Then number two, that we need a vision-setting, goal-setting exercise that will provide a more comprehensive structure and a more elaborate structure into which we are building these tactical issues and that this group, however it needs to be changed to, you know, depending on who's willing to serve and so on and so forth, is the group to take that on and that, in general, you are willing to do that. Okay. If – so since I am not a member of the workgroup, would some member of the workgroup like to make a motion to this effect?

Dr. Hyman: Well, I guess then I have to say, is there a motion – so that we have due process.

Ms. Marvin: So moved.

Dr. Hyman: Is there a second?

Dr. Shore: Second.

Dr. Hyman: Any discussion?

(No response)

Dr. Hyman: All in favor, aye.

(Chorus of ayes.)

Dr. Hyman: Okay. Anyone opposed?

(No opposition voiced.)

Dr. Hyman: Okay. That's good.

Mr. Foote: Good. So –

Dr. Hyman: I think “work in progress” as opposed to “rough draft,” right, is a non-pejorative – “rough draft” came from me, so – yes, right–

Mr. Foote: Me, I like “rough draft.” A working rough draft is a significant accomplishment

Dr. Hyman: It is, yes. Depends on the old writer's block, doesn't it? Okay.

Mr. Foote: Okay. We're done with this part of the –

Dr. Hyman: Okay.

Let me–before we move to budget, let me just ask the group, while we're in this brainstorming, constructive mode and assuming that Alison's invitation gets ratified by the whole IACC that this is the right group to do strategic planning, how would we maintain momentum but really think in terms of strategy or something bolder and more of a clarion call as opposed to more of business as usual? Maybe before we get to budget, it's more important to just talk about how we would actually do that.

Dr. Dawson: This is Geri. Could I make a comment on that?

Dr. Hyman: Yes.

Dr. Dawson: Well, so I like the way the discussion is moving and a work in progress is a great way to conceptualize this. My sense is that the prioritization of the research initiatives that have been developed really need to come from that overall visioning exercise where some specific goals and objectives are identified by the group.

I guess I'm a little uncomfortable with the rating process that we went through today for a couple of reasons. One, because it does lack that broader context within which to set priorities but also just the mathematical way that it was set up and by chunking them into the different categories; and, I think someone raised this earlier, there is some sort of mathematical problem built into it that would make one emphasize priorities that one doesn't really want to emphasize. So for those two reasons, I'm just questioning whether – we could certainly use the information.

I think it would be fabulous, for example, if we–there are certain initiatives that were just rated so highly by so many people that it would give us a good start for our discussions and we can rally around that. But I wouldn't want to take too seriously the detailed information that would come out of the exercise that we did. That's just my opinion.

Mr. Foote: Well, I was just ready to ask that question, if whether the group wants this – well, I don't know that it's up to the group, but I am interested in the group's sentiment about communicating this information to the IACC. One point of view is that it's premature and prejudicial, and there isn't any special value in communicating it. The other point of view is, well, the group was commissioned by the IACC, and we took this vote, and they ought to have the information, and it's just something that they can deliberate about or see how it came out. So we ought to make a decision about that. Denise?

Ms. Resnik: I think that information will be, if we analyze that information, very helpful in terms of setting our goals and objectives. So I think that has great value for this group for further discussion. And if it's presented as, you know, part of our work in progress but not necessarily as our prioritization but part of our analysis that we're doing in advancing the plan, I would feel comfortable with that.

Mr. Foote: Okay. Is there anybody who's really opposed to sharing this information with the IACC with those caveats?

Okay. Good, done.

Dr. Hyman: Okay. So we are now just going to take a few more minutes to talk about how we would get sort of above the 41, right? I mean how do you decide which parts of the – if we have all the parts of the pie chart, which parts of the pie chart are underinvested in, or how we have a strategy to get more treatments? How would we do that? How would this – I mean this doesn't have to be binding, but I think while we're here, we're engaged in the discussion, we're sort of happy with what we did but we're sort of unhappy, and how are we going to make it better?

Dr. Pessah: This is Isaac Pessah. I think at this point then, I think we need to establish some clear overarching goals for each of the priorities, which will help us try to put them in perspective. Then you could go back to the tables that were generated and identify which ones with the really, really large imperatives, overriding goals, if you want, are actually underfunded. They would rise to the top. I think we need to refine this by establishing vision and goals.

Dr. Hyman: Do you want to create some straw-man visions and put them on email? Mark, I've seen you write some very – I worry about you getting repetitive stress injury from some of your emails.

Mr. Blaxill: I wanted to make a point, Steve. I'm trying to process Lee's point because I actually find that mind-expanding and thinking about aspirational goals as opposed to, you know, more of a corporate kind of model, and I've been thinking in a corporate model but often a good, you know, DC model thinks aspirationally. And I think we should do that because, obviously, we all are thinking that way about our children. So I think that's worthwhile reflecting on, and that's the sort of thing where – and maybe the DoD experience is a model. You know, I've heard those who were there really found it helpful.

I was going to make a more mundane and corporate observation, which is, you know, it's been helpful to have the frame that, you know, I think it was Alison who provided it, which is a customer perspective on the problem, and it does, I think, put the right lens on things. There's a useful distinction anytime you're doing corporate strategic planning, which is – you know, there's a distinction between the customer perspective and the market perspective. And we're adopting a customer perspective a bit, but we're not thinking that well about the market yet. And that's kind of important for when you want to spend money, because you’ve got to sort of ask yourself, how big is this problem? You know, how big is the market? How large is the population?

If we're going to start talking about budgets, we need have a view about the population and the trend. And one of my own hobbyhorses on this is I don't think we can have a rational strategic planning discussion if we don't confront the question not only about the size of the population but how it's changing. I think a lot of us are very concerned about the tsunami, as I think Lee was putting it, of children that are going to enter adulthood very soon.

And we can't make a case for budget to Congress as we've been asked to; we can't make rational choices about science. We can't make rational assessments of the performance of different research programs or, you know, the need for revising our view of what research programs are important if we don't face the reality.

Jack Welch was famous for saying that, you know, the most important part of any Strategic Plan is that you face reality. And, you know, a lot of us worry about something we call “epidemic denial.” And if we let that infect, you know, a strategic planning process, we'll end up with an inferior product. Now I've been saving that point because I think as we get budget questions, we've got to start asking ourselves that question. If we're going to have a meaningful response to Congress on the budgetary request, we're going to have to come to grips with those issues.

Dr. Hyman: Other – you had a –

Ms. Marvin: I was thinking if it's possible or somewhere in this process, do we just undertake a traditional like SWOT analysis of autism? I mean, would that make sense?

Dr. Hyman: Meaning, strengths, weaknesses

Ms. Marvin: Or maybe just strengths and weaknesses. I mean I think that everything that Mark and Lee – I'm not a good vision person, so maybe I'm not good here–but I would like to hear from the scientific community what they consider low-hanging fruit, because I think that that's –

Dr. Hyman: I think what I've heard, but correct me if I got it wrong – we've heard actually two very complementary issues. One is to look for gaps, really important gaps in the portfolio. And, you know, a few have been raised today, although this hasn't been as content focused a day as some of the others – presumably the – workshops were, but we've heard about some gaps. But then we've heard about some really big strategic goals, right, which would motivate, which would say, you know, look at this whole category and figure out why it's underrepresented in the portfolio.

And there's the market, and there's the consumers, but there's also the issue of supply of scientists that we have to think about and the infrastructure to do the science. So one of the things – forgive me, I'm a bit out of it; I haven't really focused on these issues in a number of years – but, you know, one of the things when I was NIMH Director that was quite clear is that there isn't actually much of an infrastructure to do pediatric treatment trials, whether they're psychosocial or pharmacologic. And so there's a whole issue – there's a general growth, I mean, not just in autism, of cases of pediatric-onset behavioral disorders, and so in some sense, there are these gaps. The microlevel gaps you can find in the portfolio, but there's this big issue of what's America doing about its kids, you know? So I think we have to keep both things in mind.

Ms. Resnik: Denise Resnik and a few process comments in response to your question. First, I agree with you in terms of that SWOT analysis, because that would identify new opportunities, and Mark, some of the things that you've raised as well and also help us identify the low-hanging fruit, also identify the gaps. I question whether our workshop leaders might be best positioned to help at least begin the process of drafting those aspirational goals, vision, objective statements that we can then respond to. It's a tall order to do that, I believe, as a group. But I think they're uniquely positioned to help us lead that effort based on what they've heard and the experience and, obviously, the expertise and why they were chosen in the first place.

Dr. Hyman: All right. So I don't know that we're going to come – I mean it sounds like pieces of what needs to get done have surfaced in terms of an actual process by which we would get there. Maybe everybody's too tired to offer up more hours and days right now. But I do think it's really very critical that it not just be NIH and CDC, because I think in terms of the different interventions that need to occur in the scientific food chain, again, different agencies are going to be – or voluntary organizations are going to be better suited to different kinds of funding.

All right. So, deep breath. Are we ready for budget? Can we put up the pie chart? Because I think if we look at the detail of the prior year's budget, we're going to – I think the two useful – I guess we can only see one slide at once. It's the pie chart and then the summary. There's this summary page by subcategory. Maybe everybody could have that as well.

This doesn't say what we should do, but it says where we are with all of the caveats that we've heard about the quality of the input data and the differences to date and how different NIH Institutes bin things. I think I'd be surprised if that pie chart really were off by more than a few percent, even with very detailed, improved categorization.

So I know there are issues in the community about the total budget, but I think one of the issues, given what will correspond to the voting, although this is a five-part system with other, and it's not the six-part scheme that Alison bequeathed to the group, but any further – we've heard comments already about this pie chart, but I think it wouldn't be bad just to look at this or to look at this page and to ask about budgetary priorities. Denise?

Ms. Resnik: To your point, Steve, I do think that there should be an alignment in terms of how the budget is expressed and how the plan is expressed. So if there's some work that we need to do in that regard, that is one recommendation I would have. Second, within each of these areas –

Dr. Hyman: I don't think anyone would disagree. Yes, right.

Ms. Resnik: Okay. Second, within each of these areas, perhaps there is an opportunity then to slice it another way whether we look at that, the leverage opportunity, leveraging the investment opportunity in terms of the higher risk but maybe potentially greater reward, those areas that haven't been studied.

So I wonder in terms of, you know, some criteria here, how we look at the budget, whether we might be able to slice it. When we look at Autism Speaks and their significant investments to date, you know, the biology, etiology, you know, they're first and second, and then they just seem to reverse the treatment and diagnosis in terms of investment priorities. But there seems to be some nice alignment there with what private investment is doing as well.

Dr. Hyman: You know, it's here.

Mr. Bell: Peter Bell. It's hard to look at this pie graph and say one area is more underfunded than another. And I completely agree with Lyn in that you look at treatment at 13 percent, and you're, like, you know, that just can't be, or it's just not enough. And I think some of that has to do with, you know, it wasn't that long ago, 5 years or so that people basically said autism's not treatable. And since we don't know what autism is, we don't know what a target is, why put a lot of investment into that?

But I think we've changed that, and I think that more and more people are starting to realize that there are treatments that are available where kids are getting better. Unfortunately, not all kids are getting better with those treatments, but a significant portion or a decent number of them are. But they're all important, and I think we could get into a little bit of a, well, how do you divide them up individually.

So for example, risk factors that, generally speaking, you know, you have both genetics and the environment. And so people would argue that we're very underfunded on the environmental side of things and that a lot of the focus has gone to genetics. And I think that we need to continue to do both. And what is the right mix? Should it be 80/20 like it probably is right now or maybe 90/10? Or should it be 60/40 or something along those lines?

But I think that, you know, there needs to be some dialog and discussion about why each one of these things is important. You know, I think there's a strong argument that a lot of effort needs to go into biology, because we still do not know what autism is at a biological level. We can tell you what it is by looking at it. My 9-year-old daughter can go to a grocery store and say that child has autism. But you know, she doesn't have a blood test or a scan or anything else, and we don't know what the underlying pathology of autism is. And it's not until we do that we're probably going to make significant headway from a treatment perspective.

And so, you know, I would hate for us to see biology go down just in favor of treatment just because, you know, there are some treatments out there today that do work with some kids, but still – and this is where I think it's really important on the criteria – we need to recognize the heterogeneity of this disorder. And that's probably one of the most perplexing things that gets in our way is that there's – the kids present or people present in so many different ways.

And, you know, there are a lot of us sitting at this table who have children who have gone through every one of these treatments that are out there that some kids have recovered on and our kids, unfortunately, have not. And there's nothing more frustrating than, you know, to see some kids getting better and other ones not. And Denise and I were talking about that this morning.

But anyway, I guess my point is that, you know, we could sit here and play with this pie graph until the cows come home, but I think that we all need to recognize that how they get divided up among these initiatives or other initiatives that we identify, that's the most important thing.

Dr. Hyman: Yes.

Dr. Dawson: This is Geri. Since we mentioned Autism Speaks' research portfolio and scientific funding, I wanted to just make one comment, which is that in looking at the way that the funding is distributed for 2007, what we're looking at is a perspective and decisions that were made at the end of 2006. And so it really is a historical look, and so, for example, in 2008, I know that Autism Speaks decided to put much more funding into environmental factors and treatment. And so I just want to kind of put on the board that if we react really strongly to this information, even though I know it's the best and it's the most readily accessible, it's not very contemporaneous.

And then the second point to keep in mind is that some kinds of research are more expensive than others, and so there might be other ways to think about looking at budget distribution because you may get one area inflated not necessarily because it's been overemphasized as a topic area but just because what's needed to study it is much more expensive.

Chair Hyman: (inaudible comment.)

Dr. Dawson: I'm sorry, I can't hear.

Dr. Hyman: First, Sam and then Mark and then Judith.

Dr. Odom: Okay. I'll be quick. I am surprised that treatment is only 13 percent. It's amazing to me when you think about, at least, what I hear in the community about what we need. We just did a study of all the comprehensive treatment programs we could find, and there are hardly any randomized evaluations. One of the reasons, I think, is partly the funding the issue, but partly I think it's a match between agency and criteria that are used in the review process and who reviews the grants. That's a different issue.

But 13 percent may not be because NIH targeted 13 percent.

Dr. Hyman: No, it didn't.

Dr. Odom: But there are ways of, I think, responding to support treatment research in perhaps a more positive or progressive way.

Mr. Blaxill: Can I lobby to put up the spreadsheet as opposed to the pie chart.

Dr. Hyman: Yes, absolutely.

Mr. Blaxill: I recommend that everyone read Edward Tufte, and that the pie chart is the worst form of graphical display ever invented.

Dr. Hyman: Except for old guys like me with bad eyes.

Mr. Blaxill: There you go. The other one that has the subcategories, not the groups.

Dr. Chung: Just the NIH one you mean?

Mr. Blaxill: Yes, just the NIH one, because that's the bulk of the – yes. I just – and again, you know, it's tough to do quickly, but I have – I could click through a narrative on some reactions on resource allocations.

First of all, I want to support Peter's point, which is I think we're in the midst of all wanting to reframe autism as a biological phenomenon and understand the biology and what's actually going on inside the bodies and brains of these kids at various points, and so there's basic science that needs to happen. We need to understand mechanisms.

The one point I'd make on the biology is we ought to be careful not to make this a dumping ground for, you know, United States pet neurological projects, and I don't know enough about the projects, but I had a little bit of that reaction reading through the titles, that not all of them were, you know, the biggest bang for the buck.

I'd also comment that biological systems is really small. I mean because we're talking increasingly about autism as a whole body disorder and the gut-brain-immune connections, and so we need a better understanding of biological symptoms, including but not limited to the brain. And that's really underinvested there. I know Tom had talked about the microbiome as a pet project here. I think autism would be a wonderful opportunity to explore, you know, the bacterial flora and how they contribute to disease. And if that's a platform investment, there might be an opportunity there.

On the treatment side, I think we'd all, the parents would all agree we need more. And I think we'd also argue in the spirit of, you know, it's a biological disorder; we need more biomedical treatment ideas. And there are a lot of ideas floating around, not all well-formed, but I think we need a lot of investment there.

You know, diagnosis is really important, but it's one of these things where it's important on the front line. I'm not convinced – and I don't know enough about it – I'm not convinced that we need a lot of research on improving instruments unless we're getting into the biology better and biomarkers. This is one of these disorders where people can say you need 30 seconds and you know whether you're looking at an affected child. It's not that complicated at a level, and then it's infinitely complicated at another level. You know, I'm not sure how much importance we need to put on particularly old-style diagnoses.

The risk factors–you know, this is one of the 800 – you know, the gorilla on the table. You know, we've made huge investments in genomics. Simons is making huge investments in genomics. Maybe that's a venture capital model, and you know, I would short that stock, but–

Dr. Hyman: We've noticed.

Mr. Blaxill: Hey, you know, all power to them. I mean if they find the magic answer, you know, but I think this is an area where we've seen a lot of investment, and all the results fade. You know? And there's some positive signal, and then nothing yields. And certainly re-chartering that to emphasize gene-environment interactions, if we're going to do genetic work – I don't think we should not do genetic work – it's an important perspective and tool. All parents will talk about concerns over genetic susceptibility, but the notion that we – that the kids are defective and not sick – is, I think, one of the things we resist. And so a dramatic increase in the environmental side, you know, I think a lot of us would argue for.

And also facing up to some of the controversies there. I think we need to face up to the perspectives that parents bring, parents' experiences, the ends of one that may be inconvenient to discuss from a public policy standpoint, but they're going to be discussed, and the parents are going to keep pushing these issues, and I think we need to face up to those. And that needs to be a part of the environmental portfolio, and it needs to be something where scientists aren't punished if they investigate it.

Dr. Hyman: Thank you.

Dr. Cooper: Can we go back to the pie chart for my old eyes, too? Okay. Well, I just wanted to make two points. One, and Sam sort of alluded to this–to be sure that everyone understands that we at the NIH, in 2007, did not decide we're only going to spend 13 percent on treatment. You know, that's driven dramatically by the research community and what applications came in.

But I did want to say that treatment, since there's been so much discussion, we do have an initiative out that all the autism institutes participate in, all on intervention and services research that Lisa Gilotty the charge in. And we have a special review for that, and we've been receiving applications in response to that. So that's one small step that we've tried to make to encourage research and intervention.

Dr. Hyman: Martha has a comment, but let me just say something to that. Of course, that's right. I mean people – there's very much a bottom-up issue into where the money goes, but there really isn't the infrastructure for pediatric clinical trials in behavioral disorders in the United States. I mean, again, my information is out of date, but when I commissioned a depression trial in adolescence and then wanted to do it in school-age kids at the same time, there actually weren't enough sites and investigators for the United States to mount two such trials at once.

So I think part of it is what's coming in but part of it goes to the quality of what we could do, that is do we have–are we building an expert clinical trials infrastructure that will be there and ready as, presumably, treatment development comes along? And that is actually a top-down strategic decision that could be shared. So I think both perspectives are right, but I think part of the reason that people don't apply to do pediatric trials is there isn't really the expertise or the infrastructure. Martha?

Dr. Herbert: Whether pie chart or spreadsheet, I'd like to say that it's not just a question of apportioning between the big pie pieces but within the pie pieces. Reading through the 41 proposals, I noted that there were a fair number that were very partials, like for example, risk factors and risk factors would be entirely social factors. And it seems to me that when the 41 proposals are thought through again, when the people who formulated a particular idea for something that should be done had a not inclusive way of framing it, for example, if they left out biology, like if there's a risk factor or a treatment, that the ways that these problems should be formulated should be more inclusive so that the biology makes it into – like risk factors can be biological or social diagnosis can be biological or psychological. Treatment can be many things. And I think that we need to think through at that level of detail the apportionment, not just at the big level.

Dr. Zimmerman: Andy Zimmerman. I wanted to just point out that we are developing an infrastructure through the Autism Treatment Network that is sponsored by Autism Speaks that I think is developing in that direction –

Dr. Hyman: That's good.

Dr. Zimmerman: – really supporting a lot of the–

Dr. Hyman: That's what we need.

Dr. Zimmerman: – medical research and care in autism.

Dr. Dawson: Right, that's true. This is Geri, and as long as we're talking about that, we actually have two investments in developing Clinical Trials Network. One is the Autism Treatment Network, which is 15 institutions that are collaborating to provide a platform for clinical trials. But then we also fund separately what's called the Clinical Trials Network, which is also a group of institutions that are participating in clinical trials, and what we're funding is the coordination and also acting kind of as a broker between the clinical trials, people who are conducting the clinical trials, and pharmaceutical companies.

So I think that's just an example of where, when one sets the goals for what you're trying to achieve, then you can start to see where the gaps are in achieving that goal and then try to invest, you know, in those gaps.

Dr. Hyman: That's good. Lucille?

Dr. Zeph: Lu Zeph. One of the other pieces that was missing that we were hoping to have put in place, and I couldn't see any remnants of it here, is the pediatric protocols for pediatricians and physicians seeing children for the first time. And I'm wondering – this is one of those context questions that I feel is – that I'm trying to make these decisions without having all of this, but one of the things we were trying to do, which would facilitate some of the both treatment and provide the basis for clinical trials, is to get those protocols in place.

Most physicians are working without guidance at this point, and we may not have the perfect protocol at this point, but I think that we know a lot more now in terms of the systemic nature of this disability and the number of different systems that may be affected to being to put guidance in place. And I was wondering if there was an update, and if not, that's one of the infrastructural pieces that I would think that we could get a lot of mileage out of if we had that on the table as part of the discussion.

Dr. Hyman: Prisca, you had a comment?

Ms. Marvin: I think this is just a broader comment under – and you alluded to it several times. In reviewing the 41 initiatives, I also noticed that it just seems like we're going to have a problem with we just don't have enough people in the pipeline to do all this work. And I think that if that's going to be part of this Strategic Plan, we need to target them. And then there's something about autism that makes me think we really want the M.D.s, Ph.D.s, so I think of geneticists who've never seen an autistic child and are missing something. And so I don't know how we can encourage that or foster that.

Dr. Hyman: That's a very important point.

Ed?

Dr. Trevathan: Ed Trevathan. I do think moving beyond our current work in progress – and this group, obviously, has got an interest in moving forward – I think this suggests this whole issue of leveraging an infrastructure needed could be an area where the IACC could really use some great input from this group. I mean, if it is the case, which I know it is as a pediatric physician who has done clinical trials, we don't have adequate clinical trial infrastructure for a lot of disorders that are in neurology and psychology, developmental pediatrics. That infrastructure may need to be built upon a broader scale in order for children with autism to benefit and others do as well. And conversations like that I would encourage because I think it would be very productive.

I will just give you another example, because it's on my schedule for tomorrow. One of the issues that's on the list here is the need to answer parents' question, what's going to happen to my child in the future? When you get to those sorts of issues, that gets into longitudinal cohorts or prognostic studies. And then we had a number of other areas when we talked about longitudinal cohorts. Well, the autism community is not the only community that has that on their list of needs. In fact, this is on everybody's list of needs.

The Institute of Medicine, looking at disability overall in America, recently issued a report and pointed out that we have a need for longitudinal cohorts and basically all types of neurological disabling conditions from early childhood through adulthood across the lifespan and problems with transition that I know many of you have been very passionate about among children with autism. And those are all issues that are big infrastructure needs, which it seems like the autism community and the IACC, all of us, share with some other groups. So that's another area, like the clinical trial infrastructure, that we share that need with others.

Dr. Hyman: Thank you. Other comments? So very explicitly, how do we move from this very useful conversation to a recommendation to the IACC? It sounds like we do not feel, based on the data we have, in a position to say that we, you know, need to starve most areas in order to feed others, but there does seem to be a general view that just looking at the numbers, whether it's on the pie graph or the ophthalmologically challenged or whether it's on the spreadsheet, is that there seems to be a relative underinvestment in treatment. Is that a fair reflection? Anything else that we can affirmatively and with consensus bring to the IACC on budget? Prisca and Ed, did you have another comment?

Ms. Marvin: I just have some concerns about that.

Dr. Hyman: Okay.

Ms. Marvin: I mean I understand that that's the broader consensus, but I have been– I've experienced, at Council, where if there is a mandated shift – I mean I think–I want to put a caveat in that, still, that the treatment that is being funded, it's still of the highest caliber.

Dr. Hyman: Yes.

Ms. Marvin: So as long as, you know–

Dr. Hyman: No, no, there's no –

Dr. Mandell: – I just don't want to see a mandated number down.

Dr. Hyman: No. I think the – as I phrased it – maybe I got it wrong – is that there is a relative–that we were surprised at the small percentage of the pie that is going to treatment studies. I mean, there's probably a statement there. Ed, you were going to make a comment?

Dr. Trevathan: Yes. I was only going to add although it's a different part of the pie chart, I think there are a lot of us that when we think about the need for treatment, we're also thinking about issues related to plasticity, early identification, early diagnosis, and we don't do a very good job yet in this country, although we're making progress, at early diagnosis and early intervention. So there's a sense in which, you know, if we're robbing Peter to pay Paul from the diagnosis to treatment, we could be harming treatment by not getting adequate early diagnosis. So these discussions, I guess I'm now convinced we need to have more of these discussions to really have concrete recommendations to the IACC.

Dr. Pessah: This is Isaac Pessah. Within the risk factors, I think if one were to reapportion money so that it was more equal between genetics and environment, we would make significant gains in the next 10 years, because this is something we can do about. If you identify genetic underpinnings for susceptibility to a myriad of encounters in the home or outside the home and you inform individuals that they could, in fact, prevent exposure, you might have some really dramatic outcome. It might not reverse overnight, but if an epidemiologist were to try to track it, I think that you might see some rather astounding benefits compared to simply how do we fix this gene or how do we intervene with that gene.

Dr. Hyman: I think – did you want to say – yes?

Dr. Zeph: To add to that, I think that the whole thought of looking at, from an international perspective, the data that are available in terms of increasing numbers of individuals with autism may help inform some of the analysis that needs to be done in terms of environmental factors, because if you look at, you know, environmental factors within the home and the United States, they're very different than in some of the other countries. And if we're still seeing increases in those countries, we may want to look at something like atmospheric issues, looking at the science that's coming out of climate change and the studies of how our atmosphere is changing. And our air constitution is changing internationally may also be another area in terms of looking at truly interdisciplinary endeavors.

So there is science out there that we have not yet fully investigated in terms of some of those environmental factors. And I noticed in this work that there was mention of our involvement internationally in terms of in kind, but I'm not sure what we're actually doing to support international initiatives that might also shed some light on this global issue of increase in autism.

Ms. Redwood: I just wanted to say something real quick, because I'm leaving to catch a plane. When I looked at this, the category of “other” seemed to be a real hodgepodge of projects that I don't know how they really got put in the autism category. But what I was going to recommend is to maybe take that category and do something really creative with it. You had asked the question previously about how can we do this innovative research.

Maybe we could take a percent of the budget and earmark it toward things that are the low-hanging fruit, things that come up that we can immediately respond to, set up a special emphasis panel, maybe use the DoD model that has a third of the people on the panel who are voting to fund research who are stakeholders, look at things like the new findings with mitochondrial disorder. I think that's very promising. Low-hanging fruit – look at neuroinflammation. We're not doing that. We don't have a mechanism at NIH where we can really aggressively go after something short term.

So please think out of the box in terms of trying to develop some type of new strategy for being able to capture those really important ideas and scientific information when they present themselves. Thank you. Bye-bye.

Dr. Hyman: Yes, David?

Dr. Mandell: Sort of building on something that you just said, Lyn, and you said, Lu, about multidisciplinary and the idea that often with studies like this, one can act as the backbone for many other –all right? So a treatment trial can offer a tremendous opportunity for recruitment. I saw there was–I was trying to find it and I couldn't – but a study about genotype and phenotype and treatment response, for example. The challenge with those studies is they all have to be funded concurrently for that to happen. And so I don't know how the fund–

Dr. Hyman: NIMH historically did that for very large treatment trials, so –

Dr. Mandell: So it would be wonderful if there were sort of an explicit –

Dr. Hyman: But I can't speak for current –

Dr. Mandell: Right. They're not as enlightened now –

Dr. Hyman: No, no, no, no, no –

Dr. Mandell: as they –

Dr. Hyman: – no, no, no –

Dr. Mandell: – were in your day.

Dr. Hyman: No. I was a Neanderthal, but

Dr. Mandell: But it would be wonderful if there were explicit mechanisms to think about. I mean it's also a pitch for expanding the treatment portfolio, because I think that the treatment portfolio brings people in. It allows you to go into the community in a way that you often can't with, for example, the genetic studies. But then it, you know, creates a pool of potential subjects for many other studies, and you get that longitudinal component and you get to hang on to families, because families are very excited to stay when their kid is getting treatment.

So it would be wonderful to make those kinds of mechanisms explicit for these kinds of –

Dr. Hyman: So it sounds like what we're starting to do here instead of talking explicitly about the budget is we're actually starting to do some strategic planning now. Denise?

Ms. Resnik: And I have six steps –

Dr. Hyman: Which fortunately is being recorded by the way.

Ms. Resnik: – that I would recommend in that spirit. The first thing would be to set some aspirational goals. So let's think, you know, what, aspirationally, do we want to reach for? We'll go back and we'll evaluate that.

The second thing, and this speaks to Mark's point about the view of the population, the trend, we need some historical information that also speaks to funding, but we need to be more informed in terms of moving forward.

The third area would be that SWOT analysis, and that would also lead us to – so the SWOT analysis. And then the fourth would be the setting of our goals and objectives and engaging the workshop leaders to help us draft those that would speak to both short- as well as long-term goals.

The fifth would be the work in progress of priorities in terms of content. We talked about low-hanging fruit. We talked about an opportunity to assess the gaps, the infrastructure that would be needed so that we could do some foundation building in our portfolio and also looking for those innovative approaches.

And then finally would be the assessment of the budget, alignment with the plan, the risk tolerance that we would have, the leverage that we want to have and looking at it as a whole portfolio. So to me, that would be potentially some next steps that we could proceed with as it relates to fully developing the plan.

Dr. Hyman: Mark?

Mr. Blaxill: On the budget question, I guess I'm curious what the budget is, because a number of us have heard different stories. There was, as all of you know, a very intensive effort and campaign to get the Combating Autism Act passed. A lot of different parts of the community were active in that, and that was both negotiated in terms of language and in terms of amounts. The amounts typically happened to get cut sort of toward the end, but there was at least a sense that research was a central focus of the Act and that the numbers would go up, there would be more research.

We've heard – I've heard that there's no new money that basically – which seems that's a bit of cognitive dissonance. Right? We passed an act in Congress as a community, and there's no new money. Okay, you know what did we do wrong?

Dr. Hyman: Well, you passed–what you did wrong is that you went to an authorizing committee and not an appropriations –

Mr. Blaxill: Well, maybe it's not appropriate –

Mr. Bell: Actually, the fiscal year 2008 has been appropriated as well.

Dr. Hyman: It has been?

Mr. Bell: Yes.

Dr. Hyman: At higher levels?

Mr. Bell: Yes.

Dr. Hyman: There you go.

Mr. Blaxill: So I thought it was appropriate –

Dr. Hyman: – didn't do anything wrong.

Mr. Blaxill: So what's the gap there? What's the budget gap?

Mr. Foote: There is no new money for this Strategic Plan part of things. There is, you know, administrative money for the IACC. There are some other pieces that actually got appropriated, but there was no money appropriated for these research activities.

Now, that doesn't mean – okay, I'm done with that sentence – that doesn't mean –

Mr. Blaxill: So what happened to the Combating Autism Act, Steve?

Mr. Foote: Well, it was passed, but it was just a type of legislation that does not necessarily carry funds with it. And when it went to this state of – now I'm just talking about the research part right now – when it went to the Appropriations Committee, it did not get any money, so that's what happened.

So there is no new money for this purpose with the Combating Autism Act. Now, does that mean that the Strategic Plan does not, won't have, any influence? No, it doesn't mean that. And I – this is a very important thing to be doing, and it's very important to be identifying what the IACC now, at least temporarily, delegated to this group thinks are the highest priority things that should be undertaken, because this is a different level of consideration than what study sections do. Study sections sit down with a group of grant applications, and they decide on the quality and significance and so on of those grant applications, but they're working in that sense with kind of a fixed population, and we're doing a different thing here. And this is what people keep pushing to do, which is come at it from the other side and from a broader perspective. What are the most important things we could be doing, even if we have to go out and stimulate quality grant applications someplace? So this is an important exercise, and this kind of input does carry weight when people at NIH sit down to make funding decisions.

Now just to be fair, we do get pressured the other way as well. We do have members of Congress who come to us and say, what do you mean you funded something that wasn't the next one in line in terms of priority score? So we get pressure from the other direction also to just keep it strictly bottom up and strictly merit based. So that's what the situation is.

Dr. Hyman: But that's where the legislation helps?

Mr. Foote: Yes, that's where the legislation helps.

Mr. Blaxill: There's a real question in terms of clarifying where we stand. In terms of doing strategic planning, the community has some perceptions about what it has done and what it has accomplished that may be at variance from the budgeting reality, which has implications for our activities and ongoing organization. We need to understand that better, because I don't think–

Mr. Foote: I think that's very important.

Mr. Blaxill: – the principle that there's no new money is well understood.

Mr. Foote: Right. That's why I wanted to make that point and make it very, very clear, because I think there is misunderstanding, and it's just bound to lead to disappointment and misunderstanding. And I just think it's really important to have – to inform as many people as possible about what the real situation is. And the real situation is that there isn't any new money.

Dr. Hyman: Let me speak to the optimistic side of that, because I think this is very important–otherwise, nobody should have bothered to get on an airplane, right – which is that the NIH Institute budgets are not rigidly fixed. They're not apportioned within, and insofar as there's a really compelling plan, you're building generally important infrastructure, and the word goes out that there are scientific opportunities and you start to attract really good applications; actually, funds do move into an area. And in some sense, you're poised for the time when the NIH budget starts to rise again, because you have superb new scientists there.

So I don't think – I mean, I don't think you have to rely on an earmarked appropriation, which just at a time when NIH is losing real buying power every year is a very tough thing. But I think that within the marketplace of ideas and needs, this group could make a remarkably strong case. And I believe that.

Mr. Foote: Exactly. I agree 100 percent.

Mr. Bell: So just to, I guess, retrace history a little bit here, the Combating Autism Act was an authorization act, and it was basically to authorize the funding of close to a billion dollars over a 5-year period, but it's just an authorization. You don't get anything until you get an appropriation. There was an appropriation bill that finally got passed through Congress, signed by the President in late December of last year, which specified, I believe the number was, $166 million dollars, within the

Department of HHS budget, of which, I believe it was, $109 million dollars was to come through NIH-funded research.

We have now seen a listing of research that was conducted by the NIH in 2007 that is in excess of that amount. Now that can go back to perhaps what we were talking about before where there's research that benefits autism but doesn't necessarily quote, unquote, come out of the autism budget. I don't know. You know, I'm not familiar enough with how the NIH, and I'm sure some of these people could give us that background and so forth, and I also don't know what kind of commitments they have on research that's already been approved and funded for fiscal year 2008.

But I guess from a budget standpoint, fiscal year, there should be $109 million dollars in NIH funding targeted for autism. Now how much of that is available? I don't know. And I think what Steve is saying is that there isn't any new money that can be devoted toward these efforts, but I think we're also hearing that if there's a compelling reason that can hopefully come out of this process, there isn't anything stopping them from being able to fund it from other sources. Is that –

Dr. Hyman: This is my philosophy. Steve, I think you won't disagree. The goal of any group like this is to attract the very best research into this area, the very best people, and insofar as we do that on many fronts, partly through strategic planning, partly through the kinds of grants to young people that are now being made, you do two things. One is you send a message to the NIH leadership that this is a tractable and important priority.

But the other thing is from the bottom up, as you get, you know, leading neuroscientists for the first time doing autism research – you know, I don't know what everybody thinks of neuroligin-3, but to get Tom Sudhof to have autism in the title of one of his grants is not something, frankly, that would have happened even 5 years ago. And as you move people like that into the field, then also, by virtue of the RO1 bottom-up process, it will move not only money into the field, but it will move it to the kinds of scientists who will really make a difference.

But it's at times of extreme budget pressure like this, it just takes energy and relentless effort and really good planning.

Mr. Bell: I mean, I guess I will also just add on that's one of the reasons why this process is so important is that we have to provide a framework and some guidance to the NIH and the CDC and HRSA and, quite frankly, to the community about what are the priorities for this disease. What are the things that we need to accomplish in order to make the kind of progress that all of us are going to be proud of?

And in the absence of that, you end up with basically studies that score well. And I would imagine that for the NIH folks to be in council and to have a Strategic Plan that they can say, you know what, this addresses this need and so forth, that's going to be very powerful. And that's why I think we're all taking this as seriously as we are in that they haven't had that in the past to a certain extent. They haven't had something that was generated by both the scientific community as well as the consumer community so that we can all say, you know what, these are the important things that need to be accomplished in order for us to make the kind of progress we need to. So I think it's a combination of the financial as well as the strategic that's going to allow us to move this forward.

Mr. Foote: Just to very quickly give an anecdote–for example, we're right now getting pressure from Congress about funding anything out of priority-score order. A very strong rationale for funding something out of priority-score order, probably both in reality and politically, would be if it had been identified by a group like this as being of a very high priority in addressing a public health issue. And so we could use it in that way.

Dr. Cooper: Judith Cooper. The other way I envision NIH staff using what comes out of the Strategic Plan and I guess maybe what feeds my frustration that, you know, we didn't come to closure today is that we can develop initiatives based on your recommendations. Maybe we won't have the money set aside, but I think, Mark, you were the one that said one of the enticements is to have a special review panel. That's a big carrot to reviewers out in the community. And if we say here's a really important area, we're going to review you,, you're not going to go to the regular study section, and those scores – maybe they could fold it into our regular pay line, but still, we have increased the number of applications coming in, and we've enticed people. And so this Strategic Plan will play a huge role in what we decide to choose as maybe some of those initiatives. So I view this, at least from the Institute perspective, as a very valuable effort.

Dr. Dawson: This is Geri Dawson. I just wanted to make one other comment about the usefulness of the Strategic Plan, and that has to do with, as priorities are identified, there's a strong desire for both the private organizations such as Autism Speaks and The Simon Foundation and NIH to work together to try to achieve some of these goals. And in some cases, that means identifying a priority goal and realizing that one of those organizations by themselves can't achieve it, but together we might be able to. And another strategy is in some cases to develop complementary emphasis, so if one Institute wants to emphasize an area, then another one might want to emphasize a complementary one. So I think that's another very important use of this Strategic Plan.

Mr. Grossman: I also wanted to clarify this last point, because in looking at the Act, the IACC is to be the advisor on all things autism to the Secretary. And this role that we're in, even though we would like more money, it's just not existent at this point. But it's very substantial the fact that we do have an advisory body that has the ear of the Secretary so that we can help him categorize new priorities in our favor. And to me, that's perhaps going beyond that strategic planning is the most important role of the IACC Committee.

Dr. Hyman: At this point, we have the envelope.

Mr. Foote: So I think we've already generated our primary recommendation to the IACC, which was the motion that we covered earlier, and we have your thoughts about the budget requirement issue, but for our own interest, here are the results. And I guess we've just distributed them in hard copy to you, so none of you are going to be looking at the screen anyway. The hard copy–

Dr. Dawson: I'd like to see it on the screen.

Mr. Foote: Sorry, Geri.

Dr. Dawson: That's okay.

Mr. Foote: So Geri and others on the screen and for those of you watching in, I'll give you a minute or two to look at the voting results for category one, and then I'll kind of scroll through them as we continue our discussion here. I think it's interesting that there really is a substantial spread in these things.

Dr. Hyman: Shocking consensus.

Mr. Foote: Yes, I mean the ratio of top to bottom is 10 to 1 or so in most cases, I think. Well, the top vote-getter has about 10 times as many votes as the bottom vote-getter, so that's –

Dr. Chung: So the first number is this cumulative score –

Mr. Foote: The big number is points –

Dr. Chung: – and the second one is how many people –

Mr. Foote: – and the one in parentheses is the number of people who identified that as one of their three. And of course, the two are correlated but not necessarily in a one-to-one fashion. And in this case, for example, there's a big, you know, pretty sizeable spread for treatment between the number one and the number two vote-getter, and then there's a cluster that's no so well differentiated. And here in services where there were only four options, there's not much discrimination, not as much discrimination.

Dr. Dawson: Steve, would you mind sending a hard copy of that so I can study it?

Mr. Foote: No, I wouldn't mind, but I'm also not capable.

Dr. Dawson: Okay. Well, whenever you can.

Mr. Foote: It's in your Inbox, Geri.

Dr. Dawson: Thank you.

Mr. Foote: That's how good I am. I go from –

Dr. Dawson: You are amazing –

Mr. Foote: – being incompetent to having accomplished the task in milliseconds. Yes, the issue about adulthood came out on the top in both "treatment" and "what does the future hold." Well, of course, that's kind of a selffulfilling prophecy there, because what does the future hold, most of the initiatives are about trajectories over the lifespan.

Okay. So the floor is open for comments, whatever those comments might be.

Dr. Mandell: Steve?

Mr. Foote: Yes.

Dr. Mandell: Is this the metric in which this will be presented to the IACC? That is, do they – what are you going to do with this?

Mr. Foote: Well, we're open to suggestions. Do you want to percentile it? Is that what you want to do, or –

Dr. Mandell: Well, no. Well, okay, so there was one –

Mr. Foote: Well, okay, so let's say the default model is yes; this is the way it will be presented, with a careful description of how this was generated and a caveat about the fact that, obviously, in those categories, the fewer the options, the higher the point totals are going to be by default, you know, because the aggregate number of points –

Dr. Hyman: I would percentile them instead of explaining the numbers. I think that would be better.

Mr. Foote: Well, so that's why I was asking if that's what the suggestion was – to percentile them. But there's also – well, that could get a little bit tricky, too.

Dr. Mandell: You could score them by inversely weighting them against the number of possible actions.

Mr. Foote: Right, exactly.

Dr. Mandell: So you're scoring them against what their expected score would be in a random –

Mr. Foote: What the chance probability is, yes.

Dr. Mandell: But the other thing is that with a lot of these – so for some of these, there's a lot of spread and others there's not. Sometimes where – there's often like one that was clearly a favorite, and there are one or two that clearly were not. And then there are a bunch that were clustered in the middle.

And what's interesting reading them in this order is how similar some of them are. So, for example, the one that was particularly striking to me is “where can I turn to for services.” And looking at the number one and number two choices, they're remarkably similar. And I wonder if there ought to be some commentary that goes with this from this group. And I don't know the best way to get that, but that sort of talks about these – where talking about them in clusters is appropriate because–that we do that rather than just sending it in without comment.

Mr. Foote: Yes. We may well come back to somebody like you since you identified a services one and you were in the services workshop. So we may get you and Geri and somebody else, get the three of you and kind of force you to have a consensus remark that you send along with this that might address that issue.

Dr. Dawson: This is Geri. I do think one of the difficulties with having these in this bulleted format is that when you read the actual initiative, there is so much more meat there, and sometimes it's hard to get the full intent or the richness of the initiative by just reading the title. And so, for example, in this case, the top bullet was really focusing more on treatment that we already have shown to be efficacious and then to look at what are the barriers and costs and processes that would be involved in disseminating those into the community, so services research.

And then the second one was more based on the fact that there are a multitude of community-based intervention models that are currently being used and that have been found to be effective by many people but have never been tested and that there's a need to go out and identify those community-based interventions and actually study them, and so that then there would be a basis for insurance coverage, et cetera. But you just couldn't get that from reading the titles, and there are many other, I think, examples of this where the details really add richness that makes quite a bit of difference.

Mr. Foote: Yes, I would agree with that. My impression, reading through the initiatives, is that a parent–where there's apparent overlap judging from the titles, usually there is really strong distinction between initiatives and really addressing different issues. There may be the same keywords pop up in the title, but really, it's usually addressing different issues. Okay. So other comments from the group about what's here or not here? Anything?

Dr. Hyman: So maybe one question to ask is whether this, now that we see the vote, it looks more useful than we feared–I mean, you know, in some sense, I think we were afraid we might be all over the place and, in fact, we're not so all over the place, and so again, calling this a work in progress and, you know, not the final word, right framing really, I think is a useful thing to bring forward.

Mr. Foote: Yes, and who knows, the IACC might disagree with you –

Dr. Hyman: They might.

Mr. Foote: – although there are a number of IACC members here today, and they seem not to.

Mr. Blaxill: My overwhelming reaction is similar to David's, which is, you know, the scores may be very misleading. I mean to the extent that there is, you know, that got no votes –

Dr. Hyman: Yes, they are –

Mr. Blaxill: – that's most informative, if nobody voted for anything. There are a lot of categories where a lot of people voted for a lot of things, and so there's not a whole lot of discrimination. And some people may just have chosen to allocate their votes more strategically, so you know, I mean there's a gaming of the process.

The thing I found myself most interested in doing is not the within-category scoring but the across-category scoring, which we were not allowed to do, and I'm eager to do that at some point. So for that reason, I think there's a reason not to make too much of this. But to the extent that there's a necessary interim output that's respectful of the workshop activities, appropriately adjusted per David's suggestion, which I agree with –

Dr. Hyman: What I was looking at when I said it's not unusual is, you know, initiatives for older children and adults with ASD really rose–you know, arguably, there's a pretty smooth gradient down to the bottom, but you know, 12 people voted for it. It got 430 votes. Say what you will, you know, that's useful information.

Dr. Herbert: One thing that's interesting is some of the ones that were redundant that showed up in different categories, particularly the biomarkers; one biomarker was fairly high. The one in treatment was quite low, which might mean that people don't know what it means to have biomarkers for treatment. When these things become consolidated in some way, it may be, at least moderately, a useful information to think about what's included in the consolidated proposal.

Dr. Dawson: Excuse me. This is Geri. Responding to Martha's comment, I think that's where some of the issues that I was struggling with doing the ratings within a category where you can't really look at them across categories. So for example, I decided to, you know, put my biomarkers out on the first place that the biomarkers were given, figuring if you discovered them there, you would immediately apply them in a treatment context, or at least that would give you some movement in that direction and felt like, well, I had to use my votes in the treatment, you know, section in a different way. So, you know, it was hard, I think, to try to look at these all within a category, because it sort of forces you to rate things within a category where, in fact, I would have a tendency to rate things across the board.

Mr. Foote: Yes, an initial vote like this then helps with that kind of contingency voting, because now you know which ones other people find attractive and you can kind of focus on making your discrimination at the end of this scale that counts. Okay. Other comments?

Ms. Marvin: Steve, when we present this to IACC, can't we at least point out the areas where there seems to be general consensus in the bigger – and then maybe if they wanted to, you know, have some initiative or initiatives or some ideas to sort of run with, if we can just target just the ones that seem to have more – you know, a bigger disproportionate first vote?

Mr. Foote: Well, I think that's part of the point that was addressed in the earlier discussion that led to this motion. I mean you're kind of splitting hairs about can we have a kind of prioritization. Is that what you're saying? I mean –

Ms. Marvin: I don't want to–I don't know that this group is going to be comfortable characterizing anything, but I'm saying can't we just present to – I guess what I'm saying is instead of presenting the whole thing to them, can't we just present the ones where there's clearly a preponderance of, you know, a lot more people voted in favor of it just in terms of the scores, instead of giving them the whole menu?

Mr. Foote: Well, that was the intention of the original exercise, was to identify the clear leaders across the groups, I mean within each group. So now – so then it's a definition of well, what's clear? And I think this was the discussion we were having, was that a number of people were not yet comfortable making – endorsing even the highest rated initiatives. Now the group is free to go back and revisit that, but – and the IACC is free to consider that as well. That's–we did decide we're going to present these results to the IACC and, yes, the IACC could decide, well, you know, there really are some top dogs here, and we want to go ahead and act on that while continuing the process in other ways or whatever. I mean, that's the IACC's call, I think.

Dr. Hyman: Because there are members of the IACC here, you know, it's hard to pretend that we can be nontransparent about this. I think they fully know to take this for what it's worth, which is, you know, a reasonable first step based on 41 priorities that we agree were somewhat overlapping, and in some cases, a bit fuzzy and some too inclusive and some not inclusive enough. So we've highlighted the fact that, you know, a different kind of strategic planning would be a very good thing, but I don't see the harm in them seeing this work. Many of them, as I said, have seen it already.

Mr. Foote: So Ed Trevathan has kindly volunteered, before he knew what was really involved, to be the presenter at the IACC meeting who's going to carry back the news. Okay. Other comments?

Dr. Mandell: Just to follow up on what Geri said and, Steve, what you had suggested before, at the risk of repeating myself–I would really urge then that when each of these is presented that there be some introductory paragraph that puts it in context for the people who came up with these ideas so that the IACC is not making a decision based on a title and a score and that there is some discussion how this got to be and some interpretation about why the results might have looked this way, which would be an opportunity to talk about, you know, why biomarkers for treatment – targeting and treatment response was so low, but biomarkers in another category was so high for example.

Mr. Foote: Right.

Dr. Trevathan: One – first of all, I think this actually came out much clearer than I thought it would, so I think I feel better after looking at it. But one of the things that I find most interesting, that Martha mentioned, and I wonder if this is something you all would feel comfortable with me saying to the IACC, so let me just throw this out and see what you think.

There is quite a bit of overlap between some of these, especially some of the ones that rated somewhat high. And then some of the ones that looked like they were rated lower, in some ways, subsumed under some that ranked fairly high. So there is a sense in which that could be sending some messages that maybe we could get some more feedback on from this group as to why.

But for those of us that have been–I think there are several in the room – that have been at the workshops–I think I attended three out of four and the IACC meetings, and I know some other people here have attended quite a few – this issue of the overlap has been brought up at every meeting, and I think it's been recognized.

And so there's a sense in which having the overlap did perhaps identify some areas that people thought were important, and part of the reason for the overlap is they came out of different workshops, you know, so that the different workshops, even though their category was different, they actually came up with similar priorities, which might be useful to note.

So the overlap I actually find instructive, and now that we're here, I'm sort of glad we didn't get rid of the overlap before everybody had a chance to see it, because I think it maybe makes it a little richer in terms of the data going back to the IACC. I don't know how you feel, Martha, or others.

Dr. Hyman: Absolutely, well earned. Do you have any comments you want to make?

Dr. Chung: So I think one of the things that people are thinking about is, is this a one-time workgroup meeting, or is this an ongoing process? And I think people seem to have the interest and will to continue, and I think it's –

Dr. Hyman: That was a few hours ago.

Dr. Chung: – I know – I know –

(Laughter.)

Dr. Chung: So we're going to have to bring that back to the IACC. These workgroups are meant to be self-limited in time, and we didn't know where we'd be at by the end of the day, just to suggest that we'd see you again. But it does seem like there's unfinished work and a tremendous amount of will to continue to work. So I think that's a very important thing.

I want to assume then that that means that this group will have some kind of a life in the future, and I think that's a good thing. We don't always know if that's something that's going to happen. And I assume the IACC will have to, you know, approve that possible recommendation. But if that's a good assumption on my part, then that helps us understand what to ask. Any comments about that?

Mr. Blaxill: I went and got myself a coffee so I can get a second wind, and I do support that. I think the spirit that we had up there of work in progress – I mean I'm still sorting what messages this really communicates. There is data here. I'm not sure what inference we should draw, but it's worth sharing because it's what they asked us to do. But it's also worth putting in context, and I think that is the coherent message that we're all sort of agreed to.

Dr. Trevathan: Since, Joyce, you volunteered me for the job of presenting, I'm thinking of volunteering you and maybe Steve for something. I don't know if it would be useful for those of you in the group that have commented on this, but would it be alright for the people who have thoughts on the overlap and the details to sort of pass that along via email to you offline here? I think that would be very useful to get a little more feel for that when we present this back to the IACC, just to sort of–by way of explanation and put some comments in there, for example, about Martha's comments about the biomarkers, which

I've also heard before. So if people would be willing to do that, I think that would be useful.

Dr. Hyman: Martha?

Dr. Herbert: I just want to say that, I mean, if I'd had a million hours before I came – I had a lot of thoughts about clustering and regrouping things. And I think we can go ahead and send these ideas, but at some point if and when this group proceeds, that's something that would do well in an interactive –

Dr. Chung: So we can actually do that. I think it's often good to do that right after a meeting like this when the ideas are still fresh. So if you'd like, we can solicit that right away and then try to incorporate that and send that on to Ed so that when he presents, he can include that information, but also assume we'll be having some kind of a follow-up. So again, we don't want you to have to wait too long to get that feedback to us.

Dr. Zimmerman: Is it understood that these priorities are going to be reviewed every year, on an annual basis?

Dr. Chung: It's in the law that this Strategic Plan has to be updated yearly.

Dr. Zimmerman: Because it seems like, to some extent, this is kind of a popularity contest that may change next year. I mean it's nice that the immune questions came out at the top of the list. And I'm happy to see that because that's something I've been interested in for a long time. But I have seen that emerging over the last couple of years, but in 2 years from now, it may not be and there may be other things.

Dr. Hyman: Hopefully, that will change based on science, and hopefully, it won't be just 2 years, and hopefully, whether it becomes a land rush or it gets rejected will depend on scientific results. I mean that's got to be the goal.

Are you satisfied that people can get their cabs?

Dr. Chung: I think we're close to the end. I think what we'd like to do, though, is we do have a reserved time for IACC comment. There are probably some IACC members on the phone who may have been waiting until this point to say some things who aren't in the room. The people in the room have had an opportunity but continue to speak.

If people have to leave, we're not going to be offended. We know people have taxis waiting, so please, go ahead and make your plans. But we'd like to take a few moments now to get the IACC – okay, before we even do that, please return all the documents that were proprietary, return them back to this end of the table, and we will gather those. And then we will – Simons and Autism Speaks, please, and DoD, all those pieces of paper need to come back this way. And then maybe during that time, we can have open mic for IACC.

Dr. Hyman: Anyone on the phone want to make comments?

Dr. Dawson: No, I'm fine.

Ms. Blackwell: This is Ellen Blackwell at

CMs. I'd just like to say thank you to everyone who came in today and who tuned in. And I don't want to speak for my fellow IACC members, but I know that we appreciate your help.

Dr. Houle: Hi, this is Gail Houle. I understood that right before I came in, you were asking about the Education Department's research initiatives in autism. So while most of you realize that the Education Department is – primarily, our authority is to fund services and that's where our big initiatives are, we have a small Institute for Educational Sciences. And I contacted them after I came in, and they – we have one of their grantees here.

They have three grants that they funded in 2007, and they also let me know that they have an RFA that's open right now, advertised on the Web page of the Department of Education Institute for Educational Sciences. As I said, I'm with the Services part of the IDEA and Education, but I do have the abstracts, and they have the link on the bottom. And I think that you'll be able to also publish that in your minutes. So there are three. They're not collated.

But thank you for thinking about including Education, and we look forward to working in this area as well.

Dr. Hyman: Thank you. Steve or Ed, anybody, last comments?

Dr. Hyman: No? Well, as Chair, let me thank this group for your energy, your engagement, your civility – very hard task, very well begun, so thank you all.

Mr. Bell: And very well chaired. Thank you very much.

(Whereupon, at 5:11 p.m., the Working Group adjourned.