U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

FULL COMMITTEE MEETING

MONDAY, NOVEMBER 19, 2001

The Interagency Autism Coordinating Committee (IACC) convened at the National Institutes of Health (NIH), 31 Center Drive, Building 31, Bethesda, MD, from 9:04 a.m. until 4:17 p.m., Steven Hyman, M.D., *Chair*, presiding.

PARTICIPANTS:

STEVEN HYMAN, M.D., *Chair*, IACC, National Institute of Mental Health (NIMH)

DUANE ALEXANDER, M.D., National Institute of Child Health and Human Development (NICHD)

KATHRYN CARBONE, M.D., U.S. Food and Drug Administration (FDA) (representing Bernard Schwetz, D.V.M., Ph.D.)

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

JOSE CORDERO, M.D., M.P.H., Centers for Disease Control and Prevention (CDC)

HENRY FALK, M.D., Centers for Disease Control and Prevention (CDC) (representing Dr. Copeland)

BARBARA FISHER, National Vaccine Information Center

BARRY GORDON, M.D., Ph.D., Johns Hopkins University

LEE GROSSMAN, Autism Society of America

PARTICIPANTS (continued):

KIMBERLY HOAGWOOD, Ph.D., National Institute of Mental Health (NIMH)

CINDY LAWLER, Ph.D. National Institute of Environmental Health Sciences (NIEHS) (representing Ken Olden, Ph.D., Sc.D., L.H.D.)

PATRICIA MORRISSEY, Ph.D., Administration on Developmental Disabilities (ADD)

AUDREY PENN, M.D., National Institute of Neurological Disorders and Stroke (NINDS)

JON SHESTACK, Cure Autism Foundation

CAROL SPROUSE, Ed.D., CAN

LUCILLE ZEPH, Ed.D., University of Maine

STEPHEN FOOTE, Ph.D., National Institute of Mental Health (NIMH)

DEBORAH HIRTZ, M.D., National Institute of Neurological Disorders and Strokes (NINDS)

GAIL HOULE, Ph.D., U.S. Department of Education (Ed)

YVONNE MADDOX, Ph.D., National Institutes of Health (NIH)

GEMMA WEIBLINGER, National Institute of Mental Health (NIMH)

LAURENCE STANFORD, Ph.D., National Institute on Drug Abuse (NIDA)

TABLE OF CONTENTS

PROCEEDINGS:

Dr. Steven Hyman: While everybody is coming to their seats, let me just make sure everybody at the table has a nametag. Apparently, not everybody had a chair.

[Laughter]

This is a typical Federal hospitality. Welcome. You'll notice that we're not allowed to buy you a cup of coffee; that would be a misuse of our funds.

So just before we start, the way it works is, to speak, you want to hit the button in front of your microphone, but please remember when you're done speaking to turn it off, because only a limited number can be on. And, in essence, you short out other people if this is on.

Okay, even though there are two or three people missing, we have a full schedule, and I really want to make sure that we have time for real discussion. And, therefore, why don't we come to order. It's an absolute pleasure to begin this new Interagency Autism Coordinating Committee meeting that brings together both representatives

from diverse, not only agencies within HHS, but different departments, along with public members, in order to discuss very pressing and important issues in front of us.

To my right is Dr. Yvonne Maddox, who is the Acting Deputy Director of the National Institutes of Health, who is going to officially welcome you. But she and I agreed that, perhaps, the best way, since we don't all know each other, is to begin just with a round of self-introductions and so if we could just begin and come around.

Dr. Kathryn Carbone: Kathryn Carbone from the FDA, speaking for Dr. Schwetz.

Dr. Stephen Foote: Steve Foote from NIMH, member of the NIH Autism Coordinating Committee and the major contact point for the STAART Centers Program.

Dr. Judith Cooper: Judith Cooper, National Institute on Deafness and Other Communication Disorders. I'm here for Dr. Battey. I also am on the Autism Coordinating Committee. And in our Institute, I coordinate the language program, which includes all our autism research.

Mr. Lee Grossman: Good morning and aloha. I'm Lee Grossman from Honolulu, Hawaii. I'm President of the Autism Society of America. And it's certainly an honor and a pleasure to be here on this Committee. Thank you.

Dr. Jose Cordero: Good morning, I'm Jose Cordero from the Centers for Disease Control. I'm Director of the newest center at CDC, the National Center on Birth Defects and Developmental Disabilities. And our Center funds the Center for Excellence on Autism and Other Developmental Disabilities.

Dr. Lucille Zeph: Good morning, my name is Lucille Zeph. I'm Director of the University Center for Excellence and Developmental Disabilities Education Research and Service, formerly known as UAPs, at the University of Maine. And I’m also here as a guardian of a young man with autism.

Dr. Duane Alexander: Good morning, I'm Duane Alexander. I'm the Director of the National Institute of Child Health and Human Development at the NIH.

Dr. Kimberly Hoagwood: Hi, Kimberly Hoagwood from the National Institute of Mental Health. I'm Associate Director for Child and Adolescent Research and the Executive Secretary for this Committee and delighted to have all of you here.

Dr. Hyman: Steve Hyman, Director of NIMH. And I was going to do it in a minute, but I just want to thank Kim Hoagwood and her colleagues for working hard with NIH staff and people from DHHS and other departments to coordinate this meeting.

Dr. Yvonne Maddox: Hi, I'm Yvonne Maddox. As Steve just mentioned, I'm the Acting Deputy Director of the National Institutes of Health, but I also wear another hat, which I'm also equally as proud of. And that is that I am the Deputy Director of the National Institute of Child Health and Human Development, Dr. Alexander's Deputy. And I am very excited about this meeting today.

Dr. Barry Gordon: Hi, I'm Barry Gordon. I'm a Professor of Neurology and Cognitive Science at Johns Hopkins and also the parent of a low-functioning child with autism. And I'm very delighted to be here and very impressed at the

group that's been gathered, present company excluded.

[Laughter]

Dr. Cindy Lawler: I'm Cindy Lawler from the National Institute of Environmental Health Sciences, speaking for our Director, Ken Olden. And I'm also the Institute representative to the NIH Autism Coordinating Committee.

Dr. Audrey Penn: Audrey Penn. I'm the Acting Director of the National Institute of Neurological Disorders and Stroke. This is really an organic brain disorder, so we feel very involved and have high hopes for this endeavor.

Dr. Deborah Hirtz: I'm Deborah Hirtz, also from the National Institute of Neurological Disorders and Stroke. And I'm the representative for the Institute to the NIH Autism Coordinating Committee.

Mr. Jon Shestack: I'm Jon Shestack, one of the founders of the Cure Autism Foundation. And I'm very happy to be here since thousands of our families worked for 3 years to get the legislation passed that created these programs. So we're very

happy to see that it's starting in this nice fashion.

Dr. Hyman: Okay, thank you very much. Now we will, presumably, have time during the course of this program -- already, I've noticed that there have been a lot of initials and programs. And I hope we'll have a chance, not only to discuss what those are, but how they will all work together. Indeed, one of the goals of this Committee -- it says Coordinating Committee -- is to really think about how we can most constructively move forward in the goal, which is research and, ultimately, success against autism.

Without further ado though, let me turn the microphone over to Dr. Yvonne Maddox.

Dr. Maddox: I am delighted to welcome you on behalf of the Director of NIH. Dr. Ruth Christian, who is currently serving as the Acting Director of NIH, really gets great pleasure out of welcoming new committees and establishing relationships with individuals who serve on committees such this because this is an important Committee. But also we recognize that so many of you, not only our

Federal representatives but, certainly, our public representatives, are giving a lot of yourselves and of your time to come here and to meet with us to carry out this important business.

This is a particularly noteworthy Committee in the fact that this Committee was mandated by Congress, as most of us in this room know, under Title I, Section 104, of the Children's Health Act of 2000, which was signed into law on October 17th, 2000. Section 104 specifically stipulates that the Secretary, DHHS, shall establish a committee known as the Autism Coordinating Committee -- as we are now going to call it, the IACC, another acronym -- to coordinate all of the efforts within the Department concerning autism, including activities that are particularly carried out through the National Institutes of Health and the Centers for Disease Control and Prevention.

It was on April 25th, 2001, that Secretary Tommy Thompson, our Secretary of DHHS, delegated the authority to establish and administer the IACC to the Director of the National Institutes of Health, working through the Director of the

National Institute of Mental Health, or Dr. Hyman. The first meeting of the IACC was supposed to be convened before the end of 2001 and, hence, we are here today.

This is a tremendous opportunity for us. It is really a tremendous opportunity for partnerships and for relationships and coordination to intensify and to advance the research on autism. And NIH is, indeed, pleased to be leading this activity.

The Committee, which is comprised of Federal components, as well as non-Federal components -- and I think the thing that's most exciting about this for me is that, again, this is an activity in which sister agencies within DHHS are going to come together to discuss this important venue. But even more so, this is the Committee that now is going to have representation from the public. And this is so critical in an area such as autism. And as many of you are well aware, the Secretary of DHHS felt so strongly about the public component of this that he wanted the delegation of authority to appoint the public members to reside with him,

because he, indeed, embraces this activity.

We will be going through the agenda, as Steve has lined out for you this morning. But I think there will be lots of time for discussion and for networking about new idea and new programs. It is expected that you, particularly this distinguished group of individuals, will not only help us by helping us support the mission of this Committee, but we also believe that you will help us in carrying out a helpful exchange of information, as well as collaboration and partnerships long after you leave the meeting today.

Oftentimes, when you have a committee such as this, we put a lot on the table on the day of the meeting and, perhaps, if we are going to meet -- we said at least twice a year -- it's important to recognize that many of these activities will require commitment long after the meeting has ended. So I'm hoping that we can continue these partnerships after the close of the bell today. So, again, I'd like to thank all of you on behalf all of NIH for your willingness to do this. This is important for our children, for our families,

and for our public. So welcome, on behalf of NIH, and let's see that we can get through the agenda in an expeditious manner, but no leaving any stones unturned. Any ideas or issues that you'd like to put on the table, we all want to hear them.

So, Steve, I guess I'll turn it back over to you. I can stay for at least an hour, and I'd like to be here to entertain any questions that might come up.

Dr. Hyman: Okay, thanks. We're also still expecting a representative from the Department of Education and somebody representing the Secretary. Okay, so let me just see if we can establish here some of the goals of the meeting and perhaps hear from some of the members as to what is going to make this the most useful kind of meeting.

We're always worried about having too much of a dog-and-pony show up front because the meat of the meeting will be in actual discussion. So we've tried to create a situation where recognizing that some of you know the ongoing programs of the NIH and the CDC and so on. By the same token, what we

want to do this time is to really create a platform so that everybody is brought up to speed on some of the critical programs.

Just so that we sort of share our knowledge, but I think that it's a small enough group, as Yvonne and I were just saying, that it can be -- while there is a certain formality, you know, mics are always on -- I think for it to be as informative as possible, it would be good if members of the Committee needed clarification early on, especially if some of us Feds start lapsing into acronyms that are unintelligible, to stop us and ask questions.

The goal, ultimately, what we want to get to after you've heard about the programs, is a sense of how we can best coordinate among different NIH agencies, across different DHHS agencies, and across departments but also collaborate effectively with our public members and, indeed, more broadly with our stakeholders. And as all of you know, this is often a complex interaction, because while everybody agrees ultimately on the goal, there are a lot of reasonable differences as

to how we might proceed to that goal. And what we really hope for in this meeting are to actually enhance -- because there have been constructive beginnings -- but to enhance a constructive dialog toward this coordination.

Now, one thing I just want to remind people of, but it will be a matter for discussion at the end of the day, that there are many committees. This is the sort of OR Committee now, where everything has to be brought to the table. There remains an NIH staff-level committee, for example. And you will see reference to that Autism Coordinating Committee. For example, when we come to discussion of the CPEAs that Dr. Alexander will discuss, or the STAART Centers and we need to think about the best role for that group.

Our staff, for example, still needs to meet in order to discuss everyday mechanics of how different NIH Institutes, or sometimes different Federal agencies will do business, but the question really will be how much of that, you know, needs to be -- conducted in that forum -- reported here. So I want to just bracket that but

let you know that all of these issues of coordination, transparency, really are on the table for discussion as this group proceeds.

Before turning the microphone over to my colleague Duane Alexander, I just wanted to welcome Dr. Morrissey. Do you want to -- everybody has already gone around the table. I hate to put you on the spot, but would you like to just give your role and so forth?

Dr. Patricia Morrissey: Well, I'm wearing two hats today. I'm representing the Administration on Developmental Disabilities, and as of an hour ago, I'm also representing the Secretary.

[Laughter]

Dr. Morrissey: So, I'm glad to be here, and I'm sorry that we missed the first few minutes. Because when you're depending on Government travel and traffic, you can't always estimate how long it takes to get here. But thank you very much.

Dr. Hyman: One thing that I just would remind everyone is that the entire proceedings are being web broadcast, so that's good in terms of the public nature in transparency of the meeting, but

it's also suggested that if you feel really passionate about something, just remember, it will be recorded for posterity.

With that, let me reintroduce Duane Alexander, who is the Director of the National Institute of Child Health and Human Development. This is, obviously, an NIH Agency which has a longstanding and deep commitment to autism research.

And he is going to describe an important program. Remember, I said we would just sort of lay out for you the platform of what NIH does. And this is the NICHD Collaborative Programs of Excellence in Autism, which are a collaboration with the National Institute on Deafness and Other Communication Disorders, Dr. Alexander.

Dr. Alexander: Thank you Steve. I appreciate the chance to really set a very early part of this Coordinating Committee's meeting and have the opportunity to talk about the Collaborative Programs of Excellence in Autism, which are really one of the largest and most visible and significant components of the NIH portfolio in

autism research.

I want to give just a little bit of historical background of this program, talk about -- a little bit about -- what was done in the first phase of these studies and what our plans are for the future operation of this as a network.

When Congress first became active in urging the NIH to increase its activities in autism research in the early 1990s, one of the first things they asked was that NICHD hold a state-of-the-science conference on autism and autism research. This was done, and it was really quite a successful conference.

It provided all of the Institutes that were involved here at the NIH in autism research of various types with an opportunity to have an update from what they themselves were doing in their Institutes that not all of us may have been aware of but, primarily, hear from the scientific community what was going on in autism research, what was not going on in autism research that needed to, and where the opportunities were for expanded activities in research and autism, and

what the primary needs might be.

From that conference, two areas that were identified as particularly in need of increased attention and of great promise because of advances that have been made scientifically in the last 2 years were in the neurobiology and the genetics of autism. As a consequence of that recommendation, the NICHD and NIDCD pooled their resources and worked up a solicitation for a group of program project grants focused on the neurobiology and genetics of autism.

These were program projects rather than Center Grants or ROl Grants because it was anticipated that each of these sites that might be selected to participate in this would have their own site-specific research consisting of several projects but also have the ability to recruit a cohort of subjects on a national basis that could serve as the foundation for joint kinds of activities, that the group would develop themselves, focusing on neurobiology and genetics and autism.

This, in fact, worked out and turned out to

be the case and has worked pretty well. The solicitation resulted in the funding of 10 different sites across the country. We really recruited to this some of the most outstanding people doing research in autism and recruited into this as well some people in basic science areas of genetics and neuroscience and neuroimaging, in particular, to join in this effort where they had not necessarily been doing research in autism before.

This Network of independent projects really was congealed and formed into a functioning Network by the leadership and drive of Marie Bristol, who was NICHD's program person in the Network, with Judith Cooper participating in the same activity from the Deafness and Other Communication Disorders Institute.

Together they worked with these investigators to help develop some common protocols, particularly in the areas of neuroimaging and genetics, recruiting a cohort of about 1,600 families with one or more persons with autism in that family for the genetic and neurobiologic

studies. These were done in addition to the site-specific research at each place.

From this has come the largest cohort, I believe, in the world that has been exceptionally well characterized, according to common diagnostic criteria, entry criteria protocol, so that we, basically, have confidence that the people who have been recruited here show sufficient characteristics to be diagnosed as autistic, as well as different types of autism, some who have regression form and some who have never had any regression but have basically been characterized as autistic from the beginning.

Some of the studies that have been done in this Network include neuroimaging studies that have documented differences in brain function, in face recognition, in language use in children with autism. Also EEG-type studies that demonstrate again, brain differences in kids with autism compared to controls in relation to language development, as well as face recognition, as well as genetic studies that have identified several candidate loci, none of which have been

definitively proved yet to be associated with autism.

And give us more grounds to work on in the genetics arena than we have ever had in the past. The Network also conducted a study of secretin and its possible use as a treatment for autism. This was a multisite, randomized, double-blind controlled trial of two different forms of secretin versus placebo. And this study from the Network was just published a couple months ago.

And like previous studies that have been funded by NIH, also demonstrated no particular benefit from secretin in treatment of autism when you did this in a controlled fashion.

So we felt that this Network has functioned quite well over its 4 years of existence to date and has proved its value as a resource that should be pursued and tapped further. Now that they have this large cohort recruited, it is available for some additional studies and also a Network that we ought to keep together and functioning, but that we might make some changes in it to make it function even better and increase the usefulness

of it as a Network, rather than a group of program project grants, that because of goodwill a common interest, focused as a network even though they were not one.

So we made a determination to re-compete this Network together with NICHD and NIDCD, but we would change the mechanism of support from program project grants, POls, to Cooperative Agreement Grants, Ul9s, so that they will be set up to function as a Cooperative Agreement Network. Now, this will be a closed competition. We have a cohort that we will build the studies around.

There will be both site-specific and group studies in this Network as it re-competes, but the focus really will be this large cohort of well-characterized subjects and families that we can involve in studies in the next phase of operation of this research.

Therefore, we have issued letters of invitation to the existing sites to submit applications for Ul9 Cooperative Agreement Grants that will be received December 12th, reviewed together, and come to the June Councils of the two

Institutes. We will also be adding to this Network a Data Coordinating Center to facilitate the common protocols and activities across the 10 different sites. That is a separate competition, and that solicitation is almost ready to be issued, but that data center will be ready when the Network needs it.

The dollar amounts for the first year of the re-competition will be about $11.8 million, including that $1 million from the Centers for Disease Control for the vaccine study that I will describe for you in just a minute.

So as I said, these will come to our June Councils for funding in July and August so that there will not be an anticipated lapse between the funding for Phase 1 and the funding for Phase 2.

This will, however, be a competitive process. There is no guarantee of renewal; they are all working very hard on their submissions for both their site-specific projects and their joint projects. This will be a very rigorous scientific merit review, so that these investigators are working very hard and very conscientiously to make

sure that they get a good score so that we can renew, hopefully, both the common protocol activities and the site-specific activities. One of the things that will be featured in Phase 2 that has already been started in Phase 1 -- there is a study of the measles/mumps/rubella vaccine and other vaccines in relation to the regression form of autism.

It's common belief that roughly 20 to 25 percent of children with autism show some form of regression. That is, they lose skills that they developed -- largely, language skills, but sometimes motor skills as well. The exact prevalence of this form of autism is uncertain and a matter of some debate, with some of the research that has been done -- really in the CPEAs -- looking at the issue of regression, suggesting that many of these children who were reported to be regressors actually had some suggested signs of developmental problems and developmental delays earlier on.

So one of the things that's being looked at is an attempt to try to characterize more

carefully the regression forms of autism, both from physician records and reports, but largely from very detailed parent interviews about developmental milestones, skills that were lost, even to the extent of reviewing in some instances first-birthday videotapes of kids or other videotapes of other occasions for a more detailed developmental assessment than maybe parental recall alone is able to provide.

What we hope will be achieved from this is a more precise estimate of the prevalence of the regression form of autism to start with, and second, a well-characterized total sample of as pure a group of children with the regression form of autism as we are able to identify.

We will then use that group in comparison with the children with autism that did not show regression and the development of a normal control sample to conduct the studies in relationship to regression autism in general, as well as a specific study of the relationship between receipt of measles/mumps/rubella vaccine or other vaccines, that we can also take a look at for

comparison purposes, and the regression form of autism. We will have specific information of the vaccine history of the children with dates we hope to correlate with the data that we have on regression.

But this is a three-phase study. The first stage is complete. We have the interview data completed, we have the other data on regression completed, we're currently in the process of now analyzing that data to help us plan for Phase 2, which will be the recruitment of the normal control sample as well as some other data gathering on the regular cohort.

And then a Phase 3 study in which we will also add laboratory studies of children with regard to the vaccine status, whether it is possible to demonstrate a difference, for example, in measles antibody titer, measles virus prevalence, whatever, in these children. So that is just one example of the studies that will be done with this cohort. And that study is being funded by the Centers for Disease Control.

That's pretty much an update on the status of

this activity. As I said, this will be about an $11.8-million investment, combined by the two Institutes and the Centers for Disease Control, in addition to the funding that will be provided for the data center. We will have those applications in the 12th of December, and we'll be making awards next summer. That's pretty much where we are. Judith, anything to add from NIDCD's perspective?

Dr. Hyman: We have time, certainly, for some questions. I think one thing that would be worth just addressing; it's a general point. I know that Dr. Cordero later is going to talk about a new Centers program that you have at CDC, and we're about to talk about the STAART Centers.

One of the concerns that was expressed, I think, with some passion at the last NIH ACC family meeting was about whether these different activities in your mind, or in anybody's mind, would detract from each other or would be competitive or whether there was adequate capacity really to maintain the CPEAs. And I think you now have some view of the kinds of applications that

are coming in. And maybe you would address that.

Dr. Alexander: Yes, I think that clearly all the CPEA sites will be submitting their applications in this re-competition for Phase 2. They are very excited and enthusiastic. They have no intention of dropping these activities.

A number of them will be, in fact, applying for centers, and some will be applying for the STAART Program Centers; some will be applying to join the CDC Centers Program. All of this is anticipated to be additive and not detracting from each other. So this will be a growth program and not a program where there is competition for doing one or the other.

Mr. Shestack: In the past, what were the annual budgets for the CPEA Programs?

Dr. Alexander: It's been around about $9 million from the combination in the last year.

Mr. Shestack: Indirect costs?

Dr. Alexander: In total costs.

Mr. Shestack: In total costs?

Dr. Alexander: Yes. So this represents an increase of a programmed increase of about 10

percent built in, Jon.

Mr. Grossman: And Dr. Alexander, when you re-compete for this Network -- right now there are CPEA sites; do you anticipate the need for more or less sites? And going forward in the first year, we have $11.8 million budgeted; do you see that, again, increasing or decreasing as you go into the Phase 2 and the Phase 3?

Dr. Alexander: Okay, we do not anticipate growth in this particular program, the reason being that we have a cohort recruited of 1,600 families. And much of the focus of the research that is not site specific will be the utilization of this cohort for group studies that are developed by the Network.

So it's really not possible to add another site because they don't have this cohort that's characterized in a common protocol like the existing one does. So this CPEA Network will stay at, hopefully, 10 sites.

Dr. Gordon: Dr. Alexander, is there any special provision, beyond the usual for data sharing, for data access? I mean, this is a

fabulously well-characterized sample that's being constantly studied more. And there's normal mechanisms, of course, for sharing data and examining such people, but I wondered if there were any special mechanisms built in to these Centers for that?

Dr. Alexander: The Data Coordinating Center will be a mechanism for facilitating that. Right now, each site has basically, its data. They share that data on the common protocols with the group, but all the rest of the data is the investigators' data. With establishment of the Data Coordinating Center, we will use that for group data and for sharing data within the Network, and it's anticipated that eventually that data set will be made available on a much broader scale. That's the NIH way.

Mr. Shestack: And you're putting out an RFA for a Data Coordination Center for the CPEA Network. And then some period down the line there is going to be a similar RFA for a data management center for the STAART Network. But the types of data that are overlap tremendous amounts; is there

a need, actually, to do two of these? It seems like setting up one infrastructure that any investigator can plug into by choice, if they want to. You know, using common programming language and common diagnostic tools would save money and time. Is that something possible?

Dr. Hyman: Let me just answer that. I think ideally, ultimately, we want to -- I mean, you know I passionately believe that people shouldn't be like farrows, ultimately buried with their data, but that data paid for by public funds should be shared. The difference -- and I don't want to put Duane on the spot because I don't think he's had a chance to consider this -- but from the point of view from the STAART, the new Centers, the rules for data sharing will be clear from the outset.

And people will apply for these knowing, you know, about data sharing. I think what we have to work out, because your suggestion is a good one, are the incentives and disincentives to investigators in an existing network?

Mr. Shestack: It wasn't a suggestion that you

be prescriptive about it, that the STAART Centers have access to the CPEA data or vice versa -- that to be down the road -- but that the infrastructure to allow the sharing in the data might be one. And just, you know, invent that wheel one time. It's going to be the same wheel.

Dr. Hyman: Well, I think that's something we should strongly consider. Yes, absolutely. And the key players are here at the table, so, any other questions, comments?

[No response]

Dr. Hyman: Okay, so now let me move on to talk about the STAART Centers, which also grew out of the recent legislation that Yvonne Maddox reviewed for us at the outset. And, again, for those of you who were here at the last NIH Autism Coordinating Committee open meeting with families, there was a lot of discussion. And since that time, there have been more discussions and a lot of progress.

Steve Foote, who really has worked, perhaps, harder than anybody and worked together, actually, with Yvonne Maddox on getting these Centers off

the ground, has actually provided for you -- probably you have this. Because I think it's important for you to have some sense of clarity as to the timing of all of this, especially because the issue of timing was a major area of contention at the last family meeting and subsequently.

And, again, nobody's right, and nobody's wrong in this. On the one hand, there is this intense sense of urgency to get going. And on the other hand, there is this desire to make sure that these Centers really are as good as they can possibly be.

And, hopefully, we've come up with a compromise that's going to work. Just to give you an overview before going to the sheet, the goal -- and this was really a shared goal from the very beginning -- was that there will be Centers that, above all, would have as their role facilitating basic research and clinical research, but more than that, facilitating what has become a buzzword, but a critical one: translation of basic research into clinical. And a number of NIH Institutes have really begun to have programs

focused on translation. And at NIMH we have a Centers program which requires both basic and clinical components.

I can tell you, it's only a few years old. We were very nervous about this because basic scientists, clinical investigators, and practitioners often speak very different specialized languages. And the critical basic science for autism, which is going to include genetics and the downstream effects of genetics, and neuroimaging, among others, has developed a language that has grown extremely specialized and arcane.

Our experience, however, with our existing translational centers, I think, has exceeded any reasonable hopes. That is, the scientists really have grown to recognize that it's only together that they are going to solve these critically important problems. So there was general agreement that these Centers should be translational.

The legislation, however, really stipulates certain areas. And these include cause, diagnosis, early detection, prevention, treatment, and in

addition, very important areas of science that we all agree on: developmental neurobiology, genetics, psychopharmacology. And one could add other very important areas not even listed: psychosocial treatment development, even health services issues -- because of the question of whether there is access to treatment for families.

And the goal is to create Centers which will bring together critical aspects of this. I think there is now agreement that if we asked every Center to carry every one of these topics, we would end up with very fragmented and superficial efforts. But the goal is to have Centers that have relative weight of specialization -- all being translational -- but a relative weight of specialization in on area or another, but in aggregate to have a network in which all of these critical areas can come together.

In order to do that and to really make it translational, it was also long agreed upon that these Centers would not be fortresses or separate islands but, indeed, would collaborate with each other, and we also -- as Dr. Alexander just talked

about a Cooperative Agreement -- these will also be cooperative agreements. And what that means is that NIH staff will be very much involved from the outset, that these are not, you know, give a grant and we'll come back in 5 years and see how you're doing. But the NIH staff will be very, very much involved.

I am happy to announce that the key Project Officer working with Steve Foote on this will be Deborah Hirtz, who is at the table, which is also a nice example of collaboration across Institutes. That is, after we tried to steal her and failed, we worked out a collaborative arrangement in which she will work with NIMH staff but remain officially with the Neurology Institute. So even within NIH, collaboration and cooperation are possible, sometimes after a few hiccups.

The major discussion that many of you will recall was about whether to begin this effort with a group of planning centers or with a group of just get going with the centers. And like all passionate discussions, we've ended up with a compromise. The idea of a planning center is that

when you're asking -- part of the goal is to bring new people into autism research. In some sense, the CPEAs have a list of all-stars already on their rosters, but we all recognize that to solve the problems of autism, which are difficult problems, we want the very best geneticists, and the very best neurobiologists, and the best clinical investigators. And we want to give them time to really think about these problems, form collaborative groups that are going to be effective, and to apply for Centers.

At the same time, there was a strong recognition that there were some groups that were already coalesced and that, perhaps, they shouldn't be made to wait. So the structure now, to turn to this handout for these studies to advance autism research and treatment, or STAART Centers, is ultimately to have a network of at least five centers that will, in essence, follow out the dictates of the child's health act -- of the Children's Health Act of 2000.

We have had one complete competition already and another well underway. The first competition

was this developmental group that is here, especially, in an attempt to bring together new groups. And you can see all of the numbers the RFA was issued last April. And we've gone through the process, and six groups were funded in September. And we were, actually, very pleased with the quality and the imagination of these groups that are coming together.

Now, because these groups are developing in order to have Centers, we're going to have -- and you'll see at the back -- a full Centers competition for the people who have had this developmental step. But at the same time, for those people who already felt ready, an RFA was issued in June 2001.

Applications were due in November. It looks like there are 12 groups that have applied, so this is going to be a very vigorous competition. The peer review -- and this is a matter that we can discuss -- the peer review will be held in the Center for Scientific Review, that is, the body apart from NIH Institutes that conducts review.

My understanding is that there is a very

experienced scientific review administrator putting together this review. Her name is Anita Sestek. And we are now having discussions about how that review will be constituted. Certainly, the hope is that there will be some, just as there are public members on this Committee and success with public members of a number of the NIMH review committees, that there will be public members on that committee. The precise process will not differ from the way in which public members are recruited to any NIH review committee.

That is, people have to be qualified to do this, but by qualified we don't necessarily want our public members to sit around and be the experts and whether one statistical method or another is better for complex genetics, but rather to think about issues like the overall impact and significance of a proposal, whether the recruiting strategies for the clinical parts, for example, are likely to work with families with autism, whether the informed consents are proper. So there really is a substantial and real role for public members.

And, ultimately, the choice of the whole committee is in the hands of the independent scientific review administrator, and that's very important. The goals are that Institutes should not -- while we can make suggestions, since we are ultimately going to fund these -- we shouldn't also be in control of the review process. There is a kind of extra step of insurance that there not be conflicts of interest, and so forth.

So this competition will get awards for the first Centers in 2002. And then there will be another competition for those people who have gone through the developmental step. The commitment is $12 million; that's total costs when these Centers are funded. And each Center, as you can see at the bottom, will be capped at $1.2 million direct costs.

And, therefore, when indirects are included, for those of you who are not indirect cost educated, this is what the universities get for paying for the associated infrastructure, ranging from lights and water to supporting the IRB. The total cost for each Center will be between $1.8

and $2.1 million.

So that's where we are, and I would welcome any discussion or suggestions.

Dr. Gordon: I have served on NIH review committees, and I'm not sure how a public member would serve on a review committee for this kind of thing.

Dr. Hyman: Again, this is why I try to -- what we don't want is a kind of tokenism. First of all, let me just say, I don't want to tie Dr. Sestek's hands. You know, this is in her hands, not my hands. This is currently a matter of discussion. I can only tell you what we've done at NIMH, but there are other examples of this at the Cancer Institute and Allergy Institute for AIDS grants.

Basically, for a complex grant like this that involves clinical aspects, there are very important roles that public members can play. For example, while sometimes the scientists are focused really on the overall technical details, we have found on our study sections that public members will say, well, you know, this all sounds

great, but you won't recruit anybody in these particular protocols. And they've led to strengthening the protocols.

Or rarely, but sometimes, we've relied on public members to say, you know, this informed consent is not so clear to a layperson, you know; maybe you can understand it, but there needs to be plain language.

But in some sense, I think the most important role that we've seen our public members play is just to step back and say, explain to me how this effort is going to make progress. You know, sure, these are beautiful experiments, but how do they get us from here to there? So it takes the reviewer sometimes out of their narrow, more technical frame of reference. And we have to be careful because we also want to make sure that at a technical level, things are exactly right. We never want to fund bad science.

And it would be disingenuous to say that the details of these interactions between public members and the majority, who are going to be scientific reviewers, are always easy or that

people really know their roles. On the other hand, I think as long as we are clear about the roles that people have, our experience is there has been enormous mutual respect and a better outcome.

Mr. Shestack: Have you figured out, best-case scenario, how many would fund this round and how many you fee ethically obligated to hold back for the six people who applied successfully for [Inaudible comment] grants?

Dr. Hyman: It's going to depend on the scores. I mean, but we could imagine funding three on this round, you know, or two. I mean, it really is going to depend on the review.

Mr. Shestack: And their legislation doesn't limit you to five.

Dr. Hyman: No, no, we understand that. And we have not also limited ourselves to five. I mean, it's possible that we'll have three fabulous ones now, and there will be three fabulous ones in the next round and that we can't resist. And if the money is there, we might do that.

Mr. Shestack: Is there a mechanism envisioned

for grants which are not successful but may have particularly good components for picking some of these off and pushing them into program projects?

Dr. Hyman: [Microphone not turned on] Yes. This is one of the things that our Project Officers mean, in some sense, this is one of the things that Deborah will be really focused on -- will be if there is a great component that would do better as an RO1, we would work to get that component associated with the right genetics project officer or neuroimaging project officer or clinical trials project officer. I mean, the goal is -- and I think we talk about it, but I think it's very important that the public [Inaudible comment] is that this is not the be all and end all. This is a step for enhancing the [Inaudible comment] in autism research.

Mr. Shestack: [Microphone not turned on] So does the [Inaudible comment] community have any special charge to [Inaudible comment] about the Centers as a group as a whole? [Inaudible comment] of the things being [Inaudible comment] was that they be [Inaudible comment] CPEAs and [Inaudible

comment] and, perhaps, more regionally concentrated [Inaudible comment]. And [Inaudible comment] not every Center has to [Inaudible comment] much longer [Inaudible comment] going to have [Inaudible comment].

Dr. Hyman: Right, right.

Mr. Shestack: How does that work?

Dr. Hyman: How does that work, yes.

Mr. Shestack: Get into the process?

Dr. Hyman: That's a very good question. So the review committee, actually, will focus one [Inaudible comment]. And that is the role of the Institute, is actually then look at this as a portfolio matter. That is to say --

Mr. Shestack: Is there Council [Inaudible comment]?

Dr. Hyman: First staff and then council, that is correct, within the Institute? We can't ask the review committees to do too many things or it doesn't come out right. The review committees really have to focus on scientific and technical excellence. And this is part of the reason that the separation [Inaudible comment] functions.

And then the Institutes can look at the overall portfolio balance and make sure that we -- because we want to make sure that not only the letter, but the spirit of this legislation, gets followed. But that has to be done after we look at what there is that is so highly [Inaudible comment].

Mr. Shestack: And then the final decision is made by Council?

Dr. Hyman: Yes, Council.

Mr. Shestack: With staff recommendations [Inaudible comment].

Dr. Hyman: That's correct.

Dr. Gordon: Jon had brought up the question that's in my mind, and I'm sure it's a general question, which is who looks at the portfolio as a whole? You mention it comes up at the Institute level, but is there a roadmap that's being examined, and is there a committee looking at the Institutes to kind of judge how they're investing?

Dr. Hyman: That's a very good question. And the issue is, in this case, yes. These will be networked and as a general agreement, and right

now, Steve Foote, Yvonne Maddox and Deborah Hirtz will be making sure that we look at the portfolio as a whole. One of the reasons also to retain an NIH staff-level committee is that an Institute with a smaller budget like NIDCD might not be able to afford an entire center. And one of the things we want to do is to make sure that they can find a piece that they can justify to their Council because it has to do with language development or communication. We wouldn't be able to ask, you know, Deafness to pick up, perhaps, a very different aspect.

So, yes, it is being looked at as a whole, but in addition, we intend to report back here. And in some sense, at the end of the day, we should talk about the critical role for this Committee. But I think in terms of where it all comes together in terms of public transparency, my feeling is that it, actually, ought to be here.

Lee?

Mr. Grossman: I have a question and a comment to follow up. The first question I have is regarding the fact that we have 12 groups that

have applied in this round one. Could it be conceivable that those applications are so good and reviewed and found acceptable that we can avoid a round two?

Dr. Hyman: Well, we don't want to -- in the best of all possible worlds for the autism community, the applications are so good, that NIH has to somehow find money for yet more centers, which may not be so easy given -- you know, we thought 2003 was going to be a very good year for funding, and now the Nation has many other priorities as well.

And that's, again, something that we have got to talk about. But we don't want to avoid a round two. We really, on the one hand, think that round one will have the people who are already ready. But remember, one of our goals was to bring new people into this field. And we want to make sure one of the things we found, in all developing areas of clinical neuroscience, these are our -- I don't have to tell you -- some of the most difficult problems our science has ever faced, and we really want to recruit new ideas. Not simply

have a closed community. And so we really feel very strongly that we need to give opportunities through developmental mechanisms to have, sort of, new aggregations, new people. So we really want to have this second level.

But, again, and this [Inaudible comment] Jon's question, are we limited to five? The answer is the legislation says at least, it doesn't say limited to. I mean, the issue really for us as Institutes will be where do we get the other funds and remember that we answer as well to other stakeholders. So we'll just have to cross that bridge when we come to it.

Mr. Grossman: And my comment was I just wanted to thank you for your commitment to involving the public in these decisions. I like your description about having that broader vision that the public could possibly bring. It's important. With the incidence of autism growing at such a dramatic rate, this has now become an extremely dynamic disorder. And it's a benefit to the agencies to keep the public's mind in their minds when reviewing and looking at what direction

they should take. And I thank you for that commitment.

Dr. Hyman: I appreciate your comments. Any other questions or comments?

[No response]

Dr. Hyman: Okay, startlingly, we are exactly on schedule. This has actually never happened to me before. So we're now going to proceed to hear about some of the other activities that the NIH is up to. And then after the break, we're going to hear from ACF and the Department and CDC and other agencies. And Steve Foote is going to lead this aspect of the discussion.

Dr. Foote: What we were hoping to do here is engage in a discussion about the recent and planned activities of the NIH Autism Coordinating Committee. To do that in a way that would allow for inter-leaved discussion of specific items and rather than have formal presentations, to have myself lead off with an overview of some recent NIH Autism Coordinating Committee activities, have other people around the table, as indicated on the agenda, who have comments about their individual

Institute's activities that may not have originated within the NIH Autism Coordinating Committee forum, and have their comments also about their Institute's perspectives on NIH Autism Coordinating Committee activities, if you have questions.

So I just want to say first that the Autism Coordinating Committee has been intensively involved in the planning and implementation of the STAART Centers and the ongoing activities with the CPEA Network. All of these, as has come up in discussion, are complex endeavors in which multiple Institutes are going to be funding various parts of the program and have to be represented when planning activities are undertaken.

And as we work through what is for all of us a new process of funding a very large Centers program across several Institutes with their various legitimate interests in these programs, and yet needing coordination.

So this is exactly why the NIH Autism Coordinating Committee was constituted and put

into effect, is that science, of course, is a very heterogeneous enterprise in which a very large number of investigators in the outside world are generating applications, submitting them to us for possible funding, and this is not a -- although it's a 5-year effort in [Inaudible comment] sometimes it's not a 5-year plan. We do not dictate to the field where they are going.

And so we are often in receipt of a very large number of applications for potential funding that contain golden nuggets, but the sand has to be sifted away first. And they come into this variety of Institutes under a variety of mechanisms and our job is to remain in communication with each other, however difficult that is sometimes, about this broad spectrum of research that NIH supports on an ongoing basis.

The research that we support on an ongoing basis, using ROl mechanisms and investigator-initiated applications are three or four times the size of the investment that we do have, or are going to have, in these Center mechanisms. And although the Center mechanisms constitute kind of

a flagship enterprise because there are large chunks of cash that come in sizable quantities, really the bread and butter of the field and what the Centers have to grow out of is ongoing research that's sustained for individual investigators in an ongoing way by the various Institutes.

And so really, a large part of what we spend our time on is the routine vanilla kind of research that NIH supports. And then the Centers will be particular foci for promising developments.

In this past year, we have undertaken other RFAs, Requests for Applications, types of activities where we've created set-asides, specific funds that are accessible to investigators that are known to be there if they submit applications in particular areas, and so on. One of those was we sponsored an RFA for innovative treatment applications.

And this is based on a long history of activity by the NIH Autism Coordinating Committee, in this area, where we have held workshops in late

1999, I think it was. We sponsored a very large workshop to do a comprehensive view of treatments available for autism and to identify areas of opportunity and promise, where investigators could possibly go and make a difference in the kinds of treatments that are available to individuals and families with an autism problem.

And we created a set-aside, we issued an RFA, we reviewed those applications, and recently funded seven of those. They were a variety of applications, some dealing with pharmacologic methods, some dealing with behavioral methods. And just as a side note, we may want to discuss at some point the issue of behavioral interventions.

In the autism realm, there are rumors that float around from time to time when a specific grant might not get funded, or something like that. Rumors that NIH is no longer interested in behavioral interventions for autism, which are totally unfounded. And this was a specific mechanism by which we could elicit some of those kinds of applications and move forward with funding them. And that was done as a group

activity by the NIH Autism Coordinating Committee.

We have been active -- the various Institutes involve in the Autism Coordinating Committee -- have been active in a variety of efforts to enhance research infrastructure for the autism field. Some of those had to do with tissue resources; some of those have had to do with genetics resources.

We have felt that the tissue resources are very important, especially, post mortem brain samples. The amount of information that neuroscientists are able to get out of post mortem brain samples just keeps increasing. I mean, the genetic revolution, the ability of using immune markers to specifically localize molecules in the brain and so on, these techniques that were originally generated in basic animal research have now become applicable to human brain samples.

And the amount of information about molecular regulation, cellular communication, gene expression, and so on that we can get out of these kinds of samples is incredibly important in trying to determine what the pathophysiology of autism

is. And so we have invested resources, for example, NIMH and NINDS co-fund activities for brain collection and storage and dissemination using standardized protocols that are very high standards and getting thoughtful information about the donors of those samples. So we have undertaken that, and we are hopeful that the CPEAs' ongoing efforts in this arena and the efforts that will take place under the STAART mechanism with brain samples will considerably enhance the availability of this fundamental substrate for neuroscientists.

Similarly, for genetics, we are hopeful that the STAART Centers will provide a really critical mass of data in this area. But we have a number of ongoing efforts, including investigator-initiated submissions. Our NIMH repository, which is taking on autism samples in large numbers, and those resources from the NIMH repository are available to any qualified investigator. So we are responding both to this clear scientific need and to a stipulation in the Children's Health Act that NIH should enhance and coordinate efforts in those infrastructure areas.

Another multi-Institute initiative that NICHD, NINDS, and NIMH are undertaking together is something we call the Pediatric Neuroimaging Initiative. It's very interesting and informative to do imaging studies on the brains of affected individuals, those suffering from autism, and to try to determine what it is that's different and causing particular problems within the spectrum of those disorders. However, our biggest need right now is for a fundamental database, with publicly available data, indicating what the normal development of the human brain is.

This is a difficult, complex, expensive, long-term commitment on the part of our three Institutes to try very hard to put such a database together. And it has required an enormous investment on our parts in terms of staff time and in terms of money to get this initiative underway.

And it is not without its problems, both scientific and organizational. But we are thoroughly committed to this.

The idea is that individual experiments are experiments that take place within the STAART

Centers and the CPEA Program that run the risk of not being clearly interpretable unless the fundamental data about human brain development are available. And so we have a major effort underway in that area.

We have reissued as a public statement a document which is called the Program Announcement, which is just a way of stating in a public forum, namely, the NIH Guide of an Official Federal Document, that, yes, the NIH is interested in funding autism research. We're interested in doing it in any number of ways; anybody can at any time send us a quality application dealing with autism using any mechanism that's in the NIH armamentarium, and we will review it. And if appropriate, we will fund it. Just so that there isn't any misunderstanding in that area, and of course, that's always been true.

The NIH Autism Coordinating Committee has played a major role in establishing this Committee and in the efforts that were involved in that. And we look forward to interacting with this Committee, and it might be worth some explicit

discussion at some point later in the day about what that interface would look like. I mean, we have tried to walk the line of being responsive and being willing to take the initiative when that's necessary without dictating the organization or the structure of this Committee.

And we want to be helpful, but obviously, there is role for this Committee to play that's very important that supersedes our activities. But we do want to participate fully.

And then, finally, I should note that the NIH Autism Coordinating Committee has a history of sponsoring substantial scientific meetings having to do with the topic of autism and trying to highlight developments in that area. Earlier this calendar year we hosted a large meeting, largely organized by NICHD and then NIEHS, here at the Marriott Hotel in Bethesda that had to do with cellular and molecular aspects of autism. It was a very well attended meeting. Lots of ideas, lots of energy, and I think probably some new collaborations formed out of that meeting -- collaborations both between investigators and

between investigators and specific program officers here at NIH to pursue exciting possibilities.

And along that line, I might also note that we were excited to see the IMFAR meeting, the Meeting for International Autism Research that was held in conjunction with the neuroscience meeting recently in San Diego -- a large forum with a number of investigators contributing to the scientific content of the meeting and so on. And we have communicated to the organizers of that meeting that we stand ready to entertain an application for continued support of that meeting. We think it's an important development. I went myself to part of the meeting. There was exciting science there; there was a tremendous amount of energy focused around these issues.

So, that kind of concludes my opening remarks. Judith Cooper, and Deborah, and Cindy Lawler, I think, may have some brief comments to make. And we stand ready to answer any questions or discuss any issues that other members would like to raise.

Mr. Shestack: I would like to bring something up about them. The Autism Coordinating Committee, I think, was a pretty good thing, and it was sort of mandated by Congress.

And sometimes it's sped communication, and sometimes it's served as a bottleneck. And from our point of view -- and one thing that it wasn't particularly able to do was to, actually, get collaboration going between people doing genetic studies from funded by NIMH as opposed to say funded by NICHD. And it's still, to some extent, a problem, although, individual researchers have made alliances.

And the authorizing -- which brings me to the subject of banking -- and the authorizing legislation was very clear that it's important to do and the original language which started this, which was an autism bill. There was several million dollars that were suggested to be spent on it. You're right, every meeting we ever have scientists say we need brain tissue and we need even more DNA.

So I know that you guys have been working

with NDAR in doing this, but I don't know how much money you've put into it. And whatever the amount is, it seems like resource creation is a very smart thing for the NIH to do. From a genetic point of view, it costs like [Inaudible comment] to make a gene bank that's available to everybody about almost $5 million. If we weren't spending that money that would have been money we would have spent on pilot programs, which would then have resulted in more program projects, or ROls, or further studies that you could have funded.

So it seems like it would be a good thing for this group to talk about how to really push brain banking. And as far as the DNA, I know that people are starting to put in their DNA into the NIMH bank at Rutgers, but so far as I know, there aren't very many samples yet available. What can we do to speed it up? Get the CPEAs to put in, as well as the NIMH guys and move that fast? Because at IMFAR, what everybody said was, you know, 400 families is great, but if you have access to 1,000, you'd get there sooner. You'd get some clears to do some molecular biology. And those

families all exist out there now.

Dr. Foote: Yes, we are currently in active discussion about how to enhance the genetics efforts and the post mortem brain sample efforts. About a week ago I had an extended discussion with Jane Pickett, who has played a lead role in organizing the Tissue Resources Program. And what I would suggest -- there is an issue here of how the Committee would like to organize itself to address some of these issues. But perhaps this is an issue on which we could, for example have a more detailed focus at our next meeting, once everybody gets to know each other.

And we could discuss specific initiatives within these two arenas of genetics and tissue and see what types of coordination are feasible at this time. And this would, I think, be an opportune time to really discuss this in some detail.

Mr. Shestack: Because the volunteer organizations have staked out these territories and spent a lot of time and effort on both of them and are, actually, managing to cooperate with each

other on using certain common measures in both the gene bank and the personal tissue banks. And I think we would all agree that this would be -- to speed up this resource building -- would be a great way to leverage what we all know is a limited amount of money.

Dr. Hyman: All right, so let's make that -- before I give it to Barry, let's make sure that for the next meeting, we have to have the right people here from the voluntary organizations as well. And let's make this issue of resources for genetics, brain banking, and other tissue resources a major topic.

Mr. Shestack: And you should probably also bring people who are going to work with data management. Because the other thing is everybody is also [Inaudible comment] another resource [Inaudible comment].

Dr. Hyman: Yes, yes, of course. The database goes with the genes. Yes. Genes without phenotype won't get us very far, right.

Barry?

Dr. Gordon: I was actually going to comment

on the perspective I might bring as a cognitive neuroscientist that it's very important, as Steven mentioned, to have specific questions and details down. Because there have been many prior group efforts to collect phenotypic data and genotypic data. And there are many questions that might be examined, but as the questions get more specific, the use of the money and the tissue, and so forth, can be much, much better refined.

So I would just also add, to make sure that wherever this level of organization or steering comes from that it include people who are trying to understand the ultimate questions to what the data end users -- basically, to which this data will be put. It's very easy; I've seen it many times in data-basing -- to try to include the world, basically, and yet not have the variable that may eventually be of interest. So I'll just add that as a plea. I'm sure it was already in people's minds.

Dr. Hyman: I think one thing we do as we plan this is that the Exec. Sec. of this Committee will be in contact with you so that you don't have to -

- I'm sure you'll go home and think about other ways of organizing that to be the most effective session. And we should collect those ideas so that it really is as effective as it can be.

Lee?

Mr. Grossman: Yes, just to pipe in and add my two cents to this discussion that Jon started. Within 3 days, through the resources of the Autism Society of America, we could have an announcement out to 50,000 families regarding the need for this type of tissue and/or DNA sampling. It's not beyond the capabilities that are available today to get a tremendous surge and to get the word out that it's needed.

Obviously, what we do need is to have a coordinated effort so that it's not bogging us down by too many people coming in at one time. And I know between what Jon has to offer and some of the other organizations and, certainly, what ASA has, we can get that out.

I've worked with Jane Pickett quite a bit, and I'll be with her in January at yet another one of her presentations on the tissue banking. And

the way that it's been coordinated up to this point is you get a small group of people together, you talk about it, and, hopefully, you get a few people to sign up. We've been discussing this at ASA over the last few months to try and broaden that, certainly with the resources that we have now vis-a-vis the Internet and the communication thereof. Well, we can get as many people as is needed to develop a critical mass immediately and have those resources available.

Anyway, I just wanted to put that comment out there for us to think about for the next meeting. With that said, I did have some questions regarding the comments that you made on the RFA. And you said that there were seven RFAs that were funded.

Dr. Foote: Seven grants.

Mr. Grossman: Seven grants. Is it possible for the Committee to get the information on who received the grants and what their research is?

Dr. Foote: Yes. That is public information. We can assemble that and distribute it.

Mr. Shestack: And what was the total on the

seven grants? Do you remember?

Dr. Foote: Wait a minute somebody is waving at us over here. Oh, you were waving at somebody coming in the door behind me? Oh, an old trick, I see.

[Laughter]

Dr. Foote: So I think the total costs, and considering all the years of the grants, it came to about $3 million across the seven grants. And I think there is a little more specific information on our website, the NIMH website. And we can distribute to the members of the Committee even more. But whatever information is publicly available about those grants.

Dr. Cooper: Good morning to all of you on behalf of Dr. Jim Battey, who is the Director of NIDCD, who is not able to be with us today. I wanted to tell you a little bit about NIDCD and some of the activities beyond what you've heard about already this morning.

The National Institute on Deafness and Other Communication Disorders supports research in the areas of hearing, balance, smell, taste, voice,

speech, and language. And it's, of course, within the areas of voice, speech, and language that NIDCD forges its strong tie to the NIH autism efforts.

Communication limitations and the disabilities of children and adults with autism are of great interest to NIDCD. And we've long been committed to supporting research and research training in this area. You've heard about some of the NIDCD activities, Dr. Alexander talking about the CPEA end, Dr. Foote, some of the trans-NIH activities we've participated in.

But I'd like to take this opportunity to highlight some examples of some grants and training awards that we support that are specifically NIDCD efforts.

It's important to support scientists as they receive training in the development of skills and knowledge that will allow them to become productive, cutting-edge researchers in autism. One NIDCD fellowship award is doing just that by allowing an investigator to develop skills in genetics, to explore a possible subtype of autism.

This investigator is studying whether there is a subtype that is specifically related to the difficulties in coordinating and sequencing oral motor movements that are necessary to produce and combine speech sounds.

It may be that many people with autism who are minimally verbal or nonverbal are characterized by this difficulty, which we call developmental verbal dyspraxia. The NIDCD fellowship will allow this scientist to explore and develop this theory while also being trained and mentored on possible candidate gene regions for this subtype.

Facilitating the development of language in autistic individuals and the treatment of language deficits and disabilities are two areas of high priority to NIDCD. We're supporting two projects which are examining the efficacy of several treatment approaches in the development of expressive communication in autistic children. Picture exchange communication system, prelinguistic [Inaudible comment] teaching, a treatment which focuses on oral motor control, and

the Denver model are all being examined in carefully designed efficacy studies. Such research has obvious clinical implications, and the results can be expected to impact on our knowledge of what works and what doesn't work with particular profiles of autistic children.

Since its inception, NICDC has supported autism research. Recently, it's actually been very exciting to see this portfolio broaden and grow. Our commitment is strong, and we look forward to continuing our participation in this critical effort.

Thank you, Steve.

Dr. Hyman: Cindy?

Dr. Lawler: Hello, I'm happy to be able to speak for our Director, Ken Olden, who is unable to be here today. Our Institute, unfortunately or fortunately, is located in North Carolina so it makes it a little bit difficult to just pop over for a couple hours of a meeting. But I'm delighted to be here.

Our Institute, the National Institute of Environmental Health Sciences, is a relative

newcomer to the field of autism research. And I think we've been a member of the NIH Autism Coordinating Committee probably for about 18 months. We will and do participate in many of the joint initiatives that you heard described earlier today, including we've set aside funds for one full STAART Center, assuming that an application of high merit and relevance to the mission of our Institute is received. We'd be delighted to provide full funding for one of the STAART Centers.

And in addition to those kinds of joint activities that are really created within the framework of the Coordinating Committee, we've also been able to begin supporting autism research through one of our existing programs, which is a national network of centers for children's environmental health and disease prevention. And I'll just spend a very few minutes providing you with just an overview and highlights of this program, which really began in 1998.

And this network of centers is funded jointly through the National Institute of Environmental

Health Sciences and the Environmental Protection Agency. And it began with eight centers, and the mission is really to focus research on the unique vulnerabilities of children to environmental toxicants. Many of the original eight centers focused on children's respiratory health. So, within the last year, we decided to expand and augment that network of centers to add centers that focused on neurodevelopmental issues.

Four new centers were funded, beginning in August. So there's now 12 in this Network, and they're all funded at million direct cost per year. Of the four new centers, two of them are focused wholly or partly on autistic spectrum disorders. One is at the University of California at Davis. The second is at the University of Medicine and Dentistry of New Jersey. And both of these two centers really support research to try to identify and understand mechanistically potential environmental influences to autism.

And the kinds of environmental exposures that are of interest are broad. A few that are among the ones that will be examined include metals,

pesticides, and PCBs. And both centers have a strong interest in trying to understand how these and other potential agents may interact with genetic susceptibilities to produce autism.

The research supported is multidisciplinary, as one example, one of the projects that the UC Davis Children's Center is to develop new and better animal models of social interaction. And then use those models to try to evaluate how environmental agents may impact social behavior.

One of the projects at the center in New Jersey, Children's Center in New Jersey, is using model neurotoxicants such as methyl mercury to try to understand how environmental agents may impact some of the fundamental processes by which neurons grow and reach their synaptic targets. All of our children's centers -- I think a unique component of these two centers and all of our children's centers is that they are required to have at least one research project that is community-based, participatory research.

And this can take a number of different forms, but it always involves a strong partnership

with community groups. And for the Children's Center at UC Davis, the community groups there provided substantial input into the design of the large case-control epidemiological study that will be conducted, looking for environmental risk factors of autism.

And there, the community groups really made sure that some of the measures that would be collected would be ones that would help bear on hypothesis that were of particular interest to them, and as one example, the timing of vaccinations.

Where the New Jersey Center, the community groups there will provide volunteer families with autistic children, and they will participate in in-depth home exposure assessment and biological monitoring program and eventually, an intervention program designed to reduce the potential exposures to any neuro-toxicants that are identified. And these two projects, and all of the projects, these community-based projects in our children's centers, really are focused on trying to address the concerns of the community in the most

scientifically rigorous way possible.

I am really excited about the efforts that we've begun with these new children's centers because I think they do bring some new expertise and new paradigms to the field of autism. And it's also very important that this research that is being conducted here is placed in a broader context of autism research. And I certainly welcome input on ways that we can help foster meaningful interactions between the researchers at these programs and those that are supported with other components of the NIH and Federal agencies. And I'd be happy to answer any questions.

Dr. Penn: Right. For NINDS, as I said before, I think autism is clearly a neurological disorder. It fits in behavior, cognition, speech, development of language. It's a developmental disorder. And as such, it has been gratifying, for me anyway, over about the last 5 years to appreciate that we have, I think, much better command of criteria for this. It's all very well to talk about registries and resources, but you need to know what the disease is.

And over time, we have had major meetings, and pretty much under the Coordinating Center, for genetics, where everybody came. They really did. They may not talk to each other, but they were all there. Diagnosis, which was very, I think, in a way disappointing, although I am really, as I said, I think we do have really good scales now for making a fairly good diagnosis of this. Anybody who has a child with -- and I apologize -- you know what you're dealing with. But in order to get a scale that is validated to do some of this research, it's tricky.

And we had the molecular and cellular one just this fall. And, of course, we at NINDS, with NIMH, I think NICHD, are working on brain banking, as we do in many of our disorders, because for those disorders, we're all pretty much at the same point.

So what I think I can say for us is that we're deeply into imaging, and we have been, again, across the board. So we are interested in helping our investigators work on the criteria and what they're finding. And what they're finding is,

I think, very interesting, and I've been reviewing again this weekend, with the help of Dr. Hirtz here, that there is something that can be detected very early -- by age 2 or so. And then you, of course, have to go back and validate that these children are really autistic by age 5 or 6. But there are changes in the actual size of the brain.

And this is coming from one of our investigators who has been funded in this area for 16 years. I mean, this is not a new person to the field, but I know he's involved with everybody else in the field now and then, of course, the brain shrinks and more than the normal children.

And this bring us back to this pediatric network of centers for the normal baseline of imaging, which we regard as extraordinarily important, even though it is really very difficult to bring it about with the nine centers that we help fund and the imaging part of it. It's been demanding, but I think it's worth it.

The genetics: we're also working with people who are into autism now, as they are into a variety of other things. These are some of the

best people working on complex disorders like autism in the country. And they're coming up with loci. They don't have a gene, as you said, I think. We don't have a gene yet, but we have very impressive linkage to a variety of areas that look important.

And when you look at the list of people who are authors on these papers, you realize we really are galvanizing the community. And they are looking very hard at this. Probably, this is with the help of Jon and Lee and everybody out there who are also bringing these investigators together. So the genetics are happening, and we may actually get a gene.

And then the biomarkers -- we continue to work on the biomarkers. And we have invoked a group together last March to look very hard at the biomarker issue. The data was actually published in August in the *Annals of Neurology*. This is Karen Nelson's data. And so the question is to repeat it.

And, I think, we're just about at the stage where you have brand new samples -- again, thanks

to the California group. And we will be proceeding to repeat all of this. This immuno-affinity [Inaudible comment] has been used very successfully, but not asking question that requires as much sensitivity. So let me go back to that.

It is a terrific technique, one of our best immunologists here at NIH. Dr. Waldon has used it to study IL16. Don't ask me about IL16. It really gave him the data, and one of our own intramural investigators has the equipment and is using it.

So I think we validated the technique, but when you want the sensitivity that autistic blood spots require, you really, really have to have everything going very smoothly. And that is developing as we speak. So I'm very encouraged on that.

So, finally, just to say that the Institute is finally at the stage where it can contemplate translation. We can actually take basic mechanisms, go forth to a cure, which is not something we were really known for in the past. And this is one of the areas where we've got high

hopes. And we're lending Dr. Hirtz to mental health so we can do it.

Dr. Foote: Thanks, Audrey. Do you have a question?

Mr. Albert Enayati: I had a question for Cindy. This is [Inaudible comment]. I am a board member of New Jersey Cure Autism Now. I'm also a board member of [Inaudible comment]. Let me first congratulate you and Dr. Olden for establishing two centers for looking to [Inaudible comment] factor of autism. But let me also inform you that in the recent conference, an autism conference, the question was asked among the parents: How many percent of you parents think vaccination caused your child autism? Ninety-eight of the parents stood up, and they said they feel strongly that childhood vaccinations may cause this devastation.

What I'm asking today, who is going to be in charge of looking at childhood vaccinations? Every symptom of my son's autism and many children with autism, is mirror image of med [Inaudible comment] poisoning.

When we were in New Jersey, I attended

Governor [Inaudible comment] was present, and I spoke to Governor [Inaudible comment]. I know her for many years. And no mention of vaccination was brought in the whole inauguration. What I want to know is, as a parent, who is going to be -- which agency here would be in charge of vaccination? As, of course, in the afternoon I'm going to have a statement to say, but since Cindy was talking about it, I just wanted to know if [Inaudible comment]it take charge of vaccine issue?

Dr. Hyman: I think what we can have Dr. Alexander from the National Institute of Child Health answer your question and see if it's an adequate answer to your concern. Thank you.

Dr. Alexander: This is a topic that has received an enormous amount of attention. There have been congressional hearings on the part of government agencies and on the part of outside organizations, both here and in other countries. It has reached the point where a committee from the National Academy of Sciences, as well as the American Academy of Pediatrics, has been established separately and independently to

examine the scientific data to the fullest extent possible on whether there was any evidence that could link vaccination, particularly with measles/mumps/rubella vaccine and the incidence of autism. Both those committees, as well as the expert committee from the United Kingdom, as well as additional studies that have been done, have concluded separately and independently that there is at the present time no sufficient evidence to provide a link between measles/mumps/rubella vaccination and the onset of autism.

That does not definitively answer the question. It says that at the present time there is no sufficient evidence. A number of groups are trying to gather additional evidence. And in my initial presentation, I talked about the activities of the currently Collaborative Programs of Excellence in Autism and the activities that they anticipate in Phase 2. I highlighted the study that will be funded by the CDC to look at regression autism, in particular in relation to a vaccination history of the children, and specifically MMR vaccination. So we will be doing

that.

When I come up next, and I will just do it right now, I was going to talk about just one specific study that the NICHD is involved in that at first it may not sound like it has anything to do with autism, but it has an awful lot to do with autism, as well as many other developmental disorders. And that's the National Children's Study, for short. And for long, the National Longitudinal Birth Cohort Study of Environmental Influence and Child Health and Development, which just explains why it has a short title.

The Children's Health Act of 2000, in addition to establishing this Committee and mandating some autism research activities, also mandated that the NICHD, together with the Environmental Protection Agency and the Centers for Disease Control, lead a coalition of Federal agencies in designing and developing and planning and conducting a national longitudinal birth cohort study of environmental influences on children's health and development.

We are working together with Dr. Cordero and

the EPA, with many of the NIH Institutes, and a total of more than 40 Federal agencies to design and develop this study. We were working on this for about a year before we got the congressional mandate, so this activity is well underway.

We anticipate recruiting a birth cohort of about 100,000 families or so. We will recruit this cohort during pregnancy, and we will gather as much information as we can about environmental exposure history, as well as genetic history of both mother and father, before the pregnancy and during the pregnancy, including actual measures of a variety of environmental exposures.

We will follow those families through the pregnancy, labor, and delivery of that child, and we'll plan to follow that child with extensive information about a variety of environmental exposures and conditions, at least until that child is 21.

The exposures will include environmental toxins, chemicals, medications, vaccinations, as well as the behavioral and social and community and education environment that that child

experiences as they grow up. With the size of this cohort and the detailed information that we will gather, vaccines among them, we should be able to get some pretty clear evidence, given the size of the cohort, from this prospective study about any possible relationship between vaccines, MMR in particular, and autism onset, as well as many other environmental exposures that these children experience in relation to the development of autism.

Mr. Shestack: Dr. Alexander?

Dr. Alexander: Yes, sir?

Mr. Shestack: It sounds like that's an amazing and important study to do, but I know [Inaudible comment] it was discussing something specifically, not an issue of MMR vaccination, but the presence of thimerosal as an additive in older vaccine formulation and, in particular, there was an IOM report which made strong recommendations that people don't use this and made strong recommendations that there be further research to see what exactly the actions of toxicity were, if this was enough exposure to actually cause

autistic symptoms. If it was, what would be possible treatments?

So I think what Mr. Enayati was asking, which is a good question for this Committee, for families to understand because there is a lot of concern in the community, is there any particular agency under which whose authority this issue will come up, which is particularly heavy-metal toxicity, particularly thimerosal and vaccinations and its possible effects in creating a huge population of autistic children? Even though it may be taken out of future vaccinations, nonetheless.

Dr. Hyman: Well, yes, not only that.

Mr. Shestack: So which agency will be [Inaudible comment] us?

Dr. Hyman: CDC and, actually, FDA, probably have the major roles at this point in preexisting vaccine.

Dr. Cordero: I think there needs to be a very well-coordinated study. First, I think that to just sort of point out, and you've made already clarification, but MMR does not contain

thimerosal, and the issues with MMR are different.

Second is that in doing a study about the effects of thimerosal, it needs to be done in a retrospective fashion because, currently, the vaccines that are available actually do not contain thimerosal or may have just traces of it.

And so it is a study, for example, the longitudinal study might not be able to answer the question.

But in order to answer it, I don't think that any specific agencies could be able to do it alone. It's something that will need to be in collaboration with NIH or Child Health Institute.

And, in fact, I think that part of what we're exploring with the regression study is since this is a cohort that's been well characterized in various data that may provide us with the information to be able to answer some of the questions that have been raised.

Dr. Gordon: Just to make a comment, elicited in part by yours, since the cause or causes or autism are not yet known, and there is potentially an infinite number of possibilities that could be

examined. And science has had a well-established mechanism for trying to deal with an infinite number of possibilities in terms of evaluating what are valid hypotheses, what are reasonable hypotheses, how weight should be applied to them or not.

And since this Committee includes public members, as well as the heads of autism research in many ways, I wonder whether we might consider one of our charges might be to try to get across to the public what are these general criteria for how to evaluate, what is the plausibility of something, what kind of investigative weight should be applied. Because beyond mercury, there is undoubtedly going to be many, many, many other things until the cause or causes of autism are determined. And even when it might be determined for 90 percent of individuals, there is still going to be some individuals in whom the cause can't be determined if other medical conditions are any guide.

So we ought to be prepared for these kinds of issues, I think. And maybe this Committee might

consider one of its charges to publicly have those criteria out and keep them in the public's eye.

Dr. Hyman: Or at a minimum, I'll have to think about how we might actually do that in a way that's effective. But at a minimum, I think it's very important that we air these questions and find a way of discussing them so that families really feel that they are being heard and that, you know, their concerns are being taken seriously. But by the same token, you're right, the scientific community needs to communicate how it, you know, for example, as comprehensive as the NICHD lead prospective study is going to be, how does a community determine what variables are in, what variables are not in. I think that might be a topic that we can talk about for a future meeting. I think we had a question here and -- go ahead.

Ms. Barbara Fisher: My name is Barbara Loe Fisher, and I am President of the National Vaccine Information Center. And Dr. Alexander, I have a question for you on the longitudinal study, which, if that's what you're going to hang your hat on in terms of deciding whether or not vaccines play any

role in autism -- if you have all of the children vaccinated, if you're not making any provision to study those who are highly vaccinated, those who are lesser vaccinated, and those who are unvaccinated -- if you only do an epidemiological look at it, you’re not going to be able -- I mean, they're all going to be vaccinated. So you're not going to be able to compare the differences in development.

Is there any provision for looking at those three different kinds of children? And also, are you going to be doing work at the cellular and molecular level? Are you going to be looking at, after they are vaccinated, what changes occur?

Whether there are changes in immune functioning, whether -- that's my question.

Dr. Alexander: That is a very good set of questions. I can say that all these issues are currently under analysis as we go about developing the protocol for this study. And we are eagerly seeking input from a variety of groups as we go about setting up this protocol. Clearly, the vast majority of children in this country receive MMR;

they receive all the immunizations. But there is still 10, 15, 20 percent who do not. In a cohort this large, that number could be of sufficient size to give us an indication of differences between vaccinated and unvaccinated groups.

This is not a prospective controlled study. This is a prospective observational study. We will not randomize children to receive or not receive a vaccination of any type or another. It will be strictly observational, but we must determine what measurements we're going to take of these children.

Ms. Fisher: It's going to be very important since you've made the statement that you don't really understand what is normal development in a child's brain. If you don't understand that and you're looking at these children, you're not going to know what you're measuring because you're not going to know what normal development is.

Dr. Alexander: Well, we will have a substantial amount of data from the imaging studies about normal development by the time that this study gets launched if things go as planned.

So we will have that. We don't even know yet whether we're going to be able to afford the brain imaging studies on this cohort of children or not.

Dr. Hyman: I think this is the kind of question which could, I think, occupy us for a very long time. And if you'll forgive me, there will be more time for comments at the end. I want to give Lee right now the last word before people get a needed 10-minute break.

Mr. Grossman: Well, thank you for the last word. But just bringing us back to the agenda, I wanted to thank Drs. Foote, Cooper, Lawler, Penn, and Alexander for their update on what the Autism Coordinating Committee has been doing. But as a result of their discussion and perhaps it's just my jet lag, which is always a convenient excuse, I'm getting very lost in all the acronyms. And I'm getting very lost in all the tremendous work that you're doing. It's hard for me to keep track of it.

So what I'd suggest, and I know it's another burden on an already overburdened staff, I would like this Committee to be presented with a

flowchart, so to speak, or some sort of other organizational structured format that we could look at so that we know and we can take it back to our contingencies what is actually going on at NIH, so that it would be laid out what departments are working on which studies.

I think it would be very helpful to the autism community. It would certainly be very helpful to me and so that we could actually get a clear understanding of all the good work that's going on here.

Dr. Hyman: I think that's right. I would say though that one of the things that we have to discuss at the end really is specifically as this Committee self-organizes what the charge is so that we can really have the optimal flow of information. I don't want to consider these charts to be fixed right now. So we will do that, but I think we really need to discuss, you know, what this Committee is going to do that's going to be a unique value-added sense of coordination across these diverse efforts. And, again, not just within NIH, because after the break, you'll hear about

substantial efforts in other agencies.

Mr. Shestack: Lee, after the break, we're going to hear from other agencies, and one of the important things is, from this legislation there was a big component for the CDC, and there was a big component for Health and Human Services, which has not been acted on so far as the community know at all. And it was originally envisioned to be a fairly well funded component. So, there may be a lot of different things that the community will need information on.

Dr. Hyman: It sounds like people better get their coffee because everyone will have to be alert.

(Whereupon, a brief recess was taken at 11:15 a.m.)

Dr. Hyman: Okay, if we could please come to order. While Patricia Morrissey is coming to her seat -- she is going to have to leave for another important engagement -- so she is going to go first and then, because she's going to have to leave, if people have specific questions for her -- is that okay?

Dr. Morrissey: Sure. I suspect what I have to say, there won't be a lot of questions.

Dr. Hyman: Okay. But at this time then we're going to hear from the other diverse Federal agencies and public members on these activities. And we're going to begin with Dr. Morrissey.

Dr. Morrissey: Thank you Dr. Hyman. I really appreciate the opportunity to be here, and I'm going to make a few informal remarks. I am new to the issue of autism. I have a lot of experience on working on congressional committees on the House side and the Senate side. I'm very familiar with the work that Senator Gordon did to bring attention to autism in the early nineties, and I'm aware of how the budget for autism has changed in the last few years.

I'm also relatively new to my job, I started on August 27th as Commissioner of the Administration on Developmental Disabilities, and I recognize that autism is one of the things that we have to track and assist a wide range of people, both to understand where we are and work together to get where we need to be.

From listening to people this morning, the thing that occurs to me more than anything else is this Committee, and perhaps NIH, needs a translator. I looked at some of t publications that were here, and they are pretty powerful. But the information is written to -- that people probably, to a large extent, speak this same language. And I think one thing that will be helpful to you, and I commit our people to this, is the University Centers on Developmental Disabilities and the roles that they serve in their communities; they do function as translators for research information so that families and teachers and other people who work with a wide range of people with developmental disabilities can, in fact, understand what's going on and its potential implications and perhaps benefits.

The second thing I want to offer you is I am very good at packaging information for Congress. And I have a record that's not matched by anyone in terms of getting legislation through Congress. I would be very willing to offer suggestions and assistance with regard to how we keep the

congressional side of the House informed about things as we go on.

I have a few specific suggestions from notes I took earlier. One of the things that I think is important to people who are family members of people with autism, or people who serve children and adults with autism, is information. Clearly, they need information to do what they do on a daily basis more effectively, more compassionately, more appropriately. And I think that if this Committee could offer at some point during its tenure some criteria for when in the process, whatever the information is, information is released to the public, I think that would be an important contribution. So criteria connected to the timing of release of information.

The second thing is the issue of translation. There are clearly a wide range of audiences that can benefit from the information that research institutions collect, conduct, perform, and it is helpful to have people who are sort of a bridge or a link to people that are not directly involved in research to have them available at your call to

assist with the translation function. And I think the Centers funded by the Administration on Developmental Disabilities could clearly do that.

The other thing that I think this Committee could undertake is to figure out a practical way to put research information in context. That means the translators and the people who do the original research have to work together and somehow package this new information in a way that shows everybody on the street how it relates to information that came before it and may affect information that may come after it.

I think that will be a very, very positive thing that will assist developing a common frame of reference and also more trust among people who are family members of people with autism and the research in the medical community.

Another thing that I think this Committee could make a contribution concerning is the whole issue of conflicting information. What do we do when the one thing says this and then something else says this? Clearly, even if the full answer is not known, there has to be a good-faith attempt

to at least present conflicting information in a way that people like parents and teachers can step back and balance the facts and benefit from what they've read.

And the last observation I'd like to make is that, clearly, autism is a very complicated topic. That's one trite statement, but it affects families profoundly. It affects teachers profoundly. And I think that if we make a commitment to sharing information in an open way, in a language that many people can understand, we will be doing for families that have members who are autistic and the people that serve them a very, very important contribution.

Thank you.

Dr. Hyman: Thank you very much. Any questions for Dr. Morrissey before she has to leave?

[No response]

Dr. Hyman: I hope you will convey to Secretary Thompson what a vital area this is and the great interest of the public participants and family members. And that the Department will stay very much involved in the activities of this

Committee.

Dr. Morrissey: Well, I hope that the next meeting you have that I'll be able to stay for the whole thing. And I apologize for leaving.

Dr. Hyman: Well, thank you very much. Thanks for coming and sharing your perspective.
The next speaker is Henry Falk, who just -- you know, obviously -- had this timed so perfectly, just organizing his papers. He is the Assistant Administrator of the Agency for Toxic Substances and Disease Registry. There have, actually, already been questions for you, you won't be surprised to hear.

Dr. Henry Falk: Is that okay?

Dr. Hyman: Yes.

Dr. Falk: So I apologize for being late. And my card says I'm here for Dr. Copeland, and I should explain that in a way. You all know Dr. Copeland, probably, as the Director of the Centers for Disease Control. And I am the Assistant Administrator of an Agency called ATSDR, the Agency for Toxic Substances and Disease Registry.

And Dr. Copeland is also the head of that

Agency. So he heads both, and the ATSDR where I work is very closely linked with CDC.

Maybe I'll just take a moment to explain who we are at ATSDR. And ours is an Agency in the Public Health Service that was created by the Superfund Program. And we are meant to evaluate Superfund sites and to work closely with EPA and the communities involved and to advise EPA of potential health issues related to those sites.

And so in that sense, we work primarily on Superfund, but we work closely with the Centers for Disease Control, with EPA, with other parts of the U.S. Public Health Service.

In our work at ATSDR, we work at approximately 500 Superfund sites each year, and we look at potential for exposure and disease. We often are in a situation of estimating what exposures are to various chemicals, and in particular, we are working on evaluating the potential for disease at those sites.

In general, there are limitations to the health data that's available to us at all of these sites. We, obviously, have vital statistics data,

mortality data, birth data, cancer registry data. But for many other diseases, there is not detailed information as to prevalence and incidence across the country for use in our evaluations. This comes up with many diseases. For example, we have sites now where concerns have arisen about multiple sclerosis, ALS, a variety of illnesses, and we do the best we can. Very often we have to do studies at those sites to estimate the rates and see how they compare to what is known.

Many of you know that the Commission has recently in the past year come out with a report recommending improved tracking of disease, better surveillance data, as we would say, in public health terms for a variety of chronic disease and those that might be related to the environment. That would be a very big help to us at ATSDR and the work that we do.

The major instance in which we have been involved in terms of looking at autism arose at one of the sites in New Jersey at Brick Township. And ATSDR worked closely with the Centers for Disease Control in looking at the issues there.

The Centers for Disease Control looked at the prevalence rates, and ATSDR reviewed the environmental data, and jointly we worked on that project.

Again, I think the study highlighted the need for better surveillance data, the difficulty of actually looking at autism rates over time compared to literature rates, and how that affected that community. I think that given the intensive effort which the CDC made to identify all possible cases of autism at that particular site, it was difficult to say that the rates were elevated. I think there was concern that the more intensive effort might have turned up more information than is generally available on background autism rates. And the environmental investigation at that site did not identify particular environmental factors that were related to those cases. So that has been our involvement. We recognize that situations like this may arise in the future.

We will continue to work closely with colleagues at NIH, at CDC, EPA, and elsewhere. I

think this is really a very important issue, and our experience, coming at it from the environment, only highlights the need for better information and better data. So we are particularly interested, as I say, from potential for environmental exposures being important. That's the area that we work on. But I think we are very eager to assist and collaborate and work with others.

Dr. Hyman: Thank you very much. There was one question that really was, sort of, in the air before you arrived, which has to do with explaining to everyone how you collaborate. And, clearly, you work closely with CDC, but in what ways do you work with, say, NIEHS, or NICHD? And one thing that will be discussed at the end is how in this Committee we can get a large view of all of the efforts that might affect autism.

Dr. Falk: Sure. Let me take a moment on that then. NIEHS receives funding to do basic Superfund research. And we at ATSDR are more in the mode of actually going out and doing public health investigations. I see that as a very important

relationship in that mitt. I have been at ATSDR now for 2 years, but I've met a number of occasions with Dr. Olden, and we've been working on ways in which we can build the collaboration and make it even stronger than it is.

The reason I say that is that out of the basic Superfund Research Program, there should be lots of ideas, new thoughts coming out of the academic programs that would help us in terms of the service programs that we do at sites. And so we are very interested in what is being produced out of the basic research program at NIEHS. And we hope that the kinds of problems we face would actually simulate NIEHS in terms of the type of research that we do.

So I am very eager to link more closely the people doing the clinical work and the epidemiologic investigations with the people doing the academic work and the basic research. And that's been my focus with NIEHS.

We also work with other Institutes at NIH, for example, the National Cancer Institute and others. And, again, we see ourselves as being able

to collaborate. So, for example, we are very eager to support the work, for example, that's done in cancer registries, but our particular emphasis would be to encourage more thought about how to collect environmental data, how to link that with cancer registry data, so as to how to be able to elucidate environmental factors that might relate to cancer.

Similarly, we have had sites with considerable amount of asbestos-related disease this year and thoughts about how to work with NHLBI and others. So I think we are not in a mode of wanting to recreate the wheel. We hope we can build and benefit from the research that's done at NIH and both with CDC and NIH, kind of link up our efforts in terms of bringing environmental data and health data together to sort of look for linkages between the two.

Unidentified Speaker: First, let me tell you how happy I am to find out that Dr. Hyman grew up in Teaneck, New Jersey. I was so proud to be from Teaneck, New Jersey.

Dr. Falk: I have a daughter-in-law from

Teaneck, New Jersey, if that helps.

Unidentified Speaker: Dr. Falk, a couple of months ago during the ACEP meeting, I was [Inaudible comment] in Atlanta, Georgia, one of the representatives of your organization brought important of [Inaudible comment], which is known to cause the devastating disease called Reye's syndrome. And he informed us that your Agency will be willing to investigate this part of the [Inaudible comment]. I just wanted to know if any information you have on this research, or are you willing to investigate this part of the thimerosal?

Dr. Falk: When the concerns arose about thimerosal in vaccines -- and, I guess, maybe for the benefit of everybody else. In recent years as more and more vaccinations are given to children, the amount of thimerosal preservative became more and more of a concern. And thimerosal concern relates to organic mercury. And we, again, work closely with CDC and with the Department on U.S. Public Health Service because ATSDR has worked on mercury-related issues in a variety of Superfund

and environmental settings. And we produced, for example -- we have documents that summarize the literature on substances like mercury -- toxicology profiles.

So we coordinated and have tried to assist the Department, CDC, and others in terms of looking at issues related to thimerosal. And we continue, as far as I know, to work with the National Immunization Program at CDC in terms of providing information that we have related to mercury and how it might be important.

So, yes, I think -- you know, [Inaudible comment] mandate at ATSDR is really a Superfund Program. All of our authorities at our Agency relate to the Superfund Program, but my feeling has been that, as we work with specific chemicals and collect information and have knowledge that might be helpful, I am certainly eager to collaborate or work together with CDC, NIH, Department of DHHS and others, NIEHS. So I've taken that stance of saying that we should try to be proactive in working with others. So we have, in that sense, worked together with others in

looking at those mercury issues.

Dr. Hyman: Any other questions?

[No response]

Dr. Hyman: Then we should move on to Dr. Cordero, who is here from the Centers for Disease Control and Prevention as the Acting Director of the National Center on Birth Defects and Developmental Disabilities.

Dr. Cordero: Good morning. And I'm going to show some slides. Thank you, Dr. Hyman. It's a pleasure to be here representing CDC but also representing the newest Center of the Centers for Disease Control, as I mentioned earlier, the National Center on Birth Defects and Developmental Disabilities.

Just like this Coordinating Committee, the National Center was created as part of the Children's Health Act. We are fairly young. We were actually established -- opened our doors officially April 16th -- about 7 months ago. But we are really building on 30 years of experience at CDC, working on birth defects and developmental disabilities. So I thought that since we are a new

Center, we'd spend just a few minute describing what it is that we do, who we are and what we do.

[Slide]

We are a group of about 100 that currently has a budget of about $70 million. And we just recently went through the process of defining our organization. And, in essence, being a small group, we are basically divided into two divisions: the Division of Birth Defects and Developmental Disabilities that would address issues of primary prevention, of monitoring, basically, surveillance of birth defects and developmental disabilities and implementing the actual prevention programs.

But lesser known, but I think just as important an activity for us, is what we have in the Child and Adult Disabilities and Health Division. This is a group that actually addresses how do we help people that live with disabilities -- the 54 million people that live with disabilities? And that includes children with disabilities, including autism. And issues like assuring appropriate health care, education, and

others.

[Slide]

The Center actually is working in three areas. And they reflected on their organization. First, they are focusing on preventing what we can prevent. Basically, what we know how to prevent. Examples of that are preventing spina bifida and [Inaudible comment] that could be provided by use of folic acid before pregnancy begins. But also the involving of prevention of fetal alcohol syndrome. About two-thirds of birth defects and developmental disabilities the cause is not known.

And so we, actually, spent quite a bit of resources in developing Centers for Excellence that are pursuing causes of birth defects. And as I mentioned earlier, we also promote wellness of individuals living with disabilities.

[Slide]

I would like to focus on pursuing causes. And one of the first elements in finding causes of birth defects using epidemiological data is that we need to know what the prevalence is. And we have done a number of studies looking at the

prevalence of developmental disabilities and more recently, developed in Atlanta one of the few programs on what is really a model surveillance on autism spectrum disorders.

Oh, let me just briefly mention that this covers five counties in the metropolitan area, so it's a population base. So for the area of Atlanta, we know through intensive search for cases using both school records, medical records, records at treatment centers. So we have a very good idea of what the rate of autism is and autism spectrum disorders in the group of children from 3 to 10 years of age.

And we just presented this data at the first International Meeting for Autism Research, held in San Diego. And the rate that we found in Atlanta for 3 to 10 for 1998 was actually 3.4. Actually, this is a typo; it's 3.4.

[Slide]

We also have, as Dr. Falk mentioned, we have done special studies on Brick Township, and there the prevalence was 6.7 per 1,000. That's about 4 per 1,000 among for autism disorders. But then for

PDD and not-specified and Asperger's, that adds the 2.7.

[Slide]

We are actually funding six States in 2002 to begin population-based surveillance of autism and other developmental disorders. And here you have the States that are involved. Actually, in this area, the group -- it's Maryland and Delaware together -- New Jersey, South Carolina, Arizona, and West Virginia, plus, we continue to do the work in metropolitan Atlanta. These projects are being funded around the $300,000 range, but New Jersey, that actually has a larger study -- so about $800,000. And West Virginia, it's based on an earmark, and it's $1 million. But they also are addressing not only surveillance, but it includes prevention of secondary conditions in persons with autism.

[Slide]

In addition to that, and it's something that was included in the Children's Health Act, in September 2001 we funded four Centers for Autism Epidemiology. And these Centers are Johns Hopkins

that received a grant of about a half a million dollars and will be identifying cases of autism in Maryland and Delaware, as I mentioned earlier and the University of Pennsylvania that received nearly $500,000 also, which will cover the Philadelphia metropolitan area and then Colorado Department of Health, also about $500,000. And they will concentrate and identify in children with autism in the Denver area. And, finally, the California Department of Health, that has a grant of about $650,000, will ascertain autism cases statewide but will be having a very special focus on more intense monitoring in the San Francisco Bay area.

These areas will also be networking to collaborate in studies on, basically, case-controlled studies on autism, looking at risk factors. Plus, each of the Centers would have a specific area of interest. Some of them would be involving genetics or immunology, biological marker screening. And the first meeting of this group of investigators is scheduled actually very soon, November 27th through the 29th in Atlanta.

[Slide]

In addition, we have -- and it's part also what the Children's Health Act asked CDC to do, is to develop a clearinghouse. And we are in the process of developing this clearinghouse in conjunction with the Centers of Excellence in Autism. And it will include both data on epidemiologic studies, information and research resources, guidelines on confidentiality, but also data on information on outreach and educational materials. And we would, certainly, coordinate with other clearinghouses that are available.

[Slide]

One area that I just wanted to spend a minute speaking about is promoting wellness with individuals with disability. In addition to the treatment of the primary condition, children that have disabilities, whether it's autism or other conditions, often have significant problems having access to good health care, from dental to just primary care.

We recently had a listening session sponsored by the Surgeon General looking at cognitive

disabilities. And there are many, many stories on the lack of access to prevention services to just basic services and so our group is trying to focus on the primary -- basically, preventing secondary conditions, but also access to important health care and prevention care.

[Slide]

One example, and this is done mostly in adults, it was developed by the University of Montana. And it worked on improving access to health care, improving prevention, for example, for physical activity. And by doing that in about a 6-week course, they were able to show about a 10-percent decline in hospitalization costs, fewer -- about 25-percent reduction in secondary conditions. So we are looking at how this kind of approach can be expanded to a number of disabilities, but also through the country.

[Slide]

And how do we do all this work? Well, we do it together with a number of people, basically, by partnering with organizations to consumers and universities, State and local health departments,

other Federal agencies, other CDC programs.

Thank you.

Dr. Hyman: Do you want to take questions up there or from your seat?

Dr. Cordero: I'd be happy -- I just need a second to get the next presentation here ready.

Dr. Hyman: Okay.

Unidentified Speaker: Can I ask a question?

Dr. Hyman: Yes.

Unidentified Speaker: (Away from microphone) That 3.4 per 1,000, [Inaudible comment], is that [Inaudible comment] general autism? You know, [Inaudible comment] disorder, plus [Inaudible comment], plus [Inaudible comment] activity?

Dr. Cordero: I think that is the total. That would be comparable to the 6.7 in Brick Township. Actually, just in case I need to be correct.

Unidentified Speaker: Okay, and you don't know what the breakdown is?

Dr. Cordero: Actually, I have the paper here. Actually, I'd be happy to get that information for you. What I have is a paper from Brick Township, which you probably have.

Unidentified Speaker: Yes.

Unidentified Speaker: (Away from microphone) Dr. Cordero, I have a question for you. Did you, as part of the sample, [Inaudible comment] Township in Atlanta or it was by [Inaudible comment] or -- and why so much difference, getting twice that?

Dr. Cordero: Yes, actually the basis for doing the Brick Township was the methodology in Atlanta. But the level of intensity used in Brick was much greater. So I think that part of the -- what appears to be a lower rate, I think it is not as intensive, but we think that they are not that far away from each other in terms of the numbers.

Mr. Shestack: Could you just clarify, did the CDC fund three or four Centers of Excellence in Autism Epidemiology?

Dr. Cordero: Four.

Mr. Shestack: You did four. And these are three 5-year programs?

Dr. Cordero: There are three. I think it began at three, but they will be expanded and recomputed after 3 years.

Mr. Shestack: And so there won't be any more Centers of Epidemiology and Autism? It will be those?

Dr. Cordero: Not necessarily. Four is what we could afford. And, actually, the way that we set up the reviews, if we have more funding to send FY 2002, there is a possibility for other Centers. Actually, we had some exceptionally good proposals. We just could only go up to four. But one of the considerations, based on what the budget we may get from next year, is that we may fund more.

Mr. Shestack: And the aggregate -- the total on the four is how much a year?

Dr. Cordero: It's about $4 million.

Mr. Shestack: It is about $4 million.

Dr. Cordero: Yes.

Mr. Shestack: Okay, thank you very much.

Unidentified Speaker: Real quick, Dr. Cordero, is the CDC doing anything to determine at all -- and albeit, I know that it's difficult to go back retrospectively and look at this, but to determine whether, in fact, the incidence of

autism has increased over the last 10 or 15 years and they, basically, further dimensionalized that so that we understand -- is it truly because of better recognition and a broadening of the diagnosis or, in fact, are we seeing any sort of an increase in the overall incidence of autism historically?

Dr. Cordero: I wish we could go back and have confidence that by going back we would have accurate data and why there was the rate of autism years back. But going in the retrospective fashion always has some problems.

We intend to in metropolitan Atlanta but also in the Centers of Excellence and the six areas where we are funding [Inaudible comment], is to be able to continue to look and see whether from having a very systematic and standardized fashion for collecting data if the rate continues to remain the same or go up. And at least the data from '98 on, I think that we would feel comfortable and we could say look at the trends from then on.

Mr. Grossman: I just would like to comment on

the work that the CDC is doing. The Autism Society of America has taken the position that this research that's going on, this surveillance, is among the most important research that's occurring on the Federal level at this point. It's critical, and I can't emphasize that enough, that we get a handle on what the actual incidence of autism is in this country.

We banter about these numbers as if they almost don't exist, but what he's just presented from Atlanta of 3.5 in 1,000 -- I did some quick math, just to keep my mind activated here. It's, actually, 1 in 286 of these students have autism, which is, I think, in anybody's mind -- and no matter how you look at the statistics -- is incredibly significant.

So I just want to encourage this Committee to assist the CDC in any way possible and to find other resources, if possible, to quickly get a handle on incidence figures that this Committee and the Federal Government, as well as others, could use that to portray the true incidence of autism in this country.

Mr. Shestack: Is there a mechanism now, for instance, to get these latest numbers to the relevant Senators and Representatives on the relevant health committees or people on the Autism Caucus? There were a lot of people who had substantial interest who were also made contact with by a number of their constituents over 3 years.

And they would actually be very interested to know, because if it's 3.4 per 1,000, it's a different number from the number that the constituents presented them with. And it is a higher number.

Dr. Hyman: Well, Jon, you know, I was thinking the same thing. I was thinking all of us need to update, you know, with the right caveats. I take Lee's caveats that we really don't know the answers, but we need to update all of our information sheets with at least these ranges, because if we are portraying much lower ranges -- and I think NIH information sheets could be, actually, helpful in terms of dissemination.

Mr. Shestack: Also, earlier in this process

when we started working on this, someone said, you know, God, we don't even have a cost-of-illness analysis on autism to help guide us. And so we commissioned a fairly primitive one, a bare-bones one. But if one of the agencies were to undertake a more thorough cost-of-illness analysis for autism and related developmental disabilities, who would that be? And it would be a useful thing for all of us who are seeking to maintain funding.

Dr. Hyman: The NIH has typically provided figures on cost of illness, but they have been -- the methodologies are not pretty, when you think about not only the direct costs of autism, but the lost lifetime work potential and so on. I think we have to think about it not in a glib way, but whether that's been something NIH does or ARC.

Mr. Shestack: Or is it CDC?

Dr. Hyman: Yes, Yes.

Dr. Cordero: Steve, if I can say, if I may -- what -- we have, actually, a very good economist that's working with us. And one of the areas that we are actually going to look at is the actual cost of autism. I think it's very difficult to do

the indirect costs, but I think that we need to rely on an economist and the various standards. So, yes, we are looking at that as one of the primary issues.

And in terms of new information, we actually had a meeting with the Autism Caucus in Congress and the staffers. And we would be more than happy to visit with them again and brief them on the most recent data. I think Ms. Fisher has a question.

Ms. Fisher: Dr. Cordero, I talked to Rick Rollens last night, one of the forefathers that founded the MIND Institute. And I think it's very important at this juncture to relay to you some of the information that he has found out in the last few weeks.

Based on the most current data report obtained by the California Department of Developmental Services, California has just experienced the largest quarterly increase in the number of new cases of level-one autism in its history. According to DDS, between July 6, 2001, and October 4, 2001, a record-number 705 new cases

of autism entered California's Developmental Services System, bringing the 9-month total for 2001 to 2,069 cases -- more new cases in the first 9 months of 2001 than reported in any other full year on record. As with all DDH autism case-growth reporting, the 705 new cases did not include other autism spectrum disorders, such as PDD, NOS, Asperger's, et cetera.

Applying the year-2000 fourth quarter -- October 6, 2000, to January 4, 2001 -- figure of 566 new cases to 2001 -- a conservative number considering that so far in 2001 they've exceeded the 2000 first-quarter intakes by 68 percent, the second quarter by 38 percent, and a third quarter by 54 percent -- one could easily estimate that when all the number are in for 2001, conservatively estimated at 2,635 new cases, the year 2001 will produce a new -- 250 more new cases of level-one autism than all the level-one cases from 1994, 1995, and 1996 combined.

I think this is an incredible, incredible figure. And, you know, $12 million dedicated to this kind of increase. And if you can document

this kind of increase in every other State, $12 million doesn't even come close to what you need address what is an epidemic, obviously, of autism. At least in the State of California, if not all over this country.

And I'm wondering, how is there going to be more money taken out of the NIH budget to address this problem? Is there any plans to increase the money?

Dr. Cordero: Well, actually, the question to NIH, I think, that NIH can answer. But I'm glad to hear this information, and I think I would look forward to meeting with the group in California because they are one of the groups we are funding. So we're very interested in hearing more about those data.

Ms. Fisher: Well, perhaps the CDC could contribute some money. Now, Rick Rollens wanted to be here today but couldn't. And so I thought I'd bring this forth.

Dr. Cordero: Thank you.

Dr. Hyman: Next, we're going to hear from Kathryn Carbone from the Food and Drug

Administration. She is from the Center for Biologics Evaluation and Research.

Dr. Carbone: Thank you for this opportunity to discuss the FDA's activities in autism. And I'm speaking today for Dr. Schwetz, who is the Acting Principal Deputy Commissioner who, unfortunately, sends his regrets that he could not be here today. Today, in the brief time that we have, I'll be discussing three major areas of activity. One is in the Center for Drugs; it's just clinical therapeutic trials of agents to treat autism, clinical surveillance for vaccines in CDER, and also some basic science investigations in CDER.

[Slide]

Clinical therapeutic trials are -- I'm not going to read you this slide I'll cover very briefly. This is published information. We are, of course, prohibited from speaking of INDAs, or Investigational New Drug Applications, under review at the FDA, but I can tell you that in discussions with the individuals at CDER that are responsible for autism-related clinical therapeutic trials, they would love to be busier.

Basically, I can sum this up and say that the more objective and standard the clinical trial, the less likely is the effect is to be seen. So I can't really give you any drugs which currently are being studied and careful double-blinded, placebo-controlled trials show efficacy and then this published data.

One interesting thing I do want to point out is a "placebo effect" upward of 70 percent. And some of these trials -- which, of course, complicates detecting therapeutic effect, but on the other hand, perhaps, gives some hope in other mechanisms and some of the behavioral therapies may be applicable for the placebo effect over the years.

[Slide]

I want to also point out that there are many things that can make a clinical trial less likely to show efficacy, even in a drug. If you imagine, as an example, being an infectious disease person, if penicillin was applied to everybody with a fever and a white count, we might not show efficacy unless one knew that the few organisms

that were sensitive in the right area of the body.

So patient selection, being able to identify subtypes which may be responsive to drugs, is critical. Drug categories, I think -- this coming from the outside -- is an important change in sort of treatment of psychiatric illness where symptomatic treatment has been sort of [Inaudible comment] and very effectively so in many diseases where it appears that the symptoms once treated are the core features of the disease. But correct me if I'm wrong, but it appears that that is not the case in autism where symptomatic treatment has not been terribly successful. The endpoints I mentioned. And study design. Clearly, in a disease like this and this apparent huge placebo effect, study design is critical. So the better design the study is for objectivity, the more likely we are to find effective therapies.

And the reason I say NIH considerations is because we can only suggest. At the FDA, we like to work with the sponsors, with the individuals, but in terms of supporting studies, this is what we would like to see more.

[Slide]

And we also have an effort in CDER where we are tracking down reports of vaccine-associated autism. And this would be non-solicited. These are reports from the community. However, we would like to gather more information about clinical features in these reported cases to look at evidence for and against regression and, in a sense, assess the parental concerns. This would be also helpful in communication events. And this is being put forward by one of the offices, Biostatistics, at CDER.

[Slide]

And, finally, there are some basic science investigations. There are many things we need to do in regulating safe and effective pure and potent treatments at the FDA. And that is to have a way of assessing safety, purity, potency, and efficacy. And one of the problems has been, of course, in determining -- in terms of vaccines -- the ability to just determine prior to use in people, the safety of a vaccine, particularly for the developing nervous system. This is really a

nominal approach. In the past, the developing nervous system has not been specifically considered.

There are, essentially -- polio being the only validated neurovirulence test for polio vaccines that we have. There are other vaccines -- influenza, new smallpox vaccines, and other sorts of vaccines -- that need to be assessed for neurovirulence. And, preferably, we'd like to be able to screen out vaccines which look less safe before they get to the stage of being given to people. So a large portion of our study of the pathogenesis is to use this information to develop, validate neurovirulence assays for vaccines.

[Slide]

I'm just going to show you some thought-provoking approaches in terms of symptomatic therapy of autism. Say you have a child with the basic symptom of a hyperactivity to novel environments, sort of a core feature of autism. In some cases, there have been some good reports of normalizing with fluoxetine therapy, and some

reports have no effectiveness. And this is somewhat counter to it. So empiric may not be necessarily effective.

If you have some sort of physiological parameter, as was discussed earlier, a biological marker to follow that can sometimes enhance their efficacy, and saying he's measured the serotonin in the blood and this is something that has been measured in children in autism, hyperserotonin anemia, and the platelets. And in both cases, it's up, which is somewhat counterintuitive for the outcome of hyperactivity. But, nonetheless, you would expect this -- why you're getting a response to fluoxetine, which promotes the serotonin effect in a child which has elevated serotonin in the bloodstream. It seems counterintuitive. So this is what I call post hoc, pathogenesis-based theory -- therapy -- something is measured maybe decades after the actual insult. And it's acted upon, sometimes it works; sometimes it doesn't.

[Slide]

So I think what the combination -- and this is why, perhaps, some of these new Centers of

Excellence and new grants, the STAART grants are very effective in combining the clinical and the basic science. Is that in the model system where we have wild-type viruses, such as in humans, rubella, but in our model system, of course, it's [Inaudible comment] that cause hyperactivity. We now understand it. In one case, the case that responds to fluoxetine, we have an increase in receptors postsynaptically and the setting of high serotonin, which makes no sense. Usually, that's down-regulated.

So what we're left with is a question of is the serotonin actually being released and, therefore, once you promote serotonin effect, you actually get an outcome versus this other situation.

And it appeared to be the same setting clinically. However, what we see is a decrease in receptors, and you actually have [Inaudible comment] neuron death and, therefore, explaining why the SSRI, the fluoxetine, was not effective. So this is just to illustrate where the combination of basic pathogenesis, as well as the

clinical information together, can lead to some interesting theories.

And we're interested in this at the FDA because we're forced to deal with these questions of -- Are these vaccines bad for the developing nervous system? Are these drugs effective for autism? And so we need to know more about the basic pathogenesis.

That's it.

Dr. Hyman: Questions?

Mr. Grossman: Dr. Carbone, I don't know what, for example, role the FDA played in the RUPP studies that have been going on. I don't know whether they're involved or not.

Dr. Carbone: The RUPP studies?

Mr. Grossman: The RUPP network? Not involved. Well, then I'll give credit to someone else for those.

Dr. Carbone: Please do.

Mr. Grossman: But one of the questions, I think, that comes up, -- the analogy of giving penicillin for all fever, is appropriate. It's also appropriate for the symptoms or problems of

autism may be multifactorial and, therefore, respond to different drugs at different doses at different times. Is a general requirement of the FDA to have a global endpoint for autism?

Dr. Carbone: Absolutely not. If there was some way to separate out a subpopulation where they responded to reliably there is some predictive value --

Mr. Grossman: How about a subcomponent of the condition?

Dr. Carbone: Sure. In general, what happens is we like sponsors to come and talk before launching into large trials because we can set agreed-upon endpoints, discuss the appropriateness of endpoints, before a trial is launched.

Dr. Hyman: Let me just comment on that. The RUPP study or -- actually, it's an NIMH network. One of the things we've been working with TDC, actually, is precisely these kinds of questions. There is an overwhelming sense that in some ways our current diagnostic criteria, while they're very, very useful -- they're critical for epidemiology, for example -- also hamstring us

because we don't really know the true boundaries of these disorders.

And also, it may be that there could be really good surrogates for components of autism that we might find before we have a surrogate for syndromal autism. And one of the things that we really hoped to work on is to make sure that we -- underneath these syndromal definitions -- that we don't, in some ways, decrease the likelihood of finding novel therapeutics. And we all, I think, have a goal of finding patho-physiologically related symptom clusters that could then be targets for the development of therapeutics.

So to put it in a way that I hope will be jargon free: While we want to pursue monotherapies for autism -- you know, some drug that treats autism -- such a thing might only work very early in the pathogenesis. We shouldn't give up. We shouldn't necessarily call things merely symptomatic. I think we could have an enormous impact later in the pathogenesis if we can define symptom clusters.

And in some sense, what the RUPP studies so

far have been aimed at, which is not to detract from the need to come up with something that will affect the actual pathogenesis of the whole disorder, but we should be able to do both.

Unidentified Speaker: I have a question, just a quick question.

Dr. Hyman: Sure, yes, go ahead.

Unidentified Speaker: Thank you, Dr. Carbone, for a great presentation. You mentioned gathering information about the clinical features as part of VAERS, does that involve -- I guess the first part of my question is, if somebody reports an adverse vaccine event, that you get pediatrician records or any of that type of information? That's the first part of my question.

The second part is would you see any value in a study where that was retrospective, either through FDA or, perhaps, another agency represented here, that would actually go back and examine pediatrician records of children later diagnosed autistic, along with videotapes of those children? So you could actually see at what point in time illness, vaccine, what events actually

came into play and compare that to actual videos?

I think so much information could be gained from that.

And it's along the lines of what you were talking about in terms of looking at time of onset what's going on. And there is a lot of families that have, you know, hours and hours of videotape that are very obsessive when their children were very little. You know, took a video at 3 months, took a video at 6 months, took a video at 9 months.

I think, personally, the value of looking at that and comparing that to the records of the child's pediatrician, along with illness history, vaccine schedules, would be an extremely valuable study. That's my personal opinion. And I wanted to know if that's something -- because it could possibly involve vaccines -- if that would be a CDC issue, would that be more of an FDA study? Where would that sort of study fall?

Dr. Carbone: Well, VAERS is really a shared system between the CDC and the FDA. And the particular study that I'm talking about does

arrive out of the FDA's group, but they work hand in hand. I just want to state, as a background, VAERS has a system already where if there is question arising from the way something is reported, if it's not clear, if it sounds like it could be a serious problem, they have nurses and medical staff already that will go back and research this. So we ask for additional information, and they seek it out.

In the case of this study, it's sort of that emphasized increased.

Unidentified Speaker: Right.

Dr. Carbone: Specifically, with the study format. This is currently under formulation, so I can't give you the final pathway. And I'll certainly bring your comments to the individuals arranging it to discuss those. But that's, essentially, sort of what this group was thinking about.

Unidentified Speaker: Right. Right, so at some point, would results of that be released to the public, of those investigations, or is that always kept confidential?

Dr. Carbone: Oh, no. VAERS is public information and the investigation -- the plan -- would not be with any patient identifiers. It would break confidence, but the information would be made available, yes.

Unidentified Speaker: And that would be put together in aggregate in such a way that you could see patterns?

Dr. Carbone: Yes, I would imagine a publication would probably result with the information.

Unidentified Speaker: Great. Thank you very much.

Dr. Hyman: Question?

Unidentified Speaker: Yes, doctor, have you thought about a lymphocyte subpopulation study of children before vaccination and after vaccination, with say the MMR, DPT, hepatitis B, HIB and also the various polio vaccines? Have you thought about doing something like that?

Dr. Carbone: I think those kinds of studies are excellent. I think the limitation is really the FDA's budget. I think Dr. Cordero said $70

million and 100 people. We have $2 million and 60 people in the vaccine portion. So, we don't have the research budget available, but there are other mechanisms where we can apply for funds and do those sorts of studies. And I think that sort of study is an excellent idea.

I'm certain similarly individuals from NIH and CDC hearing that question would also put a great deal of thought toward encouraging or promoting or thinking about those studies as well.

Unidentified Speaker: Because I understand it's not only inexpensive, but it's less time consuming than say an independent long-term, safety study on all these vaccines.

And you probably could get an answer a lot quicker than doing something like --

Dr. Carbone: There is a concern at the FDA about the use of multiple vaccines. There is actually a guidance on that topic on the FDA website. So that is something we consider in every vaccine, where there is multiple vaccinations.

Unidentified Speaker: Okay, thank you.

Dr. Carbone: And we'd like to know more.

Dr. Hyman: We have time for one more.

Unidentified Speaker: [Away from microphone] Let me congratulate you for your commitment to the children with autism.

Dr. Hyman: Could you move closer to the microphone?

Unidentified Speaker: Yes. Let me congratulate you, your commitment to the children with autism at the Food and Drug Administration. In the summer of 1999, when the issue of the thimerosal vaccine came about and then there was a research [Inaudible comment] published, "Autism, a Unique Type of [Inaudible comment] Poisoning," they got in touch with Dr. Schwetz when he was at that time the Director of the National Center for Toxicology at the Food and Drug Administration.

We sent a letter to him; I must have called him more than 10 times. He never responded. And right now, as the Acting Deputy Director at the Food and Drug Administration, we had sent him two letters. And myself, I have called him numerous times to have a meeting with him to inform him of the concern of the parents regarding the issue of

vaccination.

I have two questions for you. Number one, I want to know why he refuses to respond to us. And by refusing to respond to the concern of the parents, does he think that the problem and issue is going to go away? A second question: I want a commitment from you that when you see him, to get an appointment for the Leader of Autism Organization to meet with him, and he could hear personally our concern regarding vaccine safety.

Thank you.

Dr. Carbone: I will take your request to Dr. Schwetz when I speak with him. I want to actually add some good news, perhaps, is that there now is a reduced thimerosal influenza vaccine that has been approved. So that all childhood vaccines now you can get them in thimerosal free or significantly reduced form, including influenza vaccine.

Mr. Grossman: Is this still the [Inaudible comment] vaccine, not the --

Dr. Carbone: Correct. It is reduced because it's not used as a preservative, but there's a

trace amount in the product.

Unidentified Speaker: (Away from microphone)

Dr. Carbone: It has been released. Evans is the manufacturer.

Ms. Carol Sprouse: I have one question. Carol Sprouse from CAN and a clinical researcher. On the studies you showed, there was a high incidence of parental report as showing positive change. Did you look into exactly what the parental report was and the aspects of the positive change? Because historically, parents have been often on the front end of noticing things before the medical community and scientific community. And I'm wondering if we're missing very valuable data by not getting what is used in "perceived changes" because it actually may be real changes?

Dr. Carbone: You bring up a very valid point. I think that many times a parent being in contact with the child, knowing the child intimately, can be very sensitive. And I think that this is a part of clinical research that, perhaps, needs to be addressed and refined as how to capture. And I think Dr. Hyman mentioned what to look at. Where

if these effects are real? How do we capture them? It's very important.

Ms. Sprouse: Well, and we also know that the assessment tools that we use for kids with autism are so crude at this point that we may be actually missing the data. So, guess my caveat is to be very careful that we don't dismiss this as not scientific. It may be that we're not astute enough to get to the science of it. And I'd like the Committee to at least think about that.

Dr. Carbone: Yes, a very valid point. Absolutely.

Dr. Hyman: Thank you very much.
Our next speaker is from outside of HHS, from the Department of Education, and will be Gail R. Houle, who is from the Office of Special Education Programs representing Secretary [Inaudible comment].

Dr. Houle: Thank you. I'll just stay here; I don't have any slides. And I do thank you for inviting me to the meeting.

I have some experience with a similar group for our early-intervention program for young

children with disabilities. We have a Federal interagency coordinating council that we've had for probably about the last 10 years, since about two reauthorizations ago. And it seems to work very well. We meet four times a year. It's just been a real valuable resource for the early-intervention program part, which is now Part C of the Individuals with Disabilities Education Act.

Yes, I am from outside of HHS, and they did let me know that when I came in the door.

[Laughter]

Dr. Houle: First of all, I mean, I know I was late, but I didn't know I was going to be this late. My car was checked twice, the trunk was checked, the hood was opened, my bags were checked three times, I was not allowed to come up here on my own, even with my government ID. I was escorted up, I was met halfway by somebody from HHS. And I had my agenda in hand, so I don't know whether you know, maybe they thought I just ripped off that agenda from somewhere and was walking around with it trying to get up here.

Dr. Hyman: I apologize; it is not perfect

yet.

Dr. Houle: You know, I don't mind, it's okay. It's all right. It's just so different. The variance of my agencies is so different because we don't have that. But then again, we don't have the number of people from outside the Agency coming and going for treatments and whatnot on a daily basis. But it was interesting to have that guy lifting up the hood of my car. That was the last step. And our guys, well, maybe because they sort of know us, but we drive into the parking lot at the Department of Education, which is just a block from the Capitol. And they just wave; they don't even come out of the booth or anything.

So, yes, there's a great variance of my agencies. We wish, actually, they would be more conscientious about screening outsiders such as myself. When I'm an insider, that's what I wish.

But at any rate, I also am by training a speech-language pathologist, like some other people around the table. And so I have a lot -- I feel like it's a fair amount of personal experience working with children with autism and

their families. It's been a while since I had any direct experience in interventions, but it certainly was a large part of what I did as a speech-language pathologist.

In talking about the Department of Education's initiatives, most of our initiatives are out of the Office of Special Education, which is where I work. And I received the Early Childhood Program for Young Children with Disabilities, the Discretionary Part D program. I also work closely with the formula part; I'm going to call it Idea Part C and Part B.

Just a little basic background -- Part C is a program that flows directly from the Federal Government to the States on a census basis for young children with disabilities, both through age 2 or at risk for disabilities. And Part B is the part 3 through 21 that flows from the Federal Government to the State education agencies, and then to the local school districts, to cover services for children who already have diagnosed or are diagnosed as being disabled.

I work in a smaller program, which is the

discretionary part, where we have a fairly small pot of money to support the implementation of Part C and Part B. And when we were reorganized, we were reorganized to kind of a model of broad funding authorities in the discretionary area. So we can fund research activities, we can fund training activities, we can fund technical assistance activities. And we use all those authorities to fund work in the area of interventions for children with autism.

We had -- over the past 5 years, most of our initiatives had been targeted toward synthesizing the research base and trying to come up with some conclusions that would be of assistance to families and States and school districts and service providers in terms of making decisions about interventions. What are the best interventions for children with autism? So we funded the National Academy of Sciences.

Some of you probably were involved with that study at some level. Well, they don't do, of course, their own research, but they synthesize the research base that's out there and then make

some conclusions about it. And I brought a copy of the report. They have released it in a slick book cover form, and they are selling it, actually. And they had told me that they are trying to get it into Border's Books and for the general public market because they feel like there is a real demand for information on interventions for children with autism.

I was there for another reason at the National Academy last week, and I asked them about the sales of the book. And it was selling quite briskly for only having been available for about a month. So I was pleased with that. Huh?

Dr. Cordero: I need a copy.

Dr. Houle: Okay. Okay. I keep calling them and say send me 25 more copies. So I will be glad to give out copies as long as they last and as long as they keep sending them to me.

But we are real happy as an Agency that they are taking this kind of general public active dissemination role in getting this in the book stores because it's more than we could ever do as an Agency. They really are promoting it. It's on

their web page. We have so many products from so many projects that it would be difficult for us -- in fact, we don't even have the sophisticated marketing tools to go around to say Border's Books and try to get our products stocked on the shelf. So we are very pleased that they are doing this.

We also have had a lot of investment and technical assistance because of the demands of States and school districts to provide information about how to serve children, how to best serve children, how to pay for services. We have funded over the past, say, 4 years the National Early Childhood TA Center. And they have made autism one of their priorities in terms of technical assistance to States and to the other projects that we fund, who then are in the business of providing demonstrations and evaluations of interventions.

This year, I would like to see us shifting our focus somewhat to more funding of personnel prep and personnel training programs in service and pre-service now that we have somewhat of a basis to jump off from. And we've had some

internal discussions about this, and I'm excited about some additional funding that we have in personnel prep for this fiscal year. So we are hoping to make use of that right away, and possibly, some of the ideas that have come up are to find some in-service, maybe summer institutes at school districts. Where you would work with teams of family members, related service providers, special educators, regular educators, and children who were in 12-month programs over the summer. And that way, you're working with the children, with the families who are in that school system who are going to be going back into the programs in that school system.

So rather than spend the training money and possibly not knowing where the trainees are scattered to after the training is done, we feel like we can actually maybe have some measurable impact on the quality of services by taking the time during the summer to do some real high-quality work with the service providers, the school systems, the families and the children. And we won't be doing it personally, but we would be

funding school districts who would be interested in doing this.

I would be glad to take any brief questions. I know it's 12:30, unless you just want to break for lunch at this.

Dr. Hyman: Well, let me just – I think it would be good, but we have a few more presentations, and I think it would be good, if we could keep it brief, to have a few questions. Dr. Cordero?

Dr. Cordero: Just one comment. I'm so glad that you're sitting at the table because, especially for dealing with surveillance, monitoring trends in autism, having a collaboration with schools at the local level is very important. And the work that we've done in Atlanta, what we've found is about 40 percent of the children with autism, the only way to identify is through school records. So having access and then working together is going to be an important aspect in sharing that we have timely and accurate data on what the rate of autism.

Dr. Houle: Sure. We hope that goes smoothly.

Dr. Cordero: We hope so, too.

Dr. Hyman: Jon?

Mr. Shestack: So is the Department of Education part of this Committee now or is this --

Dr. Hyman: Yes.

Mr. Shestack: Okay and Health and Human Services, where there isn't a representative any more.

Dr. Hyman: Well, she --

Mr. Shestack: Right, she was here, but the legislation mandates certain programs from Health and Human Services be created that have not been created yet. And the sense was that there would, ultimately, be appropriations. I mean, there will be appropriations for them.

The Department of Education, it seems though, can also do -- for instance, one of the mandates is physician and patient education. And you're talking about funding in-service education for, I guess, service providers and families. Is there a set amount of money year to year for these kinds of programs at the Department of Education?

Dr. Houle: There's not a set amount of money.

You know, there's an appropriation that is made every year --

Mr. Shestack: -- that is disease specific or is –

Dr. Houle: Oh, no. No, no. No, no, it's for personnel preparation for service providers who work with children with disabilities, ages zero through 21. So within that area, there may be focuses, depending on the Agency's prioritized needs. But there aren't line items as per disability. There is a research authority, there is a training authority, there is a technical assistance authority. And that cover the whole population of idea.

Mr. Shestack: Could I just ask the group, what would be ways that people here could envision working successfully with the Department of Education? For instance, it's important to you to have people who can get certain surveillance information, if there's in-service training, you know, a lot of these people applying for STAART grants have either had them or had to set up clinical care centers in order to be eligible for

them. And there may be ways to work together that would create better results for all.

Because I'm not that familiar with the Department of Education, and it's a new player at this table. And since this group is supposed to really kind of coordinate what Health and Human Services does for autism --

Dr. Hyman: -- Jon, I would say that this is a good topic for the end of the day and maybe for a broader topic in the sense that we do have experience sometimes with how difficult it can be to translate programs that come out of a research agency into settings where they may be administered. And maybe part of the reason for that is that researchers haven't necessarily familiarized themselves with the needs in this case of schools and special education programs. And they actually design interventions that don't easily fit within those settings. And so I think it's a perfect topic, actually, to have on the table.

Are you going to be able to stay through the afternoon?

Dr. Houle: Yes.

Mr. Shestack: Yes.

Dr. Hyman: So that would be really good.

Mr. Grossman: I just want to comment that, from my perspective, this is a personal viewpoint that HHS and DOE are, perhaps, the most important players at the table. That may seem somewhat different from the perspective from the researchers and maybe the perspective of NIH, but --

Dr. Hyman: Of course, it makes us sad to hear you say that.

Mr. Grossman: Well, I'm looking at situations where services are so necessary and so underfunded. And these are the agencies that should be coordinating it and promoting them. All the wonderful things that we do here at this table from a research perspective may come to fruition in many years, but I, myself, have to go home to a child that I'm having a difficult time and I shouldn't by virtue of my position, but it's an impossible task for me to get the services that he needs. And I think that those viewpoints represent

every parent that you would talk to in the U.S.

Dr. Hyman: Let me just say, we will certainly communicate this to the Secretary, and I take your point.

Dr. Gordon: Well, I was going to say, one of the goals I think we can have is to try to convert or move from research practice and theory into best clinical practice. And so I'm very gratified to hear this. And I would like to see a very detailed shopping list. Because, for example, there may be problems of the CDC getting access to educational data that is necessary for surveillance and diagnosis, under current educational and legal systems that may not be apparent to many of us. There are very big barriers. I know that every time I've tried to go into a school system to do any studies.

Mr. Shestack: Hopefully, in the afternoon -- strategies I think we all kind of could agree on, but there are certain tactical issues that this group could address that would be very useful to the whole community.

Dr. Hyman: Okay, thank you very much. We are

a little late, but can I ask your forbearance, and we'll have a slightly faster lunch. I'd really like now to turn to your public members and have them make a brief statement, if you would like.

Dr. Gordon?

Dr. Gordon: I am going to pass so people can get food, eventually. Because I'm planning to have to stay later today.

Dr. Hyman: Okay. Lee?

Mr. Grossman: I just wanted to say that over the last -- well, since I became President in July, I've been pleased by the very active dialog that I've been having and the Autism Society of America has been having with the CDC, NIH, Department of Education, and the Health and Human Services. And we would hope that that relationship would continue and prosper. And I believe now with the Autism Society's representation on the IACC, we feel proud and honored to now be included as a participant with you in addressing and formulating a national agenda on autism.

ASA is the voice and resource of the autism community. It's now, we feel, a journey that we're

sitting at the table and continuing with you. We have 25,000 plus members and 200 plus chapters throughout the U.S. And it's an organization that, because of the virtue of our size and our scope, allows access for other agencies to get readily to a very available database to address the needs of the community.

But in my opinion, our strength is that the ASA is the only national organization that truly represents all the interests of the autism community. And, therefore, I would hope that you would utilize what we have to offer in terms of our chapters, our membership, and our outreach to use us to get the sense of what is happening in the autism community.

I briefly want to describe what I hope the results will be of this Committee. And I feel strongly that autism now needs to become a national agenda. When I say that, a lot of people ask me, "What is a national agenda? And what does that mean, and what are you hoping to achieve?"

Well, what I'm hoping to achieve is that every child will have an early diagnosis and

intervention. I'm hoping that every child will have an appropriate secondary schooling. And then I'm hoping that these children, when they become adult and spend 75 percent of their lifespan as adults, will begin to receive the services and supports that are so necessary for them to lead active, involved, fulfilled lives.

The lack of response that this Nation has given toward the adult aspect of this disorder is a national shame, in my opinion, because it hasn't been addressed. And if I relate that to what's going on in the secondary schooling arena, it really makes the perspective of what's happening with the adults even that much more worse.

Frankly, I'm incredibly scared at the moment by the statistics. It's the opinion of the Autism Society of America that within 10 years autism will be the largest disability in the United States. It's growing that quickly. I think that with these types of figures, these types of statistics -- and we can argue about the causes, we can argue about the reasons why. I've taken the position that I'm not so much interested in that

as much as I am getting these children served.

I think that in light of what we're knowing and what's being presented and what we're finding out, and it's very fuzzy, but yet the clarity that it gives us in terms of the numbers demonstrates a tremendous national agenda that needs to be developed to help these families, to help these children, to support the professionals that are out there trying to help our children.

I'm hoping that the hows of how we accomplish that will come out from this Committee. We're in a position now here I think we can establish, and should establish, a National agenda, focusing on autism. The whys are obvious. The whens are immediate.

And I thank you for your participation and look forward to the next 3 years serving on the Committee.

Dr. Hyman: Thank you very much. Jon, do you want to make some comments now?

Mr. Shestack: Yes. I guess these numbers that were presented from the CDC, even if there is some discussion about fuzziness around the edges, make

clear that it's a large public health problem. It's a larger public health problem, much larger than it was, according to these numbers, than a year ago when this bill was -- Pediatric Health Act -- was signed.

You know, I feel like [Inaudible comment] is that Congress is interested in this as an issue. And it's made it clear that it is interested. And it's probably only going to get more interested as more constituents [Inaudible comment] their representatives. So I think it's important for the Committee to realize that, you know, elected officials have said please take a look at this and do it.

It's been a touchy history getting to this point. It was hard to get this law passed. And then when it was passed, there was some battles on implementation, budgets were cut and they were added to, and funding was going to start in 2003, not it's going to start in 2002. All that's good.

I feel like it's important for public members to kind of make sure that the momentum that is now started is maintained. And I know as a public

member, that's what I intend to do, is to make sure that letter in the spirit of the authorizing legislation is followed. But that doesn't only mean being a pest.

I think that's fine, too. I think that the voluntary organizations also have a lot to offer and a lot to help. And a lot of help to do on practical things like brain banking, gene banking. There may be areas where joint funding of projects that get pulled off of some of the STAART grants can be discussed. There is dissemination of information, and so I'd like to offer -- you know, down the road -- our help on all these matters.

And the one thing is that I guess this Committee won't get to get to today really is what exactly Health and Human Services is going to be doing on its education and family education. And it was a major part of the legislation, and it's too bad that we can't really address that.

Dr. Hyman: But it sounds like we could invite our colleagues to make that a critical part of the next meeting.

Mr. Shestack: Yes. No, I think that's

something that we need to do because, from a physician education standpoint, all the other agencies who are represented at this able could really profit by that being put into play and paid or by somebody else. So if coordinated, we can use that.

So, thank you.

Dr. Hyman: Okay. Lucille Zeph.

Dr. Zeph: Very quickly, because I know that everyone would like to have lunch, I want to say thank you for putting this Committee together, for being invited to be a participant at the table here.

My background is varied and long as it pertains to children and families with autism, both professionally and personally. It is the one area that I would prefer to spend my time on.

What I really hope that we will do, as I listened around the table this morning, tremendous resources in terms of both energy, time, commitment and more thankfully some doers, are going toward an issue that we all know is both complex, and it would require the needs of varying

perspectives.

I think that what we can do as a Committee is to keep that "inter" word going at every level -- interdisciplinary, interdepartmental. It's just a beginning. As we go forward and we begin to understand the complexities of both the neurology and the biochemistry of the kids that present themselves to us, and adults, that present themselves to us as having autism.

I hope that we'll begin to break down some of the barriers that have prevented really excellent communication. It's not just the alphabet soup and some of the attitudes and the preconceived notions that we bring to the table. And what I'm hoping is that if when you're open to what's possible that one of the comments that struck me the most this morning was how little we know -- and it was so refreshing to hear people put it at the table -- how little we know about normal neurological development. How little we understand. And what?

We're so clear when we have deviance. And we show clearly that that deviance is negative. I think that we really have to remain very open to

the phenomena that is presented to us and take advantage of it.

And I say that because as I've struggled to work as a teacher of kids with autism over the years and to be a person or prep person for a number of years for kids with autism, to be an early intervention as for kids with autism, and to be an administrator of a multidisciplinary center that does soup to nuts for kids with developmental disabilities of all kinds, what I've learned is that we have so much to gain by remaining open to what the possibilities are.

And the possibilities here, for kids with autism -- I'll give you one example. When I ran a school for kids with disabilities many years ago, before inclusion was on the wavelength of most people, we were struggling with kids who had no communication. And several of those kids had the labor of autism. And in my quest to bring them communication, which I felt was the way for them to express their humanness to us and is that critical to who they were. As I did that and went from varying intervention strategies, one after

another, I had to begin to break down all the developmental rules.

I started to realize that the development of a kid with autism, in order to solve their problems, might not follow the same, what we consider to be developmental hierarchy. And so I started breaking all the rules. If a kid couldn't identify an object but knew how to use it, if they couldn't point to a picture, I still went forward. If a kid wasn't learning sign language, I still kept going. And I couldn't figure out how to break through. But I knew that there was something cognitively going on. The kids were figuring out their worlds because they were functioning in the various ways and trying every day to make sense out of the world.

In my frustration in trying to study what parts of the brain I could function in with them, I turned to literacy. It was amazing. And this was in the early to late seventies. I turned to literacy for kids with autism -- written word. Not to teach them new concepts, but only to attach it to what they already knew. To help them

demonstrate. All of the other pieces that were so complicated for them in their daily lives, trying to understand the world, began to find a place.

Behaviors that we had been trained to cope with that we didn't understand began to make sense. But I only use that as an example, as I found something that I wasn't looking for because I was willing to break the rules. Everything that I have learned as a developmentalist I had to violate in order to solve the problem. And I guess that's what I'm really throwing out here. That as we begin to study the varying aspects of autism for the first time in a fairly coordinated manner, that we share information, and it will remain open to one another and possibilities of what can happen. If we look at people that we don't understand and give them the credit for getting through every day that they get through, because it's a tough road every day.

And the data that we put forward this morning related to parent perceptions and the fact that parents were seeing and reporting that there was success. Whether it was for the secretement of

whatever other intervention we are talking about. There may be multiple solutions to these issues. And there is a tendency to dismiss those that don't make sense or fit into our professional rubrics.

So my quest in this is to remain open to each of you and hope that we will remain open to the data that comes before us in ways to help piece together the important parts of the puzzle. Because we each have something to contribute toward that to solve the solution of what we call these puzzled children. So, thank you.

Dr. Hyman: Thank you. Thank you, everybody. I think it's been a very good morning. I think it's best because some of you have flights if we try to stay on schedule. This clock is actually 5 minutes fast, but if we return and begin at 1:30 as scheduled, I think that would be the best for everybody. Thank you.

(Whereupon, a lunch recess was taken from 12:48 p.m.)

Dr. Hyman: If we could start to come to order it would be terrific.

[Pause]

Dr. Hyman: It's clear that whatever we might have wanted, the Building 31 cafeteria decided that lunch would be an hour.

[Pause]

Dr. Hyman: Security here is good, but we can't track individuals around the building yet.

[Laughter]

[Pause]

Dr. Hyman: Okay, so now, personally, I think the morning was very useful in surfacing many, many issues that we wanted to follow up on. And now I think we really get to the crux of the meeting and while we've specifically scheduled 3:00 to 4:00 for an open session for public comment. And what we'll hold to that, again, this group is small enough that if people who are not at the table want to raise some issues about collaboration, it would be very appropriate and very much appreciated.

Now, a number of people have already, as I said, surfaced issues for potential collaborations earlier in the day. And I think one way of getting

the ball rolling is just to return to some of those and to think about how this Committee might help in surfacing collaborations. Now, actually, beginning prior to lunch break, we were talking about a group that was not at the table that should be at the able. And that's HRSA. And then right after lunch, actually, somebody from HRSA who is not officially represented at the table suggested that they might be.

Would it be fair, as we're thinking about collaboration, since you didn't get -- you're not here officially representing HRSA, but if you could just maybe share with us for 2 or 3 minutes the way you think HRSA might collaborate in some of these efforts. Or, if not, we can leave that abstract. But I think the issue of physician training and primary care just might be areas that might -- because we'll be sure to make sure someone from HRSA is at the table at the next meeting.

Unidentified Speaker: Certainly. You have hit on training, particularly, since we fund about 750 organizations that deliver comprehensive primary

care services and about 4,000 sites to some 11 to 12 million people. We know from the statistics that there is going to be a significant number of people with autism. And I know that there is a big need for training of clinicians in our sites. So that's certainly one way.

We're very interested in the translation of science into clinical practice. So I would suspect that there are some other ways in which we could also collaborate.

Dr. Hyman: Thank you. Jose?

Dr. Cordero: I think that there were many parts of the discussion that actually relate to HRSA, and they do have a health profession that actually their main focus is training. They have the Maternal and Child Health Bureau that includes the group, the Division of Children with Special Health Care Needs, as Rita Goodman just talked about the Bureau of Primary Health Care.

In addition, under the Bureau of Health Professions is one of the Vaccine Compensation Program is that some of the issues have been raised today that they also would have some

interest. I would think a lot of interest in that area. So it would be great to have a representative that could sort of cover all those different areas from HRSA.

Dr. Hyman: I guess one of the questions is, how can this Committee, in particular, make a difference in facilitating in coordination and collaboration?

Dr. Gordon: Actually, a number of people have commented, and Carol at lunch, I think, added to this. That one of the things that might be useful is to have a comprehensive -- I call it battle plan, but maybe -- a map, a map of what we think the issues actually are. A map of what's there already. A map of where it may be spread across a number of different Institutes or -- I don't actually know the proper term for it, so I apologize --

Dr. Hyman: -- agencies.

Dr. Gordon: Agencies or what have you and where things are potentially missing. I think also such a map might be useful because I think there is a dual problem of perspective. You know, we're

doing a lot, we're not doing enough, we're doing it in the wrong area, et cetera. For instance, there are vast areas of research that are relevant to autism that don't necessarily get counted as autism work. And other areas of research that may be relevant to autism application, but not basic science, that need to get proper credit and, basically, be revealed. I don't call it PR, but at least to have such a strategic map.

I also think such a set of maps, or whatever, strategy would highlight some of the clear differences on people's perspectives and needs. For example, there is a very different perspective of the child who has autism now and has an area that doesn't have any services at all versus future generations that we're trying to protect from having this and related problems.

And although we can agree that we know that there are going to be differences in approach and everything else, but we don't even know yet where some of these -- we need to lay out, I think, where some of these differences might be in a coherent way. And so one thing, I think, a

Committee like this could do is begin to pinpoint both some issues or themes. For example, education of physicians might fall into a subtheme of how to deal with the existing problem. It's not yet a problem of how to deal with autism in the future, I think.

And we could see how much is being devoted to that whereas studies that might not otherwise appear relevant to autism -- I'm thinking of studies like hypoglossal nucleus development -- that years ago would not have been thought relevant to autism, now might be very important to autism in view of evidence in genetic basis there.

Dr. Hyman: So let me just ask how to make this useful, in the sense that NIH is very good at printing out enormous amounts of paper with grant abstracts. And assume that what you do not want is reams of rather opaque abstracts. You know, so there are maps and there are maps. On the one hand there are -- you know, really trying to look at the potential connections -- almost like a strategic plan. That's not the right word, but the connections among different agencies, or pull

areas of research. But what is the grain size that you're --

Dr. Gordon: Actually, it is medium grain size, but that's, of course, in use. Always a good answer. No, I have in mind something more that when I try to talk to parents, for example, but interested parents, to try to show -- for instance, if you take a child at one point in time, the genes start off much earlier. There may be an environmental influence, there may be an influence of immunizations or whatever, but all that's behind you. You're dealing with a child at one point in time. But you can see on that timeline where these influences might come in. And then you're dealing with a child that at a specific point in time may have a disorder of speech perception, a disorder of cognition, a disorder of executive function, a disorder of socialization, who is dealing with socialization. What I have in mind, actually, would be more of a colored overlay.

Dr. Hyman: A hypertext.

Dr. Gordon: A hypertext. In the sense that I

think it's important from an administrative point of view to know what agency is dealing with what. But that's a subtext to this. It's important at another level for people to know that these are the problems. That the genetics, for example, long precedes the child now, okay. On the other hand, that there are many other sources of input into the genetics and what have you, including the study of the normal child and what is normalcy, which might be much, much wider than we ever dreamed, in fact.

I have a feeling that when you brought this up, Louis you were thinking exactly what I was, which is -- we now know from studying people that normalcy is much wider than we ever dreamed. And that would be important to know.

So what I have in mind would be something that wouldn't be necessarily developed by the people on the direct front lines but done in conjunction with people who are also skilled in understanding how to represent themes and condense data. So this would be highly condensed in a way but would represent a map of both a mind and how

it came about and then of the systems that are being applied to research and provide for it.

And I think we can even sketch out a couple things like that. I'm sure we're going to sketch it a lot.

Dr. Hyman: Any comments on this topic? Yes?

Dr. Cordero: Yes, actually, when I was hearing you talk about the roadmap, it sort of reminded me of another experience dealing with a different subject. And it is when we had the problem with measles in the U.S. And, actually, the discussion then -- and this was a National Vaccine Advisory Committee -- was what to do. And the same words were used, the roadmap. And out of that came a white paper that, in essence, it put together what we know, what we need to know, and how we learn it so we can be successful. And, yes, we have been successful.

But it seems to me that, perhaps, maybe instead of putting together a roadmap and the issue really is what are the questions that we are asking? Where is it that we're trying to go? And it seems to me that for starters, we're looking at

what are the causes, what is the prevalence of autism, what are effective interventions, and what, actually, are effective ways for both education, health care access. And along with those, questions come in terms of research, biologic mechanisms. Again, treatment, but also health care providers. I would say it's not only physicians, but all health care providers. And I would say also training educators to think before --

Dr. Gordon: Can I add one thing before it gets too abstract? Because it will get abstract. I also appreciate that to know what a map might look like, we ought to probably produce some samples that can be attacked and revised. And I'd be happy -- whatever the feeling of the Committee would be -- but I'd be happy to serve as the initial target of such an attack --

[Laughter]

Dr. Gordon: -- because we've, actually, been trying to do that in several areas. I do cognitive neuroscience. It's sometimes hard to get people to understand the behavioral level and the

neuroscience level the same way. So we've been grappling with that question. And I'd be happy to set up the straw horse, or whatever it is, that can serve as the takeoff point.

Dr. Hyman: Well, if you could explain that connection to some of our investigators.

[Laughter]

Dr. Hyman: I think it is important for this not to be abstract and to share it with the Committee because ultimately, something like this, an innocent thing like a map, will be an enormous amount of effort. And there will also be a lot of controversy because people will want to see whether their theory or their view or their precise real-life distress is adequately portrayed. So I think it's not a trivial issue to propose something like that.

Yes, Lee?

Mr. Grossman: I'm having a little bit of confusion on this topic here about the opportunities for a collaboration because, I guess, I'd like for us -- for you -- to define what the ground rules are for this Committee and

what our limitations are and what our powers are. If we have unlimited powers, then that will be the continuation of dialog. If we're very limited in our scope, then we know at least where we fit in, because I had some confusion on that. Either way I can, as long as I know the ground rules, I can play in the game.

Dr. Hyman: So right now, just so that we don't leave too many points hanging, Barry is offering to give us some sort of map. And the question is, you know, how does that relate to this Committee's duties, what can this Committee do? I mean, in essence -- what we hope for is based on the spirit of the legislation, which is that there really was a problem in addressing autism. Which was there were multiple research agencies and service related agencies within HHS. And then separately, the Department of Education, that we're doing things without necessarily having any clear relation to each other.

People in FDA, for example, or NIAHS, who -- FDA not even that physically separated NIH, more physically separated -- might not even know who

the people were at these other agencies who were involved in autism. So one critical aspect of this -- and this does relate to the map -- is to have a sense of who all the players are. And we can already see in this first meeting that, in organizing this, we didn't do a perfectly good job. Because one critical Agency that needs to profit is HRSA. And they were not at the table. The second thing is coordination. What we want to do in bringing these people together is to make sure not only that we're not simply duplicating efforts but that we're truly learning from each other. And that's, of course, very delicate. And I think one of the important roles of public members is that, in some sense, your interest in this is clear.

And in some sense, you have a clear moral high ground. And your sense of whether we are really, you know -- I hope we do not devolve into small chieftains again, looking for individual credit. But I think you have a very important role on this Committee to make sure that these different Government agencies are not doing that

but, actually, are working for synergies.

And then I think there is a very important creative role for this Committee in terms of thinking, you know, what can we do together that we might not be able to do just as individual parts? And I think we've already heard some interesting ideas. How we get them -- you know, what is the power of this Committee? The Committee cannot tell the Secretary of the Department of Education and can't tell the CDC that they must work together in a certain way. On the other hand, I think this Committee can have a strong voice in sending your representatives here. -- Have pointed out that there could be incredible synergies in terms of epidemiology if you approach the Department of Education properly, or, you now, professional education.

So I think those are at least the beginnings of what I had conceptualized for this Committee. I'm sure other people will have other ideas. Why don't we hear from you and then from Jon. Go ahead.

Dr. Carbone: Two quick points. One is I think

if the FDA were [Inaudible comment] to what we don't know is the problem, specifically. I think often what we see is -- phrases start -- everybody knows that, is a very scary phrase. Because if you dissect it, a lot of what's commonly assumed, common knowledge, there's actually no good data that we can rely on. I can think of an instance where we had three viruses and we had a target serology level for one, we had an international standard for the other one, we had no test, no international standard and no known protective level of antibody for the third. So that was a clear gap. So when we say what do we work on next, it's absolutely crystal clear.

So I think when we make the map, it's important to have in addition to where we are, but to be very, very -- step outside the field and say what is it we don't know. Because those will also help highlight where to go.

Dr. Hyman: That is absolutely true. The right kind of map will show us the gaps. Yes, Jon.

Mr. Shestack: Yes, I just wanted to try and -- I mean, legislation talks about this Committee

coordinating efforts toward autism. It doesn't necessarily mean only the public members; it actually doesn't mean that.

Dr. Hyman: No, no. It means -- I was trying to -- it means the people who work for the Government coordinating as opposed to -- well, I don't know what the other Autism Coordinating Committee did because the public wasn't invited to the meetings, except this one, kind of show meeting once a year. And maybe they coordinated and maybe they didn't.

But this is an opportunity to be with many more people at the table to actually lay on the table:

Do all the people, the investigators who run the PIs on the CPEAs, for instance, actually know that CDC funded four centers? And that there is work done that overlaps some of the stuff they're doing? And then if they call those guys up, they could share some useful information.

When the STAART Centers get awarded, the same sort of thing. I mean, there are some practical, tactical things, if the people representing the divisions decide to do it. And the reason I would

really suggest doing it is there is no good feeling that the NIH budget is going to keep increasing at the level it's been increasing. And although everybody is interested in autism research and we will work to bring as much pressure on you guys from Congress to spend more on it, it is always in your discretion to do. You could spend more tomorrow if you wanted to. There is no law saying you can't.

It still makes sense to leverage the limited amount of money we have. And coordination, some duplication is probably good. But coordination, certainly, will help you leverage the money you have.

And, to keep in mind that the voluntary organizations already spend, you know, $8 to $9 million of direct costs a year on research, and they may be partnerships that can be forged.

Dr. Hyman: Well, that would be, again, a very appropriate topic if we could -- I mean, the issue is, I think, for us to surface all of these topics, but then actually think of mechanisms so that we get beyond a level of polite conversation

and actually figure out how to do some of these things.

Mr. Shestack: Well, can I just ask, because I'm, like, really ignorant?

Dr. Hyman: Yes.

Mr. Shestack: For instance, FDA is like a new player for me here. How can they be integrated to working with the other agencies? Because I understand the studies that were up on your slides, I thought were mostly studies funded by various NIH entities. Except, maybe there was a fluoxetine studies. And I didn't really understand it.

Dr. Carbone: We review studies. What happens is, the ultimate goal, obviously, is to find a drug that's licensed and then used. So that individuals and investigators that may be doing trials and we consider pivotal, which would be used for licensor, we might be involved long before it ever gets made public. But we can't talk about it because it's proprietary information. So we'll work with the investigators, usually, on any large Phase 3 clinical trials. And Phase 3 would

be efficacy and safety trials.

Mr. Shestack: (Microphone not turned on)

Dr. Carbone: Both. Both.

Dr. Hyman: I think, Jon, one thing -- and forgive me -- that FDA is also not one organism. So you are actually from the Center for Biologics. And you are here, basically, because of this.

Dr. Carbone: Well, FDA is one organization.

Dr. Hyman: No, no. I understand. But they're different. But the point, just as NIH is one Agency, but you were really sent here because the issue of vaccines is so pressing on everybody's mind.

Dr. Carbone: No, actually --

Dr. Hyman: -- no?

Dr. Carbone: No, I went to CDER. I am the FDA representative as well. But I went to CDER to investigate what they were doing.

Dr. Hyman: What I was going to say is the Center for Drug Evaluation, you know -- I mean, what Jon wouldn't know is that there is a pediatrics group within the Center for Drug Evaluation that is thinking about ways right now,

recent legislation for enhancing pediatric indications for drugs. And so, yes, you represented that, but I think the issue is probably just the structure of -- I think in his question -- if I can reinterpret it, it's just the structure of FDA and how the different components of FDA could really be brought in in this synergy.

Mr. Shestack: (Microphone not turned on)

Dr. Carbone: No.

Dr. Hyman: No, they don't.

Dr. Carbone: No, we just review the data.

Mr. Shestack: You don't finance any of it?

Dr. Carbone: No.

Dr. Hyman: No, no. That's NIH or industry.

Dr. Carbone: But we do help develop with the sponsor. We work with the sponsor to develop endpoints, measurements, efficacies, what's acceptable, safety levels. If it's not safe, we won't permit the study.

Mr. Shestack: But endpoints might mean methods of evaluation, I suppose.

Dr. Carbone: Right.

Mr. Shestack: It's a giant problem in autism,

which is accepted standards to evaluate change. I mean, there's no sort of accepted diagnosis.

Dr. Carbone: Right.

Mr. Shestack: But nothing to evaluate change. So that would be a kind of research that could be funded that would benefit everybody in the CPEA Network and everybody in the STAART Network.

Dr. Carbone: Absolutely.

Mr. Shestack: To actually have an agreed-upon measure of change.

Dr. Carbone: Right.

Dr. Hyman: So already in the RUPPs network that exists, when an autism clinical trial occurs, since a company's drug is being used, whether it's -- or one of the SSRIs, they will actually work with the FDA to make sure that the design is acceptable to the FDA's experts in biostatistics, study design, and so forth. And that's, actually, already happening. But that doesn't mean that there couldn't be more involvement of the FDA in sort of creating interest for potential new therapies. Because I think we all agree, there are a dearth of both pharmacologic and psychosocial

therapies for autism.

Lee, did you --

Dr. Gordon: Again, I'm trying to find our boundaries here. So let me throw out a couple comments just to see if we're on the right track. Or you can say yes or thumbs up or thumbs down and what this Committee can do.

First of all, I think that there is very specifically some areas where this Committee can and should function, first of all. We're living under the obligation of the Children's Health Act, so we have to demonstrate that we're following the measures and documenting the results from that legislation.

I think a couple other things that we can do and should do is translate into layman's language, what the Federal Government is doing -- the progress being made and the results of what their collective goals and collective ongoing research and activities have been. And then where the public members come in is that there is ASA, there is CAN, and there is a whole other network of other groups that can be utilized to disseminate

the information to get it out to the community. Also, we all have our own respective conferences.

There is the ASA Annual Conference, and CAN has their meetings. And I think that representatives of this group and what they're doing, it would be a wonderful opportunity for them to participate and get it out to, again, a collective autism community.

I think that we need to provide a public record, the baseline of research projects that's going on, where the money is spent and the goals, in a coordinated effort so that we know what the separate agencies are doing for autism research.

And then that would come back to interplay with this group, which would create a working network apparatus to closely coordinate all of the agencies so that nobody is doing duplicate work and that there is collaboration. And so I think those are some basic baselines on what we can follow.

And going beyond that, I'm having a little bit of, again, concern because I don't know what our boundaries are. Could we see ourselves -- and

I guess this is collective thoughts for discussion -- can we be a group that could suggest policy or direction to the Federal Government in creating and establishing a national agenda for autism.

Dr. Hyman: I mean, I think, one of the goals is actually to hear from the community what your suggestions are for ways in which we can do things better. So, I mean, in that sense, that's a critical role of this community. When you say "suggest policy," you know, are you advising the Secretary of DHHS and the Secretary of Education on what they should do? The answer is, no. That's a different kind of -- there's a whole legal difference in those kinds of committees. But can this group have a strong and constructive voice? Absolutely.

Dr. Gordon: I guess that's what I was looking for. Just some sort of direction. I know, personally, if we needed information, I think what would be a very general description of what the autism community would want the Department of Education to do, for example, I can pull together in a matter of a couple of days people that I

believe are well versed in that. And in a short amount of time, come up with an executive summary for a proposed plan on what we'd like to see happen.

Dr. Hyman: Right. Okay, so I can't, of course, speak for the Department of Education. The Department of Education has a representative here, however. And I think, one would hope, in the spirit of this Committee, is that Dr. Houle would connect this Committee with the right people in the Department of Education so that there -- you know, we heard some frustration before about messages going into the Government and being unanswered. I think one of the things that we really want to do is to make sure that what you see as important needs, or as information that's not being attended to, gets an appropriate hearing.

Dr. Gordon: Yes. And I'm not meaning to pick on The Department of Education.

Dr. Hyman: No, no.

Dr. Gordon: I was using that as an example.

Dr. Hyman: Yes, the abstract.

Dr. Houle: No, I don't feel picked on at all. It's sort of falling into almost subcommittees to identify gaps in certain areas. And that would be useful that you could pull together a group. You and I could pull together a group of people who want to look at where would we like to be in the educational arena and, you know, where are we now and what do we need to do to get there. And those kind of things would be very, very helpful to my Agency.

I mean, we've had those kinds of needs assessments in the past, but they always need to be updated. And we've never had anything really comprehensive and targeted to autism in that way.

So that would be --

Dr. Hyman: -- and then we can come back.

Dr. Houle: Yes, right.

Dr. Hyman: I think Barry had a comment and then Jon.

Dr. Gordon: One of the things -- I think we also have to appreciate, Lee, I constantly envision that we're not isolated. There's a lot of other people with lots of agendas. One of the

things I think that a Committee like this could do is provide evidence for some of the recommendations that might ultimately be made. And one thing I think about autism -- I may sound a little overly expansive -- but I think autism is an amazing opportunity for the educational community and for the neuroscience community as well, in that it's much more than just autism that we'd be helping to solve here. I personally think.

And whether or not my son or other children with the condition actually get better as a result of what we're doing, I know that it will help medical science and many other neurodevelopmental disorders and many, many others besides. So I think we actually have a large number of selling points in getting the society in the conflicting demands upon funding and everything else, I think one of the things we could do is try to make that point as well as possible.

Dr. Hyman: Jon.

Mr. Shestack: Let's just forget what we have to say, let's just say -- now, Larry Stanford, you're going to be coordinating CPEA as going

forward, is that the idea? Or part of CPEA?

Dr. Stanford: No, actually I am handling the rest of the autism portfolio. Peggy McCartle is handling the CPEA program.

Mr. Shestack: Oh, I see. Is she here?

Dr. Stanford: No she's not, she's on travel.

Mr. Shestack: Oh, I see. Because the hypothetical question, for instance, would be if you were to have a conversation with people who are coordinating the STAART programs about how do I get the most out of the limited amount of money, what would you talk about? Talk about it here. Did CPEA, for instance, ever actually -- a big goal of CPEAs was actually, to produce a set of common measures that would be used.

Dr. Stanford: Correct.

Mr. Shestack: No. That didn't happen. Maybe it can't happen. But if it's in the course of happening, why can't the next group that's going to get funding benefit from that? And then you guys should discuss it. A good place to start discussing it would be here. That would be like interagency coordinating. Part of it. And so

that's -- I mean, it seems to me -- can we talk about certain tactical issues like how would you all work together to make it?

Dr. Stanford: Well, actually, one of the ways that we do that actually is through the NIH ACC Coordinating Committee. The ACC Committee --

Mr. Shestack: -- but here's the problem.

Dr. Hyman: (Microphone not turned on) What Jon is -- the issue is transparency. Jon is right, but what Jon has shared with me a couple times is we say -- and this is a serious issue. You know, we say we're talking about this in this [Inaudible comment] Committee, but then what are the results? So, you know, I think that's a major concern.

Mr. Shestack: Yes, but let's also talk about how would you do it. What is a practical suggestion? I mean, there is a lot of people here from different agencies who may be able to contribute some ideas there. I mean, the idea is to actually have some synergy that will help everybody gain speed.

Dr. Hyman: Well, I think we had a lot of complex -- I want to keep it on the same topic

[Inaudible comment]

Dr. Falk: Yes. You know, it seems to me that the only operative verb for this Committee in sticking with the charge is to coordinate. And "coordinate," actually, has a lot of levels of definition, starting from just sharing information to having greater efficiencies. But I think there is sort of a higher level coordination, which really does lend itself to a certain amount of creativity that grows out of the process of coordinating. So I think that some of the ideas really fit, within the concept of coordination.

Dr. Hyman: Steve?

Dr. Foote: Well, so we have discussed some of these issues, indeed. And most of them are open-ended right now and with very limited content because the STAART applications have not been received. By the next time this Committee meets -- we're putting a lot on the plate -- and the Committee will have to decide what the highest priorities are for future discussion, but I think that by the next time this Committee meets, which is something we ought to get some boundaries on --

when people do want to meet again -- but by the time we meet again, the STAART applications will have been received and reviewed. If we meet in about 6 months.

And I think then we will probably have some very substantial issues to consider, some of which can be publicly discussed. This is a public meeting. Some of which can be publicly discussed and some of which probably can't. But I think there would probably be some policy issues. Some guidance issues that could fruitfully be put on the table at that time for discussion. And how the total impact of these two kind of overlapping, kind of separate, kind of parallel, kind of interacting programs are -- how we are going to exert influence on those and try to get the most out of them.

And I think that's a great topic for discussion. But right now, as is the Data Coordination Center issue that you raised earlier, is one aspect of what we could discuss, because by then the lay of the land may be a little bit clearer. The CPEAs will also have been submitted

and reviewed by that time. So we'll have a lot of information that we don't have now. And I think for us, for the staff people, it would take a while to formulate what the most pressing issues are. But if we had some lead time to prepare documentation and questions for discussion that could be disseminated to the Committee ahead of time, we could have a very useful discussion about some of those issues.

And if the Committee were to furnish us that guidance, were to provide that guidance, well, then that's what we would do.

Dr. Hyman: Audrey?

Dr. Penn: Yes. Well, our Institute has worked with FDA. We do work with FDA a fair amount. So we kind of know what you do. The Department of Education in this area, I can't say I do. I mean, I remember school, but I honestly can't say I'm entirely up to speed as to what you're bringing to the table. I think the NIH talks to each other a great deal, and we have in these coordinating committees, but I think it might not hurt to look at the issues that we know exist in this disorder

and see who is doing what already. In way is saying what both of you said, but at this stage, you don't want to be redundant, and we probably don't have the funds to be all that redundant. And we want to be sure that each of us is carrying out our mission and to really help this disorder. Right?

So you might want to take the various issues, which in some ways we've already looked at, because I'm hearing Jon and I'm trying to figure out what "coordination" means. When we work with the VA, it's really a back and forth and a back and forth. And when the Department of Defense gets into it -- this is not this disorder, obviously, it's another. But that gets a little more complicated. I'm not sure what I would ask of CDC. Okay, but I do know that CDC does things that we don't do. And, therefore, it would be very nice if we could split it right there.

The epidemiology some of it. And we're working with CDC right now. We're sort of tripping over who does what. So think some of that has to be done almost before we can decide how to

coordinate who is doing what.

Mr. Shestack: But [Inaudible comment] there was a specific instance. There was somebody who had a behavioral therapy grant that wasn't renewed or something. And went around to all the [Inaudible comment] groups and said, oh, the NIH isn't funding anything in research --

Dr. Hyman: -- behavioral grants --

Mr. Shestack: -- on behavioral grants. Like, I don't know, you couldn't really go through the files and figure it out that easily. But, you know, it's an issue.

So, like, everybody sits here in this room and says, it used to be that was all that was funded. There was no biological funding. Now it's swung the other way. Everybody looks and says, "Is anybody funding any behavioral research? Ah, I guess nobody is. Maybe DOE should step up then." And that kind of just like actual conversation. I don't know what it is, but we're not allowed to say in front of the public members, but that kind of --

Dr. Hyman: (Microphone not turned on) Well,

no. But [Inaudible comment].

Mr. Shestack: Right, I understand specific discussions. But there are certain areas we can say like everybody is doing a lot of genetics, maybe they're not doing that much education, maybe they should --

Dr. Hyman: This gets back to --

Mr. Shestack: That's kind of what this -- to do.

Dr. Hyman: -- where Barry, actually, started. And one of the things like having a good -- although, again, it would be very [Inaudible comment] be really useful in [Inaudible comment] is to really see where the gaps are. Because if [Inaudible comment].

Dr. Cordero: Henry mentioned that there were different levels of coordination, and it seems to me that, sort of listening on the conversation around the table, we need to get down to the very, very basic of knowing what each other does. And I think that Audrey said it very well, that we each have a partial view of what is going on. And, perhaps, one and create the thing we need to do is

to have the brief sort of copulation of what each agency is doing. And we can list out what are the things that we are doing, and having it all in one document would be helpful.

And it might even be -- would help with the report to Congress that also needs to be done. But at the same time, would give us a clearer view of sort of this distant horizon of what's going on. And I think that from looking at that kind of document, the issue of our coordination is needed, and the gaps may sort of emerge.

Dr. Hyman: One other thing that is implicit in this, but I think should make it explicit, which is that we want to raise the profile of autism research in the science community, which is what Barry was talking about. And I just want to make that very explicit because one of the things that I know has been true, that every year I have been Director at NIMH, I've had more money to spend on pediatric behavioral and emotional disorders than we've had applications that study sections have found meritorious.

And it's been more than true in treatment

studies. And when we had -- no, I think this is very important. When we had this workshop on psychosocial treatments in autism, I think all of us were -- it wasn't the happiest day of my life in the sense that -- no, no -- you saw that in the room we hadn't yet managed to attract all of the people who were going to think of -- there weren't a lot of, say, cognitive scientists there who would work with the treatment people to come up with a new development.

So I think it's really important that we overall raise -- along with spending the money -- we want to raise the profiles so that we really get the people we need. And we can do that.

Mr. Shestack: You know, INAR does this; CAN does this. I know my wife is always out there sort of explaining to people who do basic [Inaudible comment].

Dr. Hyman: Yes, she's famous for doing that.

Mr. Shestack: -- neuroscience that they're doing autism work. Autism is a disease -- if you are interested in what makes people human, then you're interested in autism communication,

cognition. So I agree.

But you mentioned something very important, which was the study section, which -- Is this something, for instance, that this Interagency Committee can tackle? Which is one, having to get more people on study sections who actually know anything about autism so that when a grant comes through, they can say, "Gee, you know what, this is pretty interesting. Autism is important." Or, and also, how do we get more intramural research on autism?

Dr. Hyman: Okay, so these are good topics. So one thing that I think we can do either in our -- I'm sorry Yvonne Maddox isn't here representing Building 1. She had to go earlier. But I think we could invite the people from CSR, right, to come at the next meeting and talk about the structure of -- it will take some work because we review treatment studies within the Institute, but other studies outside the Institute. I bet you have also some mixture in child health.

Dr. Stanford: Yes, but it's mostly along the lines of mechanism.

Dr. Hyman: Yes. But I mean we could get, again, we can use the map word, right -- A map of how the difference -- because it's so many different kinds of science, from molecules to health services research. You know, where these things are reviewed. And maybe even a sentence of how they do when they are reviewed.

Mr. Shestack: (Microphone not turned on) It's going to be investigated, and it's [Inaudible comment] the time. But whether or not [Inaudible comment].

Dr. Hyman: Well, all investigators should be complaining until all of their grants are funded.

Mr. Shestack: [Microphone not turned on]

Dr. Hyman: Yes. Yes.

Mr. Shestack: [Microphone not turned on]

Dr. Hyman: Absolutely. I think we're going to end up, actually, with too big an agenda for the next meeting. But I think this is a very important issue and, certainly, one very much worth hearing about.

Mr. Shestack: [Microphone not turned on]

Dr. Hyman: Yes, absolutely.

Mr. Shestack: [Microphone not turned on]

Dr. Hyman: Yes. Intramural is separate. You could invite the scientific directors of, you know, three or four Institutes and hear about what the intramural plans are.

Mr. Shestack: [Microphone not turned on]

Dr. Hyman: Yes, that's right.

Mr. Shestack: [Microphone not turned on] But doesn't that [Inaudible comment]?

Dr. Hyman: Absolutely. I mean, I could describe to you what we're doing, but it might be interesting to hear from Bob Desimone and Story Landis. We've been trying to recruit in this area.

Mr. Shestack: [Microphone not turned on]

Dr. Hyman: Oh, we have. We were trying to recruit in this area. It's, you know, this issue of the profile number. It's a zero-sum game. If we recruit somebody good that doesn't make a new scientist, it means somebody else loses a good scientist. But we can talk about all of these things as well.

I mean, one issue is that you might -- intramural, when it's done right, has a certain

platform. You know, there is a certain platform that could help raise the profile on this kind of research. And, again, it's something this Committee could talk about.

You've been waiting patiently.

Unidentified Speaker: [Away from microphone]

Dr. Gordon: Can I interject? I didn't envision -- by the way, the question was the grain size of this map. But I did envision -- although I didn't want to say it -- a map that allows drilling down, because at some point you have to see the overview. As I use when I try to drive through D.C., for example. You know, I've got to have one that just says it's below Baltimore, and then I drill down from there to try to find my way.

And issues like yours, by the way, would be at a different level. Because some of these are terminologies that reflect what once was thought about how diseases should be approached but aren't necessarily appropriate any more.

For example, genetics is a lot of things these days which don't necessarily look like

genetics used to look. So a map might make some of that clear. Just the sheer process of arguing about it might help show where we need to break off some of these boundaries or include people from other disciplines or what have you.

So, I mean, I think I'm in agreement with you, but I did want to mention that the view of this, we'd try to get people enough detail, but also provide enough of an overview so you can see where you are. That you are in the genetics area as opposed to in the education area. Although, there might be a lot of that, too.

Dr. Hyman: Carol?

Ms. Sprouse: Yes. I was going to say earlier --

Recorder: -- since we're recording this, could you talk into the microphone?

Ms. Sprouse: What I was going to say earlier was that the roadmap becomes so strategic because it's the terminology of it all. And, Jose, you were talking about causes. In other disciplines, they would call it identification. And then you would say, well, is it early identification or is

it late identification?

So I think for the Committee to be effective, the roadmap has to -- although it's tedious and innately boring to some extent -- has to be hammered out, or you're going to just end up spending months saying what is it that we haven't done.

And then the other pieces, Jon is talking about coordination. In order to coordinate, you have to disseminate. So people have to understand what other people are doing in order to know what they need to do or what they haven't done. And that may be -- you almost have to back into that. Like CPEA -- I'm not sure I'm using the right initials, but anyway, to get people up to snuff, what is it that they've done in a short one-page summary or two-page summary? And then where are the holes from what they've done? Which then goes back to your roadmap.

That was my thought on it.

Dr. Hyman: So that we keep moving forward, to Kimberly has been recording potential topics for the next meeting. But I think that we still have

this project on the table here of a roadmap. Some way of, you know, a substrate for a coordination.

And we have to think about if this is how we want to proceed. Barry has offered some drafts, but do we have some comments before we concretize this? Jon?

Mr. Shestack: Yes. I just want to caution against -- we brought up all these possible areas for things the Committee should be working on and doing. And then we talked about having a meeting in 6 months. And then we talked about producing --

Dr. Hyman: -- We haven't talked about --

Mr. Shestack: Well, but this was a reasonable time maybe, perhaps. I mean, you'll get grants in, you'll have a better sense of the lay of the land, but in the meanwhile -- so, you know, many things sort of get tabled towards -- for 6 months. It's like, there are concrete things that people could be discussing between now and then -- maybe offline. One of the most concrete ones is strategies to do better brain banking and gene banking. And get more of the DNA that's already out there and available into common hands.

I mean, it exists right now. You can sit and have meeting and talk about it and figure out a plan and then do it. You could allocate more funds to do it, which you know the Congress asked that be done. So I just want to make sure that not everything is put off for 6 months.
Because I know how hard it is to get all these people in this room. It's a nightmare to schedule these meetings.

Dr. Hyman: Yes, they are.

Mr. Shestack: And that you're actually all here in this room is kind of a miracle, I think. Take advantage of it and let's try and get some specific discussion on them possibly.

Dr. Hyman: Jose?

Dr. Cordero: I think that what we have on the table is that we at least need to have -- we all need to have at least -- we need to describe as one-pagers of all the activities that actually are going on. And I think that if we could have that as something that could be developed over the course of the next several months and it could be distributed prior to the meeting. I think that

that would be extremely helpful. And we'll be happy to help with that.

Dr. Hyman: Okay.

Dr. Zeph: I think that one of the things that the department people can do is to go back. And I know, for example, Gail, that there is research [Inaudible comment]. There are other parts of Department of Education that may be doing things that we don't know about and whether those are demonstration projects, whether those are research to practice. In order to do the kind of mapping that I think is critical, kind of have a status report on what exists, and how to coordinate what you don't know exists, and so part of the job -- and maybe part of what Pat Morrissey's job is representing HHS to go back to the other places within HRSA. There are all kinds of subcomponents.

I know that the LEND projects and the MRRCs -- MRDDCs, I guess, now -- are doing research that would really inform this discussion. So I think there are a lot of players that aren't at the table that are represented by departments. I haven't even tried to figure out who else isn't at

the table. Gail, because of your experience with the ICC on Early Intervention, you probably might have an idea of players that are at that table that may also be able to inform us.

You know, there may be people who -- we identified HRSA not being at the table. There may be other players that we haven't even thought of that aren't at this table yet. And if we're going to do the map -- no one has tried to do this before, and I think it is a great contribution to get what is out there across the departments. And then begin to strategize around how we make those linkages.

And that will deal with all the informing that need to be done. But if we're going to share information, let's make sure that the information -- let's make sure that the information is comprehensive and complete.

Dr. Gordon: By the way, I have tried to map before. I suspect that any researcher who tries to tackle an area tries to understand the general territory before he or she dives into one particular area to explore. What I certainly have

never tried to do is wade through the Federal Government levels, except in the form of MEDLINE® searches and SILIT, which puzzled the heck out of me in terms of what I got back, and try to create a map that way.

For example, there is work being done in speech perception, and I know you mentioned your background was in speech-language pathology; it's also being done under the auspices of deafness; it's also being done by private industry right now and being done by many people. And being done in many different areas that don't necessarily ever show up on a map because no one ever thought of putting them together, although, they are, perhaps, relevant to the problem of how do you reach train speech perception, how do you train speech perception in children with autism?

The only comment I actually started to respond was, to the extent that we get together a group that tries to do a map, I would ask for the rest of the Committee to be patient in the following sense: You can either make it perfect or get it done. And I volunteered to be the one that

belled the cat, in a sense, or be part of the committee that tries to bell the cat. But I've learned, as in data management, for example, there is always somebody who wants time -- not the millisecond, but to the tenth of a millisecond -- synchronized to an atomic clock. And, you know, I'll do it to a millisecond, but I may not be able to get further than that.

Dr. Zeph: What I think would be most helpful though is not necessarily that we get to the tenth of the millisecond, but that the people who are at the table that are representing departments really have a responsibility to go back to their departments and kind of get the lay of the land within their departments and bring that back so we don't [Inaudible comment] big, big holes. We don’t wind up, you know, missing something huge.

Dr. Hyman: Also, you know, it has to be living, right. I mean, it's not going to be static.

Mr. Shestack: If there is a map, there is also a report. I mean, there is a report that has to be prepared by January. Right?

Dr. Hyman: [Microphone not turned on] Yes. This is being circulated within NIH.

Mr. Shestack: Right. But see that report is, actually, a very useful blueprint if it's actually giving a little more detail and a little less publicity, as compared to the last one. And as it's circulated around, everybody will really know what the main programs are. And as it got circulated around, it would be good. And, you now, maybe it's something that people of the Committee should also get a chance to look at and weigh in so that things could change before they get to Congress instead of being pointed out by Congress afterward, like, this isn't an actual -- the math wasn't right.

Dr. Hyman: You know what? I don't know [Inaudible comment] if we can do that.

Unidentified Speaker: [Away from microphone] Well, we have, as you know, Jon, clear procedures we have to go through the Department and we have [Inaudible comment]. So whether or not we could --

Dr. Hyman: We can try.

Mr. Shestack: It was just a suggestion.

Because I think, ultimately, it will save you time down the road. And time answering questions.

Dr. Hyman: Just because it's a rational suggestion doesn't mean our bureaucracy tolerates it. So I just want to find out, you know, if we can do it.

Mr. Shestack: But circulating that report -- I mean, that report goes to Congress. Because that report also went to everyone at this afterward even, for instance. But every other day, a quick little overview of what everyone else is doing. It's right there. It exists.

Dr. Cordero: If you want to be technical, this is just like other committees. The members that are sitting on the table for today, are all our employees?

Dr. Hyman: No.

Dr. Cordero: Well, you are now employees today.

Dr. Hyman: We'll teach you “black-belt bureaucracy” afterward. There is a special indoctrination.

The only way we could get this -- we've been

trying to get this Committee organized for a long time. And it turned out that turning it into an FACA committee would have just delayed it intolerably. So we've just proceeded.

Dr. Gordon: Again, I'm trying to --

Dr. Hyman: I think I'm going to miss all his aspect of Government when I leave.

Dr. Gordon: Well, we'll know where to find you, though.

Again, I'm trying to find my boundaries here. And I work best when I'm charged with doing certain things. And I think Jon's point was very well taken. Is that we're going to meet in 6 months, there is a lot that can be done in the interim. So I'm asking, is it because, essentially, all the players that need to be here, except for a few, are at this table, is it appropriate for members of this Committee to reach out to others on the Committee to try and form exactly what it says, coordinate activities?

Because there is a lot of ideas that the Autism Society of America, for example, there are a number of specific initiatives that we're

wanting to forward and some of the players here -- some of the people at this table are exactly who we'd want to be speaking with.

So is it part of my charge, and the rest of the Committee, is to take those ideas and pursue them and then bring them back to the Committee?

Dr. Hyman: Yes. But I think we can do more. I think we should be literally working in the interim. And I think, you know, as we're developing, or everybody is talking about Barry's notion, as I understood it, he has still continued to offer to give us some drafts. And we do have this HHS report that Jon reminded us of, even though it's going to need some more pieces. And we could add to that, you know, if we could ask our colleagues in Education to provide pieces. And then ask some of the voluntaries. And, in some sense, it's better if those requests to some of the voluntaries come mutually from all of us because not everybody got to be represented on this Committee. And I think we want to put all these pieces together.

Mr. Shestack: The other thing we want to try

to partnership with, in collaboration -- you know, voluntaries sometimes -- you know, we're not only here to, like, say spend more money on autism, for instance. You know, I think we're also here to find out maybe we can help get more money for autism. Now, obviously, NIH doesn't -- there is no earmarks; it can't do it for NIH. So you're out of that equation. But CDC has to write a directed and appropriated budget that's earmarkable.

Dr. Cordero: He'd be in a funny position.

Mr. Shestack: Well, you know, or DOE. I mean there are all programs we could all identify and say somebody needs to do this. Let's shift it and maybe -- there is an appropriation budget that's going to be for --

Dr. Hyman: Jon, one useful thing about us identifying the gaps and needs is, in essence, that becomes an educational document for the Congress. I mean, there's no doubt about it. And then we, obviously, can't talk -- we can talk to them about it, but you can have a different conversation about it.

Mr. Shestack: (Microphone not turned on)

Right. The only thing I can't [Inaudible comment]. I mean, the reason we got as far as we have so far is there is now an organized population that there just wasn't before. And they got effective. So put them to work for you as well, for programs you want to do. It's a good offer; let's take it. And let's try and get some more programs going.

Dr. Hyman: Okay. So now, I really want to -- we have a break scheduled, but if you don't mind, I'd really like to bring -- before we have the break and the public comment -- I'd really like to get some closure here so we feel that this has been effective.

So, we should resolve to communicate, first of all, about this map, or this view of where we are. And NIMH staff will facilitate this in any way. One question is whether it will be helpful to have a list-serve or at least some other way of communicating related to this Committee.

[Nodding of heads]

Dr. Hyman: And I see mostly yeses. So we will look into that.

And Gemma Weiblinger, if you could just --

everyone probably knows you, but -- so Gemma and Kimberly Hoagwood will work together to get together a list-serve, number one. Number two, we'll generate a kind of reminder memo about finding the missing pieces.

Obviously, Gail Houle is already going to work on this, but we should, just out of politeness, communicate through Gail to our colleagues at Education. We will also work through channels to make sure HRSA is very much at the table. And we should communicate with all of you to make sure we have a comprehensive list of voluntaries who could say, "We're working on this." You know, people who should be involved in this.

Mr. Shestack: [Microphone not turned on] And [Inaudible comment] in terms of putting things [Inaudible comment] the map [Inaudible comment].

Dr. Hyman: Well, that's exactly right. And at the same time, Barry is going to show us a picture of what he thinks a map ought to look like. And then if we all agree, then we should probably pay for a contractor to work to put together,

literally, this map on the Web. Or however we would envision it. And use it, perhaps, for us as one of our tools for this coordination and for facilitating collaboration and for identifying gaps. So does that seem like a fair thing to do?

The other thing which, in the interim, which Jon has raised, which I think is also fair, is to begin to think about, or maybe to communicate with all of you, about progress toward shared gene banks, databases, and tissue resources. And Steve Foote will take the lead on that to make sure that that happens.

And then the other thing we ought to do is to list -- we have an enormous list of outstanding topics. What we should do is -- I'll read them to you now so you can think about them, but we'll circulate this list to you about things that we -- and we can decide which of these can wait until the next meeting and whether some of these really could be dealt with in the interim.

So we've already talked about the tissue banks and the DNA material. Now that still could be a topic for the next meeting, but we should

have an interim report. One of the things we were going to talk about which is related, but as a somewhat different expertise, which is to find the opportunities for data sharing and coordination.

We will have at the next meeting for sure a report on progress in the refunding of the CPEAs and of the STAART Program, but the discussion will focus on how best to coordinate the science so that we maximize communication between the two, but also instead of having everybody going their own way and potentially duplicating efforts, how we can create synergies.

We will by then have this comprehensive map, and we'll probably have to find a way of displaying it. First draft. We could even call it a zero draft. And we should display that.

We should discuss, but I think this is a sort of thing a list-serve would help us with in the interim. Ways of having better partnerships between Federal agencies and associations. I mean, what is it that we can do to give associations a leg up and what are they thinking about that we ought to know about and so forth?

And then one thing we really should do at the next meeting, I believe, is to have CSR in and come with a comprehensive overview of review. And, of course, we're very lucky to have Larry Stanford here because he knows the review system pretty well. And so he can heckle or cheer or whatever as we hear from CSR.

But we ought to be prepared then to -- ahead of time, we should send out to members of the Committee information about NIH -- I mean, it's not the most riveting reading, but people will need to know the difference between how we review applications -- the difference between review and the Institutes and why that separation and so forth. Just so that everybody's roles are clear. And then we could potentially talk about intramural plans; we could have --

Mr. Shestack: [Microphone not turned on]

Dr. Hyman: Yes, we could have Bob DeSimmone and Story Landis and maybe Owen Rennert, because Owen has become very active in some of these. Come and talk about intramural plans.

Mr. Shestack: [Microphone not turned on] And

what if we had some autism researchers [Inaudible comment].

Dr. Hyman: Well, I think that's a very good idea. Any other?

[No response]

Dr. Hyman: If not, let's just take a 10-minute break and then return and hear from -- a number of people have signed up for public comment.

(Whereupon, a brief recess was taken.)

Dr. Hyman: Can we try to come to order again?

[Pause]

Dr. Hyman: Let me just say, when we organized this meeting, a number of people actually told us ahead of time that they wanted to address this Committee. And I know that not everybody on the list could make it. I know Rick Rollens has a family issue at home. And it's a shame, but I'm sure he'll be very much involved the next time.

So let me just read down in alphabetical order. But then at the time, if there are others that do want to say something, it would be most welcome.

Sally Bernard, Executive Director of SafeMinds from Cranford, New Jersey. If you could just come up to a microphone or even at the table. Whichever is more comfortable. No, you're the first in alphabetical order.

Ms. Sallie Bernard: I just wanted to take 2 or 3 minutes just to say what SafeMinds is about, for those who are not familiar with it. We're a new organization that is involved in investigating the relationship mercury and, in particular, thimerosal in autism and other neurodevelopmental disorders. And we have a four-part mission, which is to facilitate research, encourage the removal of thimerosal from medical products, and to raise awareness of the issue, and also to investigate why mercury was put into medical products in the first place. And in all those areas, we've had some achievements to date.

What I'd like to talk specifically about, moving forward in regard to this Committee, is, as most of you know, the Institute of Medicine recently released a report where they did a review of thimerosal and neurodevelopmental disorders.

And in that report -- for those of you who haven't read it, I strongly recommend that you read it because it's very informative -- but in that report, they have very comprehensive set of research recommendations. And we would like to see those research recommendations fulfilled.

Right now, we've heard that there is a working group operating under the Interagency Vaccine Group that has assumed a responsibility for the implementation of these IOM research recommendations. And we feel that that's not an appropriate group to do these investigations because they are too closely linked to vaccines.

And we would like to see that research undertaken by a more independent body. And this may be, in fact, be the body to sort of take ownership of those research recommendations.

And, basically, two reasons: One is we feel there is an inherent conflict of interest with the vaccine group, looking at this research. And also thimerosal is a toxicology issue. It's not infectious disease. And we think it's more well placed with an agency such as NIEHS.

So as you're doing your maps and figuring out what should be done, we hope you will look at those IOM research recommendations and incorporate them into what you do.

Dr. Hyman: Thank you. Can I ask if there is any comment? Would anybody like to make a comment? Yes, Jose? No?

Cindy, is it premature -- I know you can't address NIEHS policy, but anything you wanted to say?

Dr. Lawler: Not at this time.

Dr. Hyman: Okay. Thank you very much Sally. The next speaker is Agnes Cushing-Ruby from Colonial, New Jersey.

Ms. Agnes Cushing-Ruby: What I want to ask you to do is look at a really biomedical approach and start to investigate that fully. I'm the parent of a 15-year-old daughter with autism. What I know is she has a lot of comorbid disorders that go beyond psychiatry. And, essentially, she has a level of rheumatoid arthritis affecting the joints, she has very low heart rate variability. What we're starting to find are so many medical

issues that go far beyond things like epileptic activity and the [Inaudible comment} types grossing patterns.

And I'm asking you to do more than count heads when we're talking about comorbid disorders. But, perhaps, use this as a model to look at subcategories of children with autism. And then, essentially, investigate those and maybe use those within the reference point of clinical trials.

Dr. Hyman: Thank you. Maybe Audrey Penn from the Neurology Institute or -- I don't know whether you have any knowledge of what Child's Health is doing in some of the comorbid disorders. Certainly epilepsy. Maybe Deborah Hirtz seems to?

Dr. Penn: Deborah can chime in. We do know that there are several developmental disorders that --

Dr. Hyman: -- Yes, but specifically about the research.

Dr. Penn: What the research -- well, yes, of course, we do know we have research going on in epilepsy and tuberous sclerosis, for instance. And in some of the others that look like autism and

biomedical, too. But Deborah Hirtz may want to add something --

Dr. Hyman: Deborah, why don't you -- you know some of the things you're doing.

Dr. Penn: -- in terms of specifics.

Dr. Hirtz: Specifically, we are working with a group of investigators to develop more research on the issue of the interaction between abnormal EEGs and/or seizure disorders and autism and possible treatments that are linked to that approach. So I think that's one very important area, and we have been working on it.

In addition, as Audrey said, we've had work in imaging, the correlation between imaging, and specific functional deficits in tuberous sclerosis and what that means for pathophysiology. We do a lot of work in Rett syndrome.

Ms. Cushing-Ruby: I think it's also my sense of just seeing enough other children as a lot of them do have things like GUI issue; a lot of them do really present with immune system dysfunctions.

And if we don't really use this as an opportunity to really take a look at the comorbid

disorders and find out if some of them actually have sort of a core relationship to autism, then we're just not being effective.

Mr. Shestack: One of the things I think is it's not just what we know to be the comorbid disorders, like TS or epilepsy, but other things that may be reported by families and clinicians, you see a lot of patients are starting to pick up.

And it's true that the STAART Centers provide a unique opportunity because I'm assuming that kind of every Center will have a clinical core so if they don't have trained clinicians, there will be trained clinicians.

Dr. Hyman: Yes. Yes.

Mr. Shestack: And this is something that as a group, they could start to look and tease out in a way that the CPEAs weren't really set up to do. But there is an opportunity.

Dr. Hirtz: No, you're right. Exactly one of the purposes of having and increasing our numbers in terms of collaborative studies, we need much more work on the epidemiology. And descriptive epidemiology that will come from these Centers.

And also, this is one of the areas of a collaboration that we've been talking about in terms of NIH and CDC. And getting more out of our epidemiologic work that we can sort of work synergistically to get some of these answers.

Dr. Hyman: I think Barry and then Jose.

Dr. Gordon: I just wanted to comment that one reason to have a map is so you can see what's not on it. And that after all, what was autism before 1943? And it's always important to keep in mind that where you characterize diseases [Inaudible comment] isn't necessarily the way biology categorizes them or expresses them. Autism may be the common expression of a number of different conditions, some of which we already recognize, such as perhaps, tuberous sclerosis or fragile X, and some of which are not yet recognized.

So, I think such a thing should be kept in mind, but for map making and far beyond map making, and just be patient because the map is meant to be an iteration to also begin to show what should be included on such a map.

Dr. Hyman: Jose?

Dr. Cordero: I think that having the population base surveillance and monitoring is going to be very important because one of the questions always is, are these things that are carrying by change alone or because they are more frequent? And having a population base is going to be critical in answering that question.

Dr. Hyman: You know, just a reflection: It's very interesting how this discussion about the diversity of kinds of pathogenesis in autism really mirrors all of general medicine. I mean, even "simple things" like adult onset diabetes will turn out to be -- or turning out to be -- genetically complex and many different illnesses that sort of cluster with a final shared pathogenesis, but very specific features that importantly will have treatment implications.

And I think one of the things we may find is that this will direct subsequent research. Maybe NINDS will be doing a clinical trial for treating epilepsy in autistic kids. Maybe those will be different from others. You know, I mean, we just really need to get there and, hopefully, we can do

it expeditiously.

Yes?

Dr. Carbone: As the only animal-model person here, I'll serve as the dartboard once more. I do a lot. I, actually, agree completely. That's a very important point, because it would be almost foolhardy to think that the brain would be the only target of whatever this abnormality is. And we see in our model clear involvement in the autonomic and peripheral nervous system as well, in these rats that are developmentally affecting the brain. So I think that's a very wise use of it, is the ability to make subsets, for example, might be additional information. That's an excellent idea.

Ms. Cushing-Ruby: [Away from microphone]

Dr. Hyman: That's very helpful. A very good point. Okay, the next speaker, Albert. If you're not --

Mr. Enayati: Thank you. First, I just want to again thank you. And I just want to let you know how heartbroken I am that you're leaving NIMH. And that is the truth.

And also, I just wanted to inform everybody that the IOM report regarding thimerosal is extremely important to autism because they could not conclude, based on the research available, they could not conclude whether this causes autism or not. But they concluded that it is plausible that ethane mercury could cause autism. And we need more research to be done in this area to make sure that if this does cause autism, and if this is the cause for a fact, then the course of treatment should be applicable. So I just wanted to emphasize on that.

So I'm going to read my comments. Good afternoon, I'm Albert Enayati; this way you can pronounce my last name next time. Albert Enayati.

I am the Secretary at SafeMinds and board member of Cure Autism Now, New Jersey Chapter.

Please allow me to express my appreciation to the entire Committee for organizing this Committee. Twenty-two years ago when I started to work as a scientist at Pfizer Corporation, I learned one important lesson. That I would like to share it with you and the Center of Disease

Control and Food and Drug Administration representatives. Without safety data, the safety of product is just another opinion.

As we speak, the safety of U.S. immunization program is just another opinion by the FDA and CDC officials. There are still many components in the vaccine that have never been tested. As we were guaranteed by the Institute of Medicine, with full assurance, concerning the safety of MMR vaccine and recent published report funded by Center of Disease Control revealed that both DPT and MMR vaccines may cause [Inaudible comment] seizures. Most of the children with autism suffer from these seizures. Every symptom of autism is mirror image of mercury poisoning. The only possible way our children were exposed to these mercury poisoning is through childhood vaccination.

I'm assuring you that the issue of vaccine and autism is not going unnoticeable. The U.S. immunization program may have damaged our children. We need the Interagency Autism Coordinating Committee to initiate in issuing RFA on much needed medical research regarding

childhood vaccination and autism.

Finally, I am here because of my son Payam. My wife and I and family believe that this devastation is caused by mercury, along with [Inaudible comment], which were repeatedly injected to him when he was just born and repeated approximately every 2 months until the age of 15 months. Again, every single month, my son's autism is mirror image of mercury poisoning.

I'm here to appeal to this Committee to review the overwhelming evidence on the adverse reaction on the childhood vaccination and when you do so, you will quickly conclude as we did, autism may be caused by U.S. immunization program, predominantly mercury. Your positive response in enhancing the medical research in this field will save thousands of children across the country to have a better future. The lack of positive response will jeopardize the future of many generations to come.

And thank you so much.

Dr. Hyman: [Microphone not turned on] Thank you. Okay, I think [Inaudible comment]

to make sure everybody here has access to a copy of the IOM report [Inaudible comment].

Any comments from members of the Committee? Yes?

Mr. Edward Wong: [Away from microphone] I have a comment.

Dr. Hyman: Okay, well, I think we just have ahead of you, in alphabetical order, Raymond Gallup. Raymond Gallup is the President of the Autism Autoimmunity Project from Lake Hiawatha, New Jersey.

Mr. Raymond Gallup: My name is Raymond Gallup. I am a parent of an autistic child with autism due to the MMR vaccine. And I know it's so because of what I've seen with my son in 1995. We measured his titer levels, and they were 10 times higher than normal -- his measles titers. He also had T-cell abnormalities and as well as that tested positive for basic protein antibodies.

My son is 16 years old; he's not getting any younger. And I also want to say I'm a U.S. Navy veteran from the Vietnam era. And I'm also President, as you mentioned, of the Autism

Autoimmunity Project, which I started in 1998 because I went to the NIH and asked them to fund immunology research and it didn't come about.

With the CDC, I know that, basically, I had heard about the Brick study, and I questioned the officials there about that. And I asked them why don't you do some immune blood panel tests on that, but it didn't seem to be within their realm to do that test. And to me, I thought that that was something that was lacking that could have been done. And we could have checked these children in Brick to see what was wrong with their titers or T-cells and that type of thing.

I have 400 parents that have contacted me across the United States that believe that the MMR has caused their children's autism. And I've been involved in Dr. Yazbak's study, where my wife mentioned that she got the Rubella vaccine after birth, and then my son got the MMR about 14 months later. And being that the MMR is a live virus, we feel that he got this from the live virus.

As Albert said with encephalitis and seizures, that's been noted in the DPT and the

MMR. And I think it should be seriously looked into. There have been parents that contacted me about the DPT and the hepatitis B vaccine causing their child's autism.

There is one other factor that -- with the VAERS report, there was one doctor in California that mentioned that the oral polio vaccine, MMR, and DPT caused a case of autism. And he mentioned 10 other cases that he knew about. This really -- I know that there is a privacy law and everything -- but it should have been investigated, I think, to find out what the doctor had found on this, and we could have looked further into what this doctor found and why he mentioned that.

I know that the epidemic is out there. There were 20 children in my school -- in Eric's school -- in 1992. And at present, there's over 100. In England, David [Inaudible comment], another parent, reported a case of the Wakefield Authority Schools there; 1 in 69 children was autistic. So, the numbers are there. They are increasing, and the clock is ticking.

Like on my son -- here is a picture of my son

and my daughter and my family. And, like all parents, we look at our sons and our daughters, and we say “What can we do?” And quite frankly, I think that if we fund some research into the [Inaudible comment] arthrology and immunology research, on this, we might be able to get some answers and get some immune therapy treatments. Because with our son, we did the intravenous gamma globulin, and some children it helped; some it didn't. But there are treatments out there that we could look at and really improve the lives of these children. But we have to look at them, and there has to be the research for that.

There is one last thing I would like to say. I've got a report that I'd like to give you, called the "International Research Group on Epidemiology of Autism." I think there is a very good epidemiology report, and it should be something that's looked at. It's by Dr. Hyman and Dr. Spitzer. And I think it's a very good report that should be looked at.

Dr. Hyman: Duane Alexander is no longer here. So we can't ask him. I don't know if it's fair to

put you on the spot about what potential measurements there will in this enormous perspective observational study. The longitudinal study, whether there will be any immunologic measures. But that's certainly one --

Dr. Stanford: I'm not that familiar with the study, so it's a little difficult for me to answer. I know that there was a committee that met just a short time, about a month or so ago, to develop the protocols and the kinds of analyses that were going to be done in the study. But at this point in time, I can't really say exactly --

Dr. Hyman: Deborah, were you on that Committee?

Dr. Hirtz: Well, I am on the Neurodevelopmental Subcommittee. But, clearly, this is part of the plan. It's a question of deciding what the exact protocol is, timing, you know, what kinds of specimens will be drawn. But, certainly, this is an area that is going to be covered.

Dr. Hyman: And do you have a sense of -- I think Duane said it, but also not only for Mr.

Gallup, but everybody -- about when this study will be in the field?

Dr. Hirtz: 2004?

Dr. Hyman: 2004.

Dr. Hirtz: Before that. It will be in pilot.

Dr. Hyman: Okay. It will be in pilot. Okay. I think, Mr. Gallup, again, this is research. It's really done mostly in NICHD or the Child Health Institute on the gastroenterologic aspects. But there is at least some research going on in these areas, and we might, perhaps, if you wanted to leave a card or something, the NICHD could get back to you with the kind of relevant research that is being done.

And the last person on the official list, since Rick Rollens isn't here, is Edward Wong from SafeMinds in Ridgewood, New Jersey.

Mr. Wong: Thank you, Dr. Hyman and the distinguished panel, to give me 5 minutes. My name is Edward Wong from New Jersey. I am a scientist and was Assistant Director of Research for a former medical technology division of Pfizer. And I have a Ph.D. and over 25 years research

experience in biotechnology and sciences.

Also, I have a deep compassion for children with autism. Four and a half years ago, we were blessed with two beautiful fraternal twin grandsons, Justin and Calvin. When they were 3 years old, Justin was diagnosed with autism. We love Justin dearly and would do anything for him.

My son and daughter-in-law tried very hard to enroll him in an ABA school. But the waiting list is over 200 and the school capacity is only 25 students. Since time is of the essence for autistic child between the ages of 2 and 5, their brain is still plastic and moldable.

He is enrolled in an intensive home program, 5 days per week, full time, plus speech, occupational, and physical therapies, costing over $70,000 per year. Unfortunately, their school district in Connecticut does not believe in the ABA early-intervention program and refuses to subsidize.

Today, I'm not here to talk about my grandsons, but to address the distinguished panel about autistic research. I am happy to see that

today NIMH and the Interagency are addressing the problem of autism. With the current estimate of one in five [Inaudible comment] born autistic, the number may be increasing. In fact, today we find out that in Brick County the number has already gone up. If we don't do anything to prevent it and reduce it now, the cause of managing autism will be insurmountable. We have to solve the problem soon.

To find a cure, we have to know a cause. Autism is a lifelong developmental disability with no known cause and cure yet. And most autistic patients require lifelong care. Caring research is studying the cause and have concentrated in two areas, the biological approach, such as genetic factors, and the environmental approach, such as the heavy metals area and other toxicants.

The symptoms of autism in the children's suffering mercury poisoning are similar. And I don't want to beat the dead horse since Albert already talked so much about that. But I would like to give you a different perspective.

It has been estimated up to 237 micrograms of thimerosal received by a full vaccinated children. In the new report by the Institute of Medicine of the National Academy, thimerosal containing vaccine and neurodevelopmental disorders, the title. This morning, Dr. Alexander already mentioned that safety review committee concludes that the evidence so far is inadequate to accept or reject the relationship between thimerosal and vaccines.

And, however, the Committee also concludes that from the analogies of ethyl mercury and the level of maximum mercury exposure from thimerosal in vaccine given to children, the hypothesis is still biologically possible. The Committee has recommended the removal of thimerosal from vaccines administered to infants or the pregnant woman. Although thimerosal-free vaccines -- hepatitis B, DTAP -- are now available in the United States, there are still remaining supplies of thimerosal containing vaccine available here and abroad. Because of the [Inaudible comment] facts of mercury, the Committee also advised the

pharmaceutical industry to remove the thimerosal in eye drop nasal spray products that are used by children.

The information on ethyl mercury exposure from fish and seafood products compared with ethyl mercury of thimerosal in vaccine are deemed indirect. It is plausible that we may compare apples and oranges. Also, the information on the low exposure of ethyl mercury is inadequate; the Committee recommended further studies.

But I would like to draw the attention that thimerosal has a very similar molecular structure as aspirin. Both have basidium salt or salicylic acid group. And it can be delivered to your brain as fast as aspirin and hydrolyzed to give you the salicylic acid, thimerosal acid, and the ethyl mercury. And the thimerosal is a sodium salt that probably is why they designed it so that it can be absorbed faster, it can penetrate the cell body of the bacteria. And then the ethyl mercury itself, which is not water soluble.

I have the hypothesis of the research, and I hope I don't oversimplify it. Please bear, I beg

your indulgence. I just wanted you to listen to this and since I'm from the outside and maybe I don't look at the problem as close.

My hypothesis is a three-pronged approach to distinguished and environmental and/or genetic factors that cause autism in neurodevelopmental disorders. First, I thought from the report I read, that thimerosal-free vaccines have been available since May 2000. But this morning, Patricia mentioned that they have reduced or trace thimerosal in there. But I thought if we have a thimerosal-free vaccine now, soon we should have enough data to compare a large population of certain period of time to study statistically any significant reduction on neurological disorder, compared with the same period with the children who have thimerosal vaccine. But if there is trace, then it's complicated the comparison a little bit.

It's important to examine the low-level toxic exposure of thimerosal compared with ethyl mercury. This morning, Dr. Lawler mentioned to look at the methyl mercury in the seafood and fish

products. But, again, we may get into trouble of comparing apples and oranges. And I think it's much more better to compare thimerosal with ethyl mercury. And also to study the safety and efficacy, like FDA [Inaudible comment] procedure and other detoxification methods used in children with autism and disorders, as recommended by the safety review committee.

And I think it's very important because now the parents are crying for help, and they are really looking into all kinds of methods. And right now, we really don't have any study to show whether this method actually work or not work and how safe it is.

And second, I was thinking vaccines have serious --

Dr. Hyman: [Microphone not turned on] Mr. Wong, if you could begin to wrap up. You said only 5 minutes.

Mr. Wong: Okay, sorry. The second approach I was thinking of hypersensitivity and hypoallergenicity is [Inaudible comment] blood tests to just light testing allergy. And in that

case, we can use it as a prevention. If we know that the pregnant woman or the baby is highly allergic, then maybe we can postpone or develop doses that can be much lower. Because it's not the so-called normal dosage can be -- it may be already too high. For example, for 300 micrograms, maybe it's low for the average normal person, but for people who are allergic to it, maybe 10 micrograms is effective.

Third is, I say that autistic children have higher probability and develop infections and other allergies. And, basically, I thought studying fraternal twins that one of them is autistic, maybe we can find out any genetic factors or any immunodefective factors, biological factors. Maybe triggered off by this [Inaudible comment] and mental factors. A combination of not just the genetic factor or biological, but also the [Inaudible comment] that triggers it.
So I think that's another project that during the -- which I thought is interesting, is to study the inactivated lymphocyte and [Inaudible comment] that examine whether this next could be the

vaccine pathological factors that may cause the development of autism. Thank you for your time.

Dr. Hyman: [Microphone not turned on] Thank you very much. Do you have a written copy of --

Mr. Wong: Yes, I have.

Dr. Hyman: We'll take that. Any comments? Yes?

Dr. Lawler: I think several of the speakers have hit on a common theme. And then there is a need to really coordinate research efforts that are now ongoing to evaluate the safety of specific vaccines or vaccine components. And I know that in our children's centers and through funding of another one of our grantees, we will be looking at potential effects of thimerosal. And I do not know a lot about this interagency vaccine group that was mentioned before, that is charged with implementing research recommendations from the IOM report. So I think, you now, that is evidence enough that there is not -- that we could use improved coordination.

And, perhaps, one possibility is to create some sort of overlay that would be on this map

that Barry has agreed to help draft that would try to assign the pieces of the puzzle. Because I know many of the different data that's already available is resonant in different Institutes and different agencies. And I think it would be very useful, and I could, certainly, help provide that type of overlay. Because I get questions about this a lot. And it would help direct my thinking, if that would be a useful.

Dr. Hyman: We will get you a copy of Mr. Wong's comments.

Mr. Shestack: Is there epidemiological data coming out of Canada where they removed thimerosal from most vaccines a couple years ago?

Dr. Cordero: Actually, not Canada, but from Denmark. We are in the process of conducting a study with the Danish looking at autism and use of vaccines, because they removed it about 3 or 4 years ago.

Mr. Shestack: Is that part of the Centers' project, or is it a separate project?

Dr. Cordero: This is an independent project that is partly funded by us and the National

Immunization Program.

Mr. Shestack: Great. I want to point out one thing. You hear this all the time from many families about immunizations, if it's MMR or if it's thimerosal. And, clearly, I mean, maybe the Government is doing a good job researching it, maybe they aren't. They are definitely not doing a good job convincing the families that they are researching it. They are doing a terrible job. And what I think what you see here is whatever the underlying facts is, families feel handled. When they feel handled, what it does is it throws more doubt on the process and on the auspices. And if what the Government's concern is from a public health point of view, is universal vaccination -- and I'm sure it's a very reasonable goal, then the way it has been handled from a publicity and marketing point of view, right now has been counterintuitive to the point of, like, ridiculousness.

And, you know, the last IOM report and on the previous one on MMR, but you could do a lot better on letting people know that you take it seriously

enough to explore it. And if you were to find a connection, then you would correct a formulation of vaccine. Because what you have now is a community that just thinks Government is afraid of litigation. And maybe that's not the case, but that's something you have to work on.

And I don't know, it's probably not --

Dr. Hyman: [Microphone not turned on] [Inaudible comment] this isn't -- these are [Inaudible comment].

Mr. Shestack: -- but it's taking up a lot of this Committee's time, so I think it's something that recommendations have to be made to the Secretary because it's a public health issue.

Dr. Hyman: Do you want to make a comment from FDA's perspective?

Dr. Carbone: Yes, I do, because in many ways, I agree with you. When I first proposed to Kathy [Inaudible comment], Center Director, that we start a group and investigate the pathogenesis of autism in relationship of viruses and neurovirulence with the developmental bend, I have to give her a great deal of credit because a lot

of people -- this was before Dr. Wakefield's publication, but I was concerned that there was a gap in the knowledge. And that we needed to fill that gap.

And when Dr. Wakefield's papers were published and the concern was raised, we were very glad we already initiated them, and the group already contains the behaviorist and neuroanatomist, a virologist --

Mr. Shestack: Which group is this?

Dr. Carbone: My group doing research at FDA. And one of the arguments we used even -- again, with the thimerosal being removed, et cetera -- was we -- epidemiology studies that have been reported by the IOM are pretty clear. And there really is no association. However, in every report, here is also the mention that they cannot rule out a rare causal association. And that has to be really studied at the pathogenesis, the biological level. And we felt that it wasn't possible -- we didn't want to simply use placations. Trust us, vaccines are good, fine, use them.

We wanted to be able to say here are the data at a biological level that suggests that this attenuated virus is attenuated for the nervous system and the developing nervous system, as well as a positive thing to protect from measles, which was much worse for the nervous system, the wild type, than, presumably, the vaccine because it kills 1 in every 1,000 kids who gets infected, often, usually, from brain infection.

So that's exactly why we started this group, because we feel the same way. There must be data with which to respond to these concerns, not simply placations. So I agree with you.

Mr. Shestack: I think the important point that you made which, perhaps, everybody got, but which is really critical, is that for a small subgroup, we simply cannot have epidemiologic samples that are large enough, which is why research at the level of pathogenesis is the only way to approach this. And I think that's really very important.

Dr. Gordon: I don't know, Jon and others, whether there is any mechanism, for example, where

you think review of protocols in advance of actually putting the study in effect might address some questions. For example, in other areas of research, protocols are sometimes circulated in advance so all critics can weigh in, not necessarily always be recognized, but at least weigh in to see if their questions are addressed. Or even refine the questions.

And, for example, I'm still happy with my son having been immunized. In fact, everything I've read has convinced me that it was better for him to have been immunized than not to be immunized. But, apparently, some other people have taken a different slant on that data. But there is a study ongoing now that's examining in Scandinavia are there holes in the study, or is it appropriate for people to comment? Because if that study then goes forward and comes up with a negative result, will it convince anybody? What themes need to be addressed?

Mr. Shestack: It seems a reasonable thing to do for either way it comes out on the issue, but let your information have more validity. It's just

like what plagued autism research beforehand. It was like crappy study design and tiny sample size.

And so, like, there might have actually been good findings that people just sort of like other scientists pooh-poohed, didn't follow up on them because there was nothing verifiable in it. And so if extra precautions can be made to get buy-in then from the entire community on the results, would certainly be effort well spent.

Dr. Hyman: I think you're invested in that.

Dr. Cordero: Yes, well I agree. I think that what this is saying also is that aside from the coordination in terms of all the people that are working on autism, in terms of what's described here but, perhaps, there is a need to have coordination. Because there are other advisory committees, and there are three advisory committees that relate to immunization. The National Vaccine Advisory Committee, and they report to the Secretary. Excuse me, the National Vaccine Advisory Committee -- yes, Advisory Committee. Yes, I think that Barbara Loe Fisher was -- were you a member of that Committee at that

time?

Dr. Fisher: [Nodding]

Dr. Cordero: Yes. And the Advisory Committee on Immunization Practices and the Advisory Commission on Childhood Vaccines -- all three have different roles. But I think that all of them are concerned about the issues of vaccine safety.

Unidentified Female Speaker: Yes, I want to just go back to Rick Rollens' figures. He says that it took California's Developmental Services 29 years, from 1969 to 1998, to reach 10,206 cases of level 1 autism. It has taken California just two and three-quarters years, 1999 through October 2001, to add an additional 5,942 new cases. And this doesn't include the numbers of children with autistic spectrum disorders, which could well double that number.

So I think it's fair to say that if this were 5,942 few cases of measles, the CDC would declare a public health emergency and go to Congress to get emergency funds to address that emergency. Now, with a 600-percent increase in a disability as serious as autism in one State, and there's no

reason to believe that California is any different than any other State, that we do have a public health emergency.

Now John and Porcia Jestack, and other parents who represent organizations of parents with autism, have managed to get this legislation passed and $12 million devoted to autism research. But it shouldn't depend upon the lobbying efforts of parents. And I think that the CDC and NIH, which receives the lion's share of the DHHS congressional appropriations, should make autism research a significant funding and program priority within their own agencies so that they can find out why we have got these extraordinary increases in autism. Because, frankly, we haven't got 5 more years. We can't wait 5 more years.

And I think, finally, that I'd like to say that parents across this country are not going to be satisfied. The educated parents are the ones that are driving this issue, and they're not going to be satisfied until the good science is done. And the NIH longitudinal study, if that's what you're going to depend upon on the vaccine

question, for example, you know, if the methodology is not sound and if you don't design it in a way that will yield reliable answers, parents are not going to believe the conclusions, and you are going to continue to have this problem.

It is not just a problem of not communicating, of throwing more PR at it. It's a problem of whether or not you do the good science. Now, I've been doing this work for 20 years on the vaccine safety issue, and I'm telling you, there are more and more parents who are coming forward to the National Vaccine Information Center reporting their children are going down after vaccination after developing normally. You can't continue to deny and not deal with this, try to avoid dealing with this in a scientific way.

[Applause]

Dr. Hyman: [Microphone not turned on] Okay, any comments?

Mr. Ron Oberleitner: Thanks. My name is Ron Oberleitner. I'm the father of an autistic son, Robby. A beautiful boy. We're from Princeton, New

Jersey. He's my most important mission. My second most important mission today would be the chauffeur for these great people from New Jersey.

[Laughter]

I wanted to share with you, because some of the parents in the room will also know that I spent 3 months of this year traveling with a great group of people across the country on a bicycle, who went 6,700 miles to raise money and awareness for autism research. And some of the things maybe to help add to the human component here, is that when we were riding to different towns and there would be a group of people waiting for us, there were autistic children who were practicing months to, first, be able to be on a bicycle with training wheels so that they can go with us for about 20 feet.

What that tells me is that they know what's going on. People who don't deal with autism might think there is, you know, mental retardation. We have very smart kids who are motivated and practice hard to overcome their disabilities to do something like ride a bike for a little bit.

Number two, when we got into Philadelphia, we got to meet Jeff Lurie and all the TV and media. And Jeff Lurie is the owner of the Philadelphia Eagles. He told us the story that his brother is autistic and is 41 years old. When he was 35, they first gave him one of these special little communication devices that a lot of parents know about. And through some work, this man who never spoke a word to his parents or anybody beforehand, the first things that he ever said were from this computer. And they were, I am not stupid. I understand everything.

And that puts chills in parents' minds because we know our kids are there waiting for us to do something and motivated people who are coming and forming a group like this, that's kind of the urgency that we feel. And we can definitely be the most supportive people because we see it in our children's faces when we're back home.

Thirdly, and maybe these are miscellaneous points, but things also we learned along the way that might add to some of your efforts going forward, we met Congressman Mike Doyle. He and

Congressman Chris Smith, who a lot of people know have been so active to support our disabilities.

He surprised me where we were out there saying, hey, there's 500,000 people in this country -- you know, using ASA numbers -- that suffer with autism. He said, you know, from our subcommittee's efforts thus far, we're seeing more like 1.7 million. I don't know if that's good, helpful information, but if it's not, please get together and see what they're doing. That has power to it.

There are thousands of people, and they are trying to deal with this without an educational system to support them. They are hiring therapists from New Jersey, as one example, down to Louisiana to educate a bunch of 18-year-olds on how to work with our kids on one-on-one therapy. Just on their own, because there is no resources there locally. So it's a dire issue. And it's not all money related.

In Princeton, we are known for having two of the best schools, in maybe the country or so, dealing with autism. And I'm pretty connected in

town. And even so, my little guy has to get on a bus and go an hour and 45 minutes each way to get to the school out of district because that's the place that's opened up for him. And that's a dire issue.

And then the other part is our school district said you can have it. You can have 15 hours additional therapy; we will pay for it. We know Robby needs it because that will improve him. And probably one of the best States for resources like that. We can't find the therapists because everybody has just tapped out the available professional services.

So I'm pursuing technologies right now that will be able to help out the shortage of professional help to reach the autistic children. And I want you all to know that there is this human element, where we're trying to get our kids services that will get them contributing. Like, you know, many of the autistic kids who get the help are doing that.

And one last anecdote is that for those who haven't heard, I just attended a meeting where a

Cure Autism Now has been hosting this great young man, Tito, from India. And up through the age of 11, if I understand the whole background correctly, Tito was as nonresponsive as my son, who doesn't communicate at all. And he just appears like he doesn't understand much. Through a lot of hard work, they were able to facilitate communication. It didn't come out of his mouth, but it came out through some augmented device. And now by 13 he is on par with literally giants in the field of poetry, where he is communicating through this special way and contributing to society in such beautiful poetry.

Mr. Shestack: Actually, he writes independently. He's very good.

Mr. Oberleitner: But the idea, we're not just handling a handicapped issue, necessarily. I think, Lucille Zeph, you mentioned the gifts there are in these kids. And they are being kidnapped right now until we can release them. It's just not like somebody doesn't understand what's going on. They know they're trapped and they are looking to get help. So thanks.

Mr. Gallup: Just a quick couple of things.

Dr. Hyman: Yes, go ahead.

Mr. Gallup: My son tells me in his word picture book that when I ask him, do you want to get better, he shakes his head yes. And my Julie, she says she hopes that my son one day speaks and does get better. But this is the concern as parents and, you know, our children, and our siblings. They really want these kids better, you know. And we've got to do what we've got to do for them.

Mr. Shestack: All of the autism meetings I've ever been to kind of have this moment. And I'm sure that when other groups come in, they have this moment, too. And, you know, everybody who suffers, suffers, and every parent's pain is painful. And it's not a competitive sport, and we're not asking for it to be a competitive sport. But one of the things that you have to realize is if you have a heart attack, there isn't an emergency room in the country that won't take you, whether you have insurance or you don't.

There is no safety net for people with

autism. And there's no indication that IDEA, for instance, is going to get more funded in the years ahead. In fact, probably less, so kind of, really, the entire burden of hope for families who have people with autistic children and who have other children who potentially will have children of their own with autism, rests on the NIH. And the amount of money and the differential it might take NIH to make progress compared to the amount of money you'd be asking for full Federal funding of IVA, it's staggering with this proportionate, right? It's like billions compared to hundreds of million.

So when you hear Ron and Ray and, usually, I give this speech and I feel the same way and all of us who are parents who just -- our kids feel this way, there is nothing else out there. And there's not going to be anything out there. All of the hope that we have really is going to come from educational and medical research. And it's the people in this room who are charged with the responsibility. It's really important that you feel it. And that you feel it when you go away

from this meeting. And that you find ways to put aside whatever [Inaudible comment] things there may be and try and work a little bit harder to leverage the small amount of money we have on it to make it go further, because it's not coming from anywhere else.

Dr. Gordon: I've had the pleasure of knowing Ron even before either of us had any children. And here's an individual that lives in a community that, in my mind, has the best available services in the country, if not the world, for autism. And yet he's telling us about the difficulties he's having in obtaining services.

The issues that are being presented to us here, in terms of being an Interagency Coordinating Committee, I think go well beyond the research aspects. For us to focus entirely on research and this body as most of the discussion has centered on, would not represent the true intent of what I consider an Interagency Coordinating Committee to do.

We are seeing this, and I think everybody around this table will admit that this is a

national health crisis. It's an emergency. We've had other public health emergencies before, and we've responded. This one has been well known; it's been well-documented; and we haven't responded yet. It's time that we do respond. It's time that we take action.

And I'm hoping that this Committee will take the steps forward and invite others who will provide what is my major emphasis, and that's to have these children receive services so that they can lead more productive lives. So that parents won't have to be out there every day advocating and giving up of their lives and their normalcy and affecting their other children's lives.

It's an important issue. Research is only one aspect of what we need to do in autism. Seventy-five of these children will live their lives outside of the secondary education system as adults. There is nothing out there for them. It's as if you had a person in a wheelchair and at the age of 21 you took that wheelchair away from them.

What are they going to do then? Well, that's what it's like for us as parents with our

children.

I guess I see my role on this Committee as being that drum beater for services. And if that's the role I have to take, that's the one I will, because I see that as an important aspect that needs to be addressed. We will continue to address it and we have to do something about.

Dr. Zeph: If we are talking about services, we may want to get what was HCFA to the table.

[Microphone not turned on]

They said we'd never remember HCFA, and now it's just been ingrained.

Dr. Gordon: [Microphone not turned on] But part of the map is going to have to be the acronym section, I can see that.

[Laughter]

Dr. Gordon: In fact, that may be the largest part of it.

[Pause]

Dr. Hyman: Well, it's very hard now to kind of focus on our next steps. You know, it's very emotional, but we've got to do it. We've got to do it.

I read a list of potential topics. What we'll do is circulate these topics to this Committee. We know where everybody lives. We'll set up a list-serve. We will ask for you to think about these topics; comment on the priority, the timing; add additional topics. So we should really work -- guess it's easy for me to say -- but we should really work, you know, and I take Jon Shestack's point, not wait 6 months. I think there's a lot of momentum. There was also a list of things that NIH would do with respect to genetic and issue resources and information resources.

And not to reiterate it again, but we will -- you know, I think one of things that I was saying before, even if -- just so that, because I know you also have a day job and a family.

Dr. Gordon: Not any more.

Dr. Hyman: No, no. I mean, even if on this map we just listed every important agency and linked to a short description of what they felt they had to offer, you know, that would be a fabulous start. Because what we notice is that here we get to 4:00 before anybody mentions HCFA.

So I think, you know, there is a certain amount of -- on the one hand, everybody is preaching to the choir. We're all here because we want to make a difference. But by the same token, clearly, there are enormous holes, enormous gaps, that we really -- it's almost embarrassing that we don't have all of the right people at the table.

Jon?

Mr. Shestack: Can I just ask a procedural question?

Dr. Hyman: Sure.

Mr. Shestack: After [Inaudible comment] the funding cycle for the centers, obviously, when a group of centers are funded, this Committee will have something to contribute to make sure there actually is inter-Institute cooperation.

Dr. Hyman: Right, yes. Yes.

Mr. Shestack: Is there anything really to the election process that this Committee might have to contribute in terms of distribution or waiting of interest percent or sort of a -- more as Barry was talking about -- a map about dealing with the problem in a more -- looking at it with a more

global overview --

Dr. Hyman: Yes.

Mr. Shestack: -- or is that inappropriate to where this process starts?

Dr. Hyman: I'll tell you -- this Committee can't legally do that with respect to replacing Institute councils. But what this Committee ought to do is to look at the first group that gets funded and should make clear comments to the Institutes about where you feel the gaps are, you know, what got left out in the first round. And I think that's a perfectly -- not only legitimate -- but an important function of this Committee. Jose?

Dr. Cordero: You might think you know where I live, but I just noticed that my email and my address were not exactly accurate.

[Laughter]

Dr. Cordero: And I was wondering if everyone needs to look at what is on the list and be sure that we get an accurate

Dr. Hyman: Yes, yes.

Dr. Cordero: The second thing, I think the

point that --

Dr. Hyman: It's a little diluted, but you know.

Dr. Cordero: There is really a lot of work that needs to be done in between the meetings. And I think that Barry developing the map, as an example, I think that the other theme that seems to be sort of circulating is the issue of services. And I wonder if there is a need to have another designated person to work on even raising what are the issues with services and have that as a topic for discussion at the next meeting.

Dr. Hyman: Well, why don't we add that to the list of topics to circulate and also, Lee, you were yes, that's right. You two, actually, were going to work on that. So let's just expand your -- yes, why don't you do that.

Unidentified Male Speaker: We'll put together our map.

Dr. Hyman: That will be really good.

Dr. Gordon: Can I just comment? Several people have already volunteered to help contribute to the map or list or wish list, or whatever. And

you're more than welcome to do so. And I think the email address listed is correct, although very little else is on there. So you're more than welcome to --

Dr. Hyman: Now is your chance to improve your identity.

Dr. Gordon: Yes. Well, or keep it more hidden.

Dr. Hyman: Okay, great. Steve?

Dr. Foote: Is it time for the last word?

Dr. Hyman: Just about, yes.

Dr. Houle: The last word.

Mr. Shestack: I want the last word.

Dr. Houle: You can have the last word. I just wanted to say that while I was here I had written down a list of about seven or eight possible topics for part of the future meeting. So, maybe I could fax these to you and they could get on the list for comment before the meeting?

Dr. Hyman: Well, yes, if you have then written down.

Dr. Houle: Yes, I do.

Dr. Hyman: Yes, then you don't have to fax

them.

Dr. Houle: Oh, well, it's my only copy. But that's okay.

Dr. Hyman: Well, you're very trusting.

Dr. Houle: Well, I thought I could -- I wanted to, you know, run them by Lee as well.

Dr. Hyman: Trust us, we're the Government.

Dr. Houle: Okay, that's all.

Dr. Hyman: Steve?

Dr. Foote: So, everybody knows that Steve Hyman is going to be leaving as Director of NIMH, and that has obvious implications for this Committee. Kimberly Hoagwood is also going to be leaving NIMH to go to a very important job in the State of New York and at Columbia University.

So I want to reassure everybody in advance that we know that these things are happening; we have a strong commitment to not having those departures disrupt the work of this Committee or our efforts in the areas of autism research and so on. We will be doing our best to maintain continuity of communication with you and among ourselves as these things happen. And I just

wanted to give everybody a heads-up so they didn't feel like they had been left out of the loop, or there was something unexpected happening or this was threatening and anxiety provoking. Any more than it is anyway.

And I will, certainly, as far as I know, be at my same email address and overseeing the STAART things, along with Deborah, and the NIH Coordinating Committee, in any case, will be in place and, obviously, extremely active over the next several months implementing the refunding and reconceptualization, to a certain extent, of the CPEA Program, of the STAART Program, and all of our other autism activities. So I just wanted to put that in.

Dr. Hyman: That's good. Well, that emoted at least three-quarters of my last words. So the only other thing I would add -- that's good, it's very good -- is that Gemma Weiblinger will be working with Kimberly to make sure that nothing gets lost in these transitions.

Barry?

Dr. Gordon: I didn't really have a last word,

I had a last thanks, actually. Knowing that you two are going, I just wanted to tell you that I suspect I speak on behalf of many people to really appreciate what you've done already to put things together with your staffs and associates and all that you've set up for the future to make this move. It's very important to us parents and researchers as well. I really appreciate it. I'm sure everybody else has, too.

Dr. Hyman: Well, thank you. I want to express my appreciation, actually, first -- this is the easy part --to NIMH staff. I mean, I knew I wasn't going to stay in Government my whole life, so I've spent my whole time making myself dispensable by having a very, very strong group of people who are really committed to this issue and many other important issues.

But I also want to thank the families and the family groups, because I really thought I understood, but I didn't. And you really have -- even, again, this afternoon, opened my eyes. And, I think, have galvanized all of us. And I know that at times there are frictions, but those

really have to do with often our frustration. We wish we could give more. We wish we had the answers. We wish the science was there. But in the end, despite some background disagreements, this is wonderful joint effort. And I'm sorry to be leaving NIMH for many reasons. But one of them, I mean, after today, I mean this was such a really fabulous beginning of this Committee. And I'm sure it's going to retain momentum and help galvanize, not only research at NIH, but actually lots of communications that needed to happen that now will happen.

And I'm also pleased that vociferous advocates are here to make sure that it stays on track.

Mr. Shestack: Well, Steve, you've fomented this. Your suggestion, really, about 3 or 4 years ago. You said, "Wow, you guys could use some centers. Some translational centers."

[Laughter]

Mr. Shestack: And I didn't know, we took it seriously. It was a good idea, thanks.

Dr. Hyman: All is well that begins well.

Great. Thank you.

(Whereupon, the IACC meeting was adjourned at 4:17 p.m.)