Medicine, we do have our Office of Research. And for us, on one aspect of looking at drugs would be residues in animals for which there would be a food product generated. And so validation is something we do an awful lot.

But at the same time when you heard mention earlier about can we get some rapid diagnostics, we also have the capability with our folks to be able to start some of that. So we do have a real time PCR that can be used, for example, for me in bone meal that we look at in dairy feed.

But it is investigatory and you'd like to go beyond that. And you'd like to do it far more quickly which means how can we collaborate with other folks who are truly state of the art to enhance this a little bit quicker because the need is there. And our folks can only do so much. So that's where there would be a real enhancement of sharing.

DR. McNEIL: Bill?

DR. SLIKKER: Well, I was just

thinking, one could argue that by the time the paper comes out and you see it in hard print, you are already behind the curve.

DR. McNEIL: Right.

DR. SLIKKER: If you are waiting for the drug to be submitted in an application, you are already behind the curve in developing technology to evaluate it.

So one way to get out in front, of course, is use the scientific conferences and scientific societies that we all belong to to help us stay in the front by attending those meetings. And I think that Frank brought this up to have more FDA opportunities to be there and see the cutting edge science and be part of it and be publishing it.

And the way is to have individual members of the Science Board help us to orchestrate symposium and other activities in conjunction with these national science societies.

And you could suggest to either

come by yourself and give a presentation or suggest individuals that would be very good to be listening to. And we can include those into our symposium topics.

So I think there are ways to do it that way that we could keep -- in front of the curve is where we need to be.

DR. PHILBERT: Yes, I'd like to echo what Bill just said in the sense that I don't think any human is really good at prognostication. It's just that a few people know what is going on in a few places before the rest of us do.

And so I'm not really sure how you operationalize that kind of thinking broadly without focusing on a specific issue.

Just on the opportunity space, there are a number of centers, not just CTSAs but there are risk science centers, there are nanotech centers, all focused on special issues that I'm sure would happily host in various venues.

And even get together to talk about issues of common interest because the FDA is frequently the first hurdle that they are going to meet -- the first real hurdle after their development of their products.

DR. CASSELL: I would like to just make a suggestion that for one of our very next meetings if it would be possible to have it on rapid diagnostics. And ask the Department of Homeland Security, DARPA, and some of the national labs that have invested hundreds of millions of dollars in issues related to detection over the last five years, six year to come and share some of that information.

Or to have, you know, ORA and CVM and also CBER, I'm thinking especially in terms of the challenges as far as detection of agents in tissues and also even for impurities as far as counterfeiting.

I still am impressed that we are not taking advantage of all the monies that

have been invested in this work. And it literally is hundreds of millions of dollars. And the FDA should be able to benefit as much as anybody from that investment.

DR. McNEIL: Okay. So we have two challenges. One is to just figure out very generically about where this Board generically should go in the next year. Just take us through the end of `09.

And then we also have to figure out somehow or other how to synthesize and be quite specific about some of these suggestions and opportunities that have been made now. And there may very well be an overlap.

In other words, the plans that we went into this meeting thinking about may get changed as a result of this discussion. But they could also be parallel activities.

So I'm wondering if we want to think about having a small subset of this Science Board. When will the other individuals be named?

DR. ALDERSON: The other nine?

DR. McNEIL: The other nine.

DR. ALDERSON: As soon as we can get them through the process.

DR. McNEIL: But when typically will that be?

DR. PEÑA: That's going to take a couple of weeks at least because we have to --

DR. McNEIL: A couple weeks? We could live with that.

DR. PEÑA: I mean it is going to take maybe several weeks because we just have to also -- the charter has to be officially renewed.

DR. McNEIL: Okay. Well one of the things I was thinking about in terms of trying to augment and be as helpful as possible to the FDA is there a small subgroup here that might work with some or all of this group here to say what very specific things could we do? Just really be very, very specific. And come to the -- either have some email traffic

between now and October or have a presentation in October. I don't know what. I'd actually rather see some email between now and October.

DR. PEÑA: I think that is actually a good approach because I believe we, at the FDA, hear very clearly that workshops are one opportunity for us to capitalize on.

What we need to be able to do is go back and evaluate all the different possibilities that are available and maybe present those at the next Science Board meeting which is in line with your thoughts.

You know we want to make sure that we are in line with the various FACA requirements and other rules that we need to abide by for these meetings.

DR. McNEIL: Right. I mean I have six pages of -- six or seven pages of unreadable notes. But Frank?

DR. TORTI: So Barbara, maybe you want a -- we could give you a job here -- just sort of lay out from those notes some, you

know, just set up some straw man suggestions for the next meeting or two or three. And then everyone can respond back.

So just as a way of getting it started, I think that will be very valuable, you know, as just a first sort of cut at how this should develop. So if you would be willing to do that --

DR. McNEIL: Well, let me -- okay. Hold on. Keep that thought.

Janet, did you want to say something?

DR. WOODCOCK: I just have a question for the Board. Would you like to hear, as we are putting together the Sentinel System?

DR. McNEIL: Yes, definitely.

DR. WOODCOCK: Okay. We can put that on the agenda at some upcoming meeting then. It will take a bit of time to discuss.

DR. McNEIL: Let me tell you, if I could, when I got together with Frank and

Norris and Carlos and what I gathered from rereading the report and just mulling things over.

And when I was trying to think about how we might proceed going forward, I had three generic areas pre this discussion. So rewind two hours.

And one of them was that we might take several of the areas that were written up as hot topics in our Science Report. And look at those, say genomic or regenerative medicine, or nanotechnology, or combination products, or imaging as a vital marker, whatever, I mean just pick some of them.

And say okay, it would be really useful if the Board and the FDA staff could hear an hour talk, no more than that, from somebody on the outside about what they think is the leading edge in that area, you know, a little bit of baby talk but then what is the leading edge.

And then that got followed by a

presentation by somebody from here about what you are doing and where you thought you wanted to go.

And then maybe in the October meeting, we could take three topics and spend two hours each with formal presentations and then questions. And then we're done for the day.

That was one thought I had. Another thought I had was, and it is a little bit implicit in something several of you said, and I actually remember who, I'd have to go back, was science is changing so fast, would it be useful to really understand how we are training our scientific reviewers.

And getting a better handle on that in terms of what they need to know, either colleges or training opportunities, the best they could be. And might you benefit from some of the collaborations that you alluded to already in terms of the training aspects of things.

And the third aspect was going back to Gail in our prior activities was do we want to continue to review that way we did NCTR and ORA this time? Brief reviews of some of the centers in that age of like CBER or CFSAN or whatever. And just have reports and presentations similar to what we heard today.

Those were my thought because Carlos said Barbara, you have to have thoughts before you get into the meeting because you are on the agenda at three o'clock for future direction. So there they are.

But now we have a number of new ones so I don't think we need to perseverate on this topic. But I think we do need some direction about how to proceed in terms of the Board's interaction with all of you with regard to the specific suggestions that were made now as well as some of the others that emerged, in part, from the Science Board Report and other discussions.

So I would like discussion on this

matter because I am integrating them. I'm not calling it matters -- matter.

DR. SLIKKER: Well, you know, I really like the idea of examining one of these sort of hot topic areas in more depth. Now only does it give us a chance to actually talk about some science but it allows us to focus on some forward-looking science.

And I there is one thing is where the edge of the field is for the universe and then where the edge of the field for FDA's interest. And I think those two things coming together would be important to look at.

DR. CASSELL: I hate to disagree with my colleague Bill but it seems to me that it might be more helpful first if we had an afternoon or a morning where we thought about what is the best mechanism for monitoring the emerging science and being able to act on it within FDA.

Maybe you have already done that and you know exactly what you want to do but,

Frank, I would be interested to know, if that is the case, or would it be important to think about mechanisms before we start talking about specific topics because as I viewed that, I mean there are ample opportunities at scientific meetings to get, you know, the latest update.

PARTICIPANT: Who is going to go?

DR. CASSELL: Well, we hope that they are going to have more resources so they can go. But anyway, that would be my bias.

DR. McNEIL: Yes, Larry?

DR. SASICH: About continued reviews if it would be helpful to the agency, I would say yes. I think it would be interesting to me and hopefully to other Board members is we have had some new laws passed that are supposed to alleviate some of the problems that were brought up in FDA Science and Mission at Risk, some of the issues that have been raised to see have we been successful, are they being implemented, are

they being implemented in the way that best serves you and in your regulatory mission.

To me that would be very worthwhile kind of feedback to see if we, as a Board, are going in the right direction or if there is something else that we should be doing.

DR. PEÑA: I think -- I'd just like to comment that a peer review process would be a task that FDA could come back to the Board with because there are many activities purported by the directors, the Bio Initiative, the NARMS Program, some of the CFSAN food activities that Dave mentioned in their comments that the Science Board could be a part of in the peer review.

And that could be something that we could prioritize and come back at the October meeting. So I think that is a very practical activity that still is in line with many of the comments from back in December. And we still have a productive meeting.

DR. McNEIL: So what was that

again?

DR. PEÑA: There were a number of comments about peer review activities by the Science Board for each of the centers. The agency could go back now, prioritize those areas of sciences that need to be peer reviewed for the next meeting and come back to the Board with the proposal.

DR. McNEIL: Okay.

DR. CASSELL: Maybe once you have -- oh, sorry.

DR. PEÑA: I would just add that that is also in line with Dr. Torti's lines on how the Board can help. There are lots of peer review self-reflection activities that we could really be benefitting from the Science Board.

DR. CASSELL: Then maybe when you have that prioritized list, you could use that as -- Barbara, your idea of selecting a hot topic and Bill's idea of, you know, an internal/external kind of presentation before

the review takes place maybe.

DR. TORTI: I don't think any of these things are mutually exclusive. The plate has gone from pretty empty to pretty full over the course of, you know, an hour and half's discussion.

So, I mean, really it is going to be not a sense of what to do over the next year but how to get in a reasonable amount of both the broad based sort of issues, you know, of understanding the techniques to understand where we are going as well as, I think, a real need that I have heard from all the center Directors of wanting to drill down on your recommendations and also give the centers an opportunity to show where they are in more detail in some of these areas.

And I think that interface between where the field is and, as Bill has pointed, where the FDA fits into that field. And where we are now in terms of the science will generate a great deal of discussion right at

that junction because I think some will say this is great, you know. You are at the cutting edge.

Some will say but you are missing X, Y, and Z. And that sort of tension will give us an opportunity to see what the proximal next steps are. And I think one of the things that I think the Board has wanted is to see what are the proximal next steps? What are steps 1, 2, and 3 to go from the recommendations to the implementation?

And so that is hard to do in a global sense. It is easier to do in a specific. So if we take your priorities for emerging science and put those together with what we are doing, we will get some answers as to where we are and where we should be going.

So I think there could be, you know, a mix of these things but both the more global and the more specific in these meetings that would be exciting, interesting, and the discussion would be very scientific at the

Science Board, which I think will generate a lot of interest around the table.

So are just some thoughts on it.

DR. McNEIL: So, Frank, in the interest of not having a meeting in October that is process driven and just, you know, let's look at all the -- that could just kill us particularly if we have new members. Let's look at the 16 things and try to array them in order of priority.

I think that wouldn't appeal to me as a way of starting off a relatively new way of doing things with an expanded Board and more meetings. I'd like to have a little more substance to the discussion.

And I'm wondering if we couldn't just arbitrarily pick something that we think it would be great -- I mean Gail put up rapid diagnostic -- but I'm just wondering if there isn't some -- and Bill was talking about what is the front of the curve for the country versus the FDA.

I'm wondering if there isn't some area that we could pick just for a couple of hours and say let's just see where we are and where the country is in thinking about that area as an important one for us.

Janet, do I see you look like you want to say something? No?

DR. WOODCOCK: I'll let Jesse.

DR. GOODMAN: Well, you know one area that might be -- that all the centers are working in and that is forward looking and that is genomics. So we could, for example, describe the things we are doing, the programs we are trying to grow, the collaborations we have. And seek input on that. That is a cross-cutting area.

If you are looking for something like that, another would be the work we are all doing with healthcare data and the beginning of the vision of the Sentinel System as Janet said. But it is early, I think, in that area.

So you might want to wait on that. But that is just one area. And I agree with -- I think Gail's issue on rapid detection technologies and certainly that also ought to include our colleagues in CDRH who, you know because one of the big issues we always see is the validation and quality of these methods. And there are experts in that.

So that's another area where we could bring FDA and outside scientists together. Not necessary a workshop but we could hear about where they see the field is going. And we could talk about how we are working to manage that. And maybe there are useful visions that could come out of that if you want to get away from the process stuff.

DR. McNEIL: What are you suggesting, Jesse?

DR. GOODMAN: Well, one --

DR. McNEIL: Either the genomics or rapid detection?

DR. GOODMAN: -- genomics across

the Board or rapid detection and diagnosis. Both to hear, you know, like Gail and I are in a lot of the same meetings. And we do -- Janet and I, for example, have interacted with DARPA. There is a lot of interesting stuff going on. We could have some presentations on that.

Probably either of those to do them right and to get the right outside people would take a day themselves. So we might want to just pick one if we were going to do that.

This doesn't get -- it becomes specific so it may be useful. It doesn't get to the much bigger picture such as Frank and Andy were talking about of you know how do we take the whole program forward. But, you know, maybe it builds that around a specific example.

DR. McNEIL: Okay, well let's go to Bernadette and then Gail. And then come back to Frank.

DR. DUNHAM: Just to pick up on

what Jesse just said, we are going to have in June two days inside FDA looking at genomics. So we are going to do basically a Genomics 101 just to invite anybody from FDA to come and learn, you know, what is genomics, how are we using it here?

And then we are going to have a second day with our breakout sessions to really delve into what you are talking about. What is regulatory science? How do we fill that gap? How do we keep genomics growing here? We have done a fabulous program with voluntary submission. And we learned an awful lot.

So this is going to continue grow. It would be nice to be able to have that. And we would probably be able to share that with you as well. And then grow from there further.

But I do think taking a couple of small things would be favorable. And I do agree, rapid diagnostics is one we all embrace.

DR. CASSELL: So we did have a sub-working group on genomics. And we collected a lot of information on what each of the centers was doing in this area. And that was just last year. Well, it hasn't been quite 12 months yet.

And I just wondered if it is time to revisit that yet. Or if we should turn to maybe a new topic that wasn't covered.

And I'm also kind of wondering, we have a dinner the night before but would it possible to start at lunchtime the day before the Science Board meeting and maybe take some of the topics that Lonnie suggested that relates to -- I've forgotten -- that innovation -- what was on your list? You had some good suggestions that could tie in to the diagnostics piece.

DR. McNEIL: So I still don't quite have what we are doing but I understand the fact that you are going to have genomics in a month for two days. And we did it a year ago.

And you will have received a lot of information from this workshop. So that might do it in terms of figuring out where you are or want to be on genomics.

DR. DUNHAM: It's going to help identify where the gaps are and how can we continue to grow forward.

DR. McNEIL: Okay, right.

DR. DUNHAM: What are the resources that we need in order to continue moving and utilizing genomics?

DR. McNEIL: So we can almost that this done for the moment at the first level?

DR. DUNHAM: It's actively being pursued, yes.

DR. McNEIL: Okay. So then we have the rapid detection and diagnosis, which was the other one. So we picked out one topic from all of the multiple suggestions you have made.

To my satisfaction, we haven't yet integrated all of the possible suggestions

that you think might be helpful. I don't think we have done that. I mean we have just picked some low-hanging fruit.

And I'm still wondering whether we want to have a few people from the Board work with you to figure out what is a more systematic way of finding out how we can be more helpful. Does that make sense?

I don't want to make work for anybody. But if that made sense, then I think that we should go ahead and do it.

One second, Jack. Larry?

DR. KESSLER: Well, very briefly, I think there are certain areas that are cross cutting. And I think the Board can be very helpful in some of those areas.

So rapid detection is one of them. It cuts across not everybody but a large number of the agencies.

There are other areas you can be very helpful in and they are going to be targeted either for one center or two centers.

And those can be very, very helpful because they will be in depth.

And I just want to echo what Jesse said, to do this right, a couple of hours is not going to be enough. You need at least a half day or a full say to really help us.

If you are going to help us identify gaps and talk about what are the regulatory issues, what are the scientific issues, which issues best fit FDA and the science we can do, and which things can you all say that is something that we need to champion elsewhere either for funding or doing academia or collaborative in a different way. And try and figure out what is what.

So I think you are going to need some more time But you need to identify separate issues. Some things cut across the agency. Genomics is one, nanotechnology is one, et cetera. But there are certain things that I need that no one else needs.

DR. McNEIL: All right. Janet And

then I'm going to ask you to come back to Jesse. And then Jack Linehan. I want to ask you how specifically to do that. But, Janet, maybe that is what you are going to say.

DR. WOODCOCK: I like rapid diagnostics as a topic. I think it is very timely. I'm not sure -- it's both science -- it's where the regulatory system is getting up against the science which, in some ways, the scientists are unwilling often, the developers to recognize what is actually need scientifically to make something robust and usable. And then they call that a regulatory problem.

So I think -- no, really -- and I think that is a very classic conundrum. And think that is worthwhile. We certainly had long discussions with DARPA and others about some of these issues.

Genomics, you know, broadly I would not support doing that just very broadly. Pharmacogenomics is a topic we could do a

week's seminar -- we could do a week's in pharmacogenomics. Done a huge amount of stuff on pharmacogenomics and so forth. So it is a really broad issue.

And I think I agree with Larry that, you know, if we are going to address something, it is going to have to be something that you can get your hands around in a day or a half a day or whatever.

So is you are going to do a topic on genomics, I would advise doing something that is manageable and also that there isn't a huge amount already of expertise at the agency that are already dealing with this.

DR. McNEIL: Jack?

DR. LINEHAN: So that segues into my comment. I think that the issues of what the Science Board can do to help you ought to be your value judgment. They ought to be adding value to your job, not adding value to our jobs so to speak.

And certainly time being of the

essence, so to speak, we shouldn't be just trying to think of things to keep the Board busy because we all have a day job, too.

But that being said, there was one issue that was cross cutting that kind of came up today and just popped into my mind. And that is on collaboration and how to build collaborations.

A CIMIT, some of you may know CIMIT. It is up at Mass General, the Center for something. An did anybody ever hear of CIMIT? You know it.

So anyway, they are holding a meeting on June 10 on collaborations, how to build collaborations, what works, what doesn't, what is the impact of technology on collaborations. And it has to do with people that are sitting across the table and other people.

And it being run by a guy by the name of John Abele, who some of you may know, who founded Boston Scientific. But his area

now of interest is collaborations. And a guy by the name of Elliott Masie, who runs a learning center and is very famous for training, how to use technology to do training and so forth.

Now something like that is attractive. He's got a very eclectic audience. So people are getting on planes to go listen to this.

Maybe that is something that would be of value here relative to the agency, particularly if you are going to start investing in technologies that are going to assist you in being more collaborative.

DR. McNEIL: I wonder -- just to kind of close off one part of this discussion that relates the Board's helping or trying to be as proactive in identifying areas as possible.

We already, I think, said we wanted to have a half day or a full day, some sort of session. I think we agreed on rapid

diagnostics. Did we?

DR. GOODMAN: Rapid detection.

DR. McNEIL: Okay, rapid detection. I'm sorry, Jesse, rapid detection. I'm in radiology so, of course, I think of diagnosis.

(Laughter.)

DR. McNEIL: Sorry, my stripes come out all the time.

So we can talk about that as something for the October meeting. And we can talk about other things as well.

But I'm wondering if two, maybe three people from this Science Board, not the new ones because they would be a little bit too green, would be willing to work with the center Directors to think about a way of concritizing the many specific suggestions that were made.

And to come back -- to have some email traffic over the summer potentially among yourselves and then with the rest of the Board. And whether we could finalize

something before October and bring it really as really a final product for final approval.

That would be much better than having -- what I don't want to do is waste October. That is my biggest fear, that we could really waste October in terms of moving forward.

So does that seem like a plan that we could get a couple of people from -- so who wants to raise -- Cathy, that's great.

Cathy, Larry? Two. Okay, Cathy and Larry. Gail, did you raise your hand for that?

DR. CASSELL: I would be willing to help but since I'm kind of rotating off and at the risk of offending everybody, I'd just like to say based on what I have heard you say, how you think we could be helpful in our deliberations in terms of how to address the many different topics that have been identified, I go back to where I started out this morning. Those areas are the very ones

you would want somebody advising your own center to be helping you with.

And you can see the difficulty, I think, in trying to ask a more heterogenous group like this to try to help solve those problems. So these are my parting words.

DR. McNEIL: Well, no they're not your parting words. You have to be here in October.

DR. CASSELL: Well, to rethink this because I just see an enormous advantage if you had that kind of system. But anyway that is what --

DR. McNEIL: We did hear an opinion on that earlier.

DR. CASSELL: I'm sorry. I know you did. Last shot.

DR. McNEIL: Well, there is nothing we can do about it.

DR. CASSELL: I understand.

DR. WOTEKI: At least in my volunteering, Barbara, part of what I'm

hearing is that you are asking for us to help sort through an agenda of work for the year coming up. And that can be topic areas that are at the broad FDA cross-cutting level. Or they may be very specific.

And Frank in his charge to us as well --

DR. McNEIL: Right.

DR. WOTEKI: -- of things that could be done, I think needs to be put into this hopper.

And what I would expect from this work over the next couple of months would be for us to come back with some ideas of what the agenda of work could be for four meetings in the coming year with the expectation as well that there would be specific requests from the Commissioner for this group to take up.

That this would be a collaborative work that we would be doing with the center Directors but there would also be --

DR. McNEIL: And Frank.

DR. WOTEKI: And Frank, I'm sorry.

And then -- but there's also always the Commissioner would be putting items on the agenda.

DR. McNEIL: Correct. So I think we could assume that the Commissioner and Frank -- for sure? -- as well as the center Directors would be putting stuff on the table. And there may be things on the table that would be culled from the report, the December report.

That on reflection seemed very salient. And that we're not going to do it perfectly. But we actually have a lot to do so we might as well -- what was the expression -- how were we building the house -- how was he building the house this morning -- design and build.

So if we take that approach and Cathy and Larry agree -- is that okay with you, Frank?

DR. TORTI: That's fine. Absolutely.

DR. McNEIL: We could do that. And then we could agree that in the fall, for sure we talk about rapid detection. And we can figure out how to work that up. That's not a -- I don't know if that is a -- and we hear this report back.

And is there anything else, Frank, that you think we might want to talk about?

DR. TORTI: Given just a little bit of time and a few emails, we can work through, you know, a year's worth of proposals.

And then, you know, the entire Board can look at that. We can get feedback from the entire Board as well as from Andy and see where, you know -- and again, I think the challenge will not be to find things to do.

The challenge will be to limit the large number of things that we should do. And it is going to be an issue of just which ones go first. So I look forward to that. And I

also thing rapid detection is a good way to start. So we can do that.

DR. McNEIL: So Cathy and Larry then have volunteered to be on this subcommittee of the Board, working with Frank and I'm happy to be involved or I would like to be involved as well along with this side of the room.

I was really impressed. I can't thank you enough for all of your comments. They were just terrific.

And it was striking to me how much overlap and synergy there was among them. So that makes me think that there really will be an opportunity for us to help.

I mean that really is the goal, to be helpful. And hopefully it will work.

Now let's see. So we have that to do. The question comes up about the four meetings a year, which presumably we will have starting in `09. And we're not going to schedule them now.

But I'd just like a show of hands in terms of how many people would like to meet during the summer -- July and August -- or would rather have the four meetings spread January to June and September to December.

So you are now voting for January to June and September to December. That's the vote. Do you prefer that over four meetings that will include one meeting in July or August? So is that clear?

If you raise your hand, you want to skip a meeting in the summer.

Oh, okay. So raise your hands if you want a meeting in the summer. Wait a minute.

(Laughter.)

DR. McNEIL: This is next -- `09. So wait a minute. Something is wrong here. I can't count. So what I sense from this, this non-definitive Florida kind of vote is that we don't have a clear consensus among this crowd because only four people voted out of eight.

So we will work on this offline then if that is okay.

Let's see. What else? Is there any other business that we need to take care of right now? We've talked about -- anything else? Comments from anybody?

(No response.)

DR. McNEIL: Well, if not, I want to thank in particular our center Directors for spending a lot of your very valuable time here A, today, and B, prior to today in terms of thinking about what is most important to you because that is very valuable to us.

And, of course, I'd like to thank all of the members of the Board and Carlos, and Norris, and Monica if she is here, and Frank.

So I guess with that we can adjourn the meeting. Thank you.

(Whereupon, the above-entitled meeting was concluded at 3:08 p.m.)