UNITED STATES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF PUBLIC HEALTH EMERGENCY PREPAREDNESS

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PRE-PROPOSAL CONFERENCE ON CELL AND RECOMBINANT-BASED PANDEMIC INFLUENZA VACCINE

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FRIDAY
MAY 20, 2005

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The pre-proposal conference met in Room 800 in the Hubert H. Humphrey Building, U.S. Department of Health and Human Services, 200 Independence Avenue, S.W., Washington, D.C., at 9:00 a.m., DAVID BECK, Contracting Officer, presiding.

PRESENT:

DAVID BECK, Contracting Officer
RODNEY CARTWRIGHT
DARRICK EARLY
TOM FUERST
BRUCE GELLIN
ROBIN ROBINSON

P-R-O-C-E-E-D-I-N-G-S

(9:05 a.m.)

MR. BECK: Good morning. My name is David Beck. I'm the Chief Contracting Officer of one of the offices here in HHS. And I'd like to welcome you to the Department of Health and Human Services.

We are here this morning to talk about the cell and recombinant-based pandemic influenza vaccine acquisition. And we are very glad that you were able to make it out in the rain. Sorry about the rain, but I have been told that when you leave here at noon, it's supposed to be sunny. So hopefully that will happen.

If we could go to the next chart, please? I wanted to give you an overview of what we will be discussing. We will start off with some introductory remarks, and I will introduce some of the participants today.

I will also tell you about the purpose of the conference. We'll also talk about the background leading up to this acquisition. Another speaker will talk about the HHS Pandemic Vaccine Program as well as the statement of work.

And then we will be talking about the mandatory criteria for eligibility. That is also

known as absolute eligibility criteria. And we have another part of HHS that refers to it as mandatory qualification criteria. But for the purposes of this RFP, we have adopted the phrase "mandatory criteria for eligibility."

I will be talking about the HHS acquisition process overall. And then we'll have questions and answers. We'll be trying to answer quite a few of the questions, you know, both questions that you submitted previously as well as questions that you submit today.

And that's the purpose of the index cards, to give you an opportunity to write out on those index cards questions that we can then pick up at a point during the conference. And we'll try to answer some of the questions off the index cards today.

We will also be talking about some of the key dates and the contact information for the acquisition as well as give you a few Web sites. The government always has to use a lot of acronyms. And so at the end of the presentation, there are a couple of acronyms spelled out.

The participants today are Dr. Bruce Gellin. He will be speaking to us later about the background for this acquisition. He's the Director of

the National Vaccine Program Office.

There's myself. There's Dr. Robin Robinson. He's the Senior Project Officer. We're both from the Office of Research and Development Coordination within the Office of Public Health Emergency Preparedness. Both the office that Robin and I are from and the office that Bruce Gellin is part of are part of the Office of the Secretary here at HHS.

Also out of the Office of Research and Development Coordination are two contract specialists. Up front here is Andre Early. And at the sign-in table where you came in was Rodney Cartwright. Andre also goes by Darrick Early. So when you've seen it in print, it's been Darrick. But he also goes by Andre.

We also have a stenographer with us today: John Mongoven. He's here primarily for my benefit so that if I misspeak today, I will have the opportunity to review my comments and we can issue a clarification or correction on the internet.

So it's best to rely on the written material that you receive on Federal BizOps, as opposed to relying on what you hear today during the next three hours.

What we plan to do, probably by Monday, is

to post a copy of today's presentation on the internet. We're also working on the next amendment to the RFP, which would include questions that we have been able to answer so far.

We have gotten over 60 questions at this point. We have probably been able to answer maybe 58 of them so far. So we will probably have at least that number with the next posting on the internet.

Let me go through a few introductory remarks. Logistics. Where you came in at the sign-in table, behind the sign-in table, there are restrooms, small restrooms. But if you also go beyond the elevators, there are some larger restrooms that are on the left-hand side as you walk out that way.

Also past the elevators, if you were to go to the right, there is a cafeteria. So if you need to get water, you know, for drinking, there is bottled water in that cafeteria. Also, if you make your way past the cash registers, there is a water fountain where you can get cups of water. So you don't necessarily have to buy the bottled water since they have a fountain there as well.

With the questions and answers, again, I would encourage you that as we go through the presentation, if you have some burning questions that

you want to jot down on the index cards, about halfway through the presentation, I'll have somebody collect whatever questions you have written out so far. And then Robin and I will try to answer some of those questions today closer to the end of the presentation.

There will be another opportunity when you are leaving. If you have additional questions on the index cards, you can drop those off to us as well. And we will try to answer those and post them on the internet.

A few more remarks about the purpose of the conference. The purpose today is to discuss and hopefully clarify the RFP that is entitled Cell and Recombinant-Based Pandemic Influenza Vaccine.

We had issued the RFP on April the 29th. And we want to have this opportunity to talk about the background of the RFP and the purpose of the solicitation as well as answer questions from the potential offerors.

At this point, I will turn over the presentation to Dr. Bruce Gellin. And after him will follow Dr. Robin Robinson.

DR. GELLIN: Thanks, David. Thanks to everybody for coming and paying attention to this priority of ours.

I'm not going to spend much time. I'm going to tell you what you already know. But this is obviously a big deal and very important to us. It's important to us here. It's important to the Secretary. It is important to the whole department. It is important to Congress, the President, and the world.

I just got back yesterday from the World Health Assembly. You may have seen some reports that came from it. But I will say that I haven't been to one of these things before, which is an interesting show for a lot of reasons.

But if there was a theme at the World Health Assembly -- and this is the annual meeting of the ministers of health from all nations around the world -- it was pandemic influenza. It was in the Secretary's remarks. It was in the director general's remarks.

There were three formal side meetings: one hosted by the Secretary, one hosted by the department with WHO, and one hosted by Health Canada, to give you updates. Some of that you have read about.

There is some concern that there may be some evolution, particularly in Vietnam. I think that

still is speculative, but it doesn't keep it from being in the headlines. I think that just reinforces the importance of what we're doing here.

A lot of the discussion that is in the press is focused on the H5N1 virus. We also know that it is the nature of this virus to do things that we worry about. And so our pandemic preparedness, which this represents, is really a broad preparedness. And the vaccine piece is just one piece of what you can imagine is a lot of moving parts.

The department put out last summer our draft of the pandemic influenza preparedness response plan. Many of you had an opportunity to comment on that. Some of those comments are posted on our Web site. We are in the process of revising that, addressing many of the comments that we received, and also filling in some of the gaps. That will happen in the near future.

There is obviously a large emphasis on vaccines and the importance of vaccines and response and, hence, why these particular activities, the one of which this is one piece, are really so important to the department.

You also know -- and I think this has been an interesting couple of years for influenza. I think

you have read the public opinion polls. And now for the first time, probably the majority of Americans could name an influenza vaccine company based on a lot of recent experience. Hopefully they will be able to name others in the near future.

We see pandemic preparedness and our annual influenza response as related. I think that is so the things that we are focusing on for the pandemic are going to help us in the inter-pandemic period as well. And so with that in mind, I don't want to dwell on this.

You are aware of a number of different things that we have been doing to secure influenza vaccine production, developing pandemic-like vaccines that we do, HHS does, NIH does as well.

The longer-term goal is to expand the production capacity, expand the marketplace, expand the demand, and to be able to have enough vaccine in any situation for those who need it, both nationally and internationally.

As you can imagine, there is a lot of discussion, particularly in international circles, about the latter because there may not be a starker example of the haves and the have nots in consideration of the pandemic.

While, as David said, we all work for the Secretary and everybody at HHS works for the Secretary, we really work for the Secretary. And I will tell you that Secretary Leavitt has picked up where Secretary Thompson left off as far as his engagement of this.

We meet with him or his chief of staff daily to discuss influenza. And it could be what is due in Vietnam or what are our long-range goals. So I will tell you that there is a high level of engagement.

I just want to read you a couple of sort of the sound bites from the World Health Assembly from Secretary Leavitt's speech. And I think that this speaks a lot to what we are all doing. "The pandemic flu is an urgent health challenge, and pandemic preparedness is our best response. The more we are prepared now, the more lives we will save in the event of a pandemic."

The part that I think is the one that got the most attention in the past couple of days in Geneva was that "There is a time in the life of every problem when it's big enough to see and small enough to solve. For flu preparedness, the time is now." I think that is sort of why we are here now.

I will end my very brief remarks. Again, thank you all for coming. But I do have a question. And maybe I'll pose it now, and, David, you can tell us. You maybe can answer it now or subsequently.

There are a lot of familiar faces and some new faces, but there are a lot of conversations about influenza, both formal and informal, structured and unstructured, e-mail and telephone. So I guess some guidance -- maybe it's just for me, but I think for many of us, it might be best to hear, how do we make sure that we have appropriate conversations about the things that are important to us in the setting of a procurement to make sure that we are all acting in a way that is not going to be problematic for us later? So I'll just pose that, and maybe you will answer that along the way.

I think it is important because in conversations I've had with many of you, they start out by saying, "Well, you know there is an ongoing thing. We can't talk about this."

So how we best structure our discussions in whatever context they may be, at meetings or personal conversations or everywhere in between, to make sure that we are all on the same page and all doing the right thing.

Again, thank you for coming. And I look forward to our ongoing conversations.

DR. ROBINSON: Thank you.

I am Robin Robinson from HHS. Over the past year, we have acted on this program for pandemic influenza vaccines. There was a contract awarded last September for the first commercial-scale manufacturing of an H5N1 vaccine. That was successful. And that is being kept as a bulk. And we will move forward with more efforts there.

Also, we awarded a contract last September to secure year-round egg supply for influenza vaccine manufacturing, primarily for the pandemic but also in cases of influenza seasonal vaccine shortages.

Third, we have awarded a contract that is the predecessor of the present RFP on cell-based vaccine for advanced development of that vaccine towards licensure with a commitment to a U.S.-based manufacturing facility.

What we are doing now with this RFP is we have expanded that somewhat to include not only cell-based but recombinant-based influenza vaccines. The idea here is that we are looking not only for second generation but third generation and moving down the road and to move that forward.

Many of you have been engaged with the NIH, with grants and contracts. And you're moving forward. And we would like to pick those up and move those towards licensure and, again, with the hope of having U.S. facilities.

In the RFP, we have explained how that mechanism will work and certainly will answer questions that were already submitted and that will be submitted today that will clarify what does that mean, commitment to U.S.-based manufacturing and licensure towards the FDA?

In conjunction with this RFP, there are two other RFPs in which the synopses were posted earlier this year. One will be for improved influenza vaccine manufacturing to increase product yield and decrease the time that it takes to make the vaccine.

The last one is one that we are engaged with the NIH on, and that is an antigen-sparing influenza vaccine so that we can stretch current capacity for a pandemic event, both with adjuvants, medical devices, or administration. So be looking on the internet, on BizOps for those RFPs to be issued. They should be issued fairly soon, hopefully by the end of next month.

The statement of work for this RFP

includes the following. And for those since you're in the vaccine-manufacturing industry, you understand when I say a product development plan. That goes from the very beginning when the ideas come for the vaccine and to actually start to characterize it and honing in on what the vaccine should be, doing preclinical testing, toxicology, moving that into an IND application. And we're asking an IND application for the FDA for U.S. licensure and going through the clinical development plan for clinical lot manufacturing; also the clinical testing; and validation of your equipment facilities, the processes; and, finally, moving toward licensure by submission of a BLA.

So that is the entire overall overview. We would like to see that plan. That happens to be the milestone one that will be due in the first six months.

The second one is a clinical and regulatory plan. And that can be expanded to really get to the nuts and bolts of what you are going to do and what you are asking us to fund clinical protocols, the clinical lot manufacturing, and the regulatory plan to support that, and how you will get through the various phases, phase I through phase III, toward

licensure and specifically within the three to five years of the contract term itself.

The next one is a domestic facility plan. Since we are asking you to commit in writing that you will have a U.S.-based manufacturing facility, how are you going to do it? And what is the actual plan to do it, time lines, where it is going to be located, et cetera? Do you have partnerships with other companies or contract manufacturing should be put in there in great detail?

The next point is product feasibility plans. So once you have your product development plan, you're going to make a facility in the United States, is it going to work? This is a place where we like to see you address the limitations to different approaches. And you basically have a decision tree. If you go down this route, what are the problems? And how are you going to overcome those problems?

Something that is new in this RFP, as compared to the previous one, is that we are asking you to actually make and start a pandemic vaccine without a program. So that we are asking you to in your IND submit to the FDA to have a plan to make an H5N1 vaccine or another pandemic-like virus vaccine and to move it through safety and immunogenicity

studies.

The reason for this is that we need more data on these vaccines. There's maybe only a handful now of clinical studies that have actually occurred and are ongoing right now. And so we are trying to stimulate that so we can understand these vaccines better because, as those of you who have worked with some of these viruses, we understand they are a little different from some of the human viruses. And so we want you to actually experience it.

The next one is contractor-defined milestones. This is what you are asking us to do, to fund. And it goes from the IND submission all the way through BLA submission. It can include clinical manufacturing and clinical studies, scale-up development, and validation of your facility, processes, equipment, and so forth. And so this you should enumerate in a number of steps and what you are asking us to fund, but be sure and tell us what the overall program is and what you are going to do yourselves.

Finally, the technical progress reports on a monthly or periodically. At the end of the project, the terms of the contract, it will be a FON report.

The mandatory criteria are here. First, there is a firm commitment in writing that you will establish a U.S. vaccine-manufacturing facility. Again, that can be the company itself, a partner of the company, or a contract manufacturing organization.

If you are unable to do this, your proposal will not even be reviewed. So we want to stress this, that you have to up front say that you're going to do it and provide the feasibility that you can do it and supportive documentation. And David may have more to say about that later also.

The next is product licensure. The purpose of this is to move the technology such that we can have cell and recombinant-based influenza vaccines and move these towards licensure. So it's not a research goal in itself. It's to move the research and the development toward licensure, that there be a product there. That licensure would be a trivalent seasonal vaccine and will need to compare with the licensed vaccines at present.

And then the master plans and time lines for this licensure. So you need to be able to explain how you are going to move toward licensure and that we actually have a milestone, one of the milestones, we actually had to do that.

Next slide. How are we going to evaluate these? Well, the panel will be assembled of individuals that have experience with vaccines, specifically influenza vaccines, from the government and elsewhere. And the five criteria of methodology and approach, facilities, organizational experience, personnel, and time line to the licensure. If you say the one that gets the highest overall weight is a methodology and approach.

Since this is cell and recombinant, we want you to tell us about the cell line, its origin, its history, were there any problems with it in your encounters with the FDA or other regulatory agencies. There are limitations and to actually say that to say that and how you're going to overcome those limitation and then to not mention it because that would show if you did put it in there, that you may not understand the problem.

Your recombinant system, to explain the recombinant system in very great detail, what plasmids, what vectors, or whatever you're using, and its genesis and where it is at this point. If you have previous results, whether it be publications or other data that you would like to share with us, those data are kept confidential and are not shared outside

of the technical panel.

And so we would ask for you to put preliminary results in there from the clinical results, from manufacturing, characterization of your vaccine product, and any other data that you would like to provide there. That would be in your appendices. You need to talk about it in general terms in an overview in your proposal, but if you want us to look at those data, put it in the appendices.

We're giving you quite a large amount of pages to actually put in the appendices. So, you know, if you want us to see it, put it there.

The other thing is that if you have any comparisons with the licensed vaccine from your clinical trials, if you're already at clinical trial, please put it in there also. We want to see that.

And then, finally, why are you using the cell reconnaissance? And why is it better? And if there are limitations, what are they? Tell us about it.

So that consumes most of the methodology and approach. The facilities, basically what facilities will be used for the project; where they are located; and if they are at different locations, then how they are going to be integrated together.

Organizational experience. This basically says, how are you going to manage this, especially if you are a consortium or you have a corporate partner? Who is going to do what? And who is going to be in charge of the reporting periods? And how is it actually going to work? And so you may want to have an organizational tree and then explain that tree, actually how it will work.

Next is the personnel. The key people from your principal investigator to your scientists to your clinical folks that are involved with this from your regulatory end and your quality assurance and quality control, that they need to be there.

List them in your proposal, your appendices. If you want us to see their CVs, put it there. And that's what we would recommend to do there.

We would recommend that you have people who have actually worked on the vaccines. If you're using a CMO or CRO, you will need to put those people, the key people in those organizations, in your proposal, in the CVs in the appendices.

Finally, the time line to licensure since everyone is at a deafened place in the development and how and what your real plan would be, charts and

milestone events, how you will move toward licensure.

I will turn it over to Dave to explain how our RFPs work and the procurement process.

MR. BECK: Thanks very much, Robin.

One other introduction that I neglected at the outset, down front here, next to Robin, is Dr. Tom Fuerst, Robin's boss. So we are glad he was able to join us this morning as well.

We are moving along pretty well in the presentation. However, once we get into the question and answer period, I'm not sure if we will take a break. So you are welcome at any point to go ahead and quietly excuse yourself from the room and then come back. Again, you shouldn't miss anything since it will all be on the Web site Monday anyways.

But there is still a possibility and if we are making good progress, maybe partway through the question and answer part of the morning, perhaps we will take a short break.

I am going to try and go through about another five slides. And then we will give an opportunity for you to turn in any of the questions that you have written on the index cards. That will give us an opportunity, then, to sort through those questions. And Robin will have an opportunity to

answer some of them. And I will answer some of the others.

If we don't answer all of the questions that are on the index cards today -- and I kind of doubt that we will be able to answer everything because there may be some that we will want to do some research on before we give you an answer, but we will try to get to all of those questions as quickly as we can and then post the answers on the internet.

Bruce had brought up a question about your contact with any of us between now and the time that a contract or contracts are awarded. We would ask that if you have any questions about the acquisition, about the RFP, that you direct them to Andre Early as the primary point of contact or to me as the secondary point of contact.

We would ask that you refrain from addressing questions to Robin Robinson because as the project officer, he needs to maintain some distance from the potential offerors during this stage of the acquisition.

If you have information that is sort of on the general topic of cell and recombinant-based pandemic influenza vaccines, you know, you may be wanting to talk with Bruce Gellin about things of a

general nature. That's fine, but we would ask that any specific questions with respect to the RFP or for this particular acquisition, please direct those to the contract specialists or to me.

There is some language in the RFP -- I think it's in section L of the RFP -- that basically indicates that we have a preference for having the contact through the contract specialists during the time that the RFP is out and before we make contract award.

Okay. This chart basically gives you an overview of our acquisition process. So some of the items that I will talk about during the next several charts have to do with what is called a request for contracts. That is an internal HHS document. I'll maybe have a few more comments about that on the next slide, but we will be talking about the request for contracts, which leads up to a synopsis which had appeared in March.

We will also talk about the RFP that was issued, then what happens on June 21st when you submit your proposals. We will talk a little bit about that and about the proposal evaluation that follows.

I will also mention a little bit about the termination that we made, which is called a

determination of competitive range. And then I will have a few comments about the negotiation process and source selection and contract award and then the last phase, which is contract administration and contract management.

Internally, we use a request for contracts here at HHS. Some other federal agencies call it a procurement request. That document basically lays out the statement of work. It identifies the evaluation factors and provides a budget estimate. And that is signed off internally.

And then that is what is used to kick off the synopsis that had appeared in the middle of the -- I think it was the middle of March. Maybe it was earlier than that, but around the middle of March, we had a synopsis about this acquisition as well as two other acquisitions. So that was what had led up to that.

Then we were a little bit late in terms of getting out our RFP. We had hoped to be able to issue it at the beginning of April, but we ended up issuing it at the end of April. It just took longer for us to do the editing that we needed to have done on it.

In that request for proposals, there is a section that spells out the supplies and the services

or costs. And it basically lays out a table for the line items that are going to be acquired under the acquisition. Then that is followed by a description or specification section, which contains the statement of work for this acquisition.

Then we also have sections on deliverables or performance under the contract. We have information in there on payment terms. We have many other contract clauses. For example, one of the clauses in there is for a subcontracting plan.

So if you happen to be an offeror that is other than a small business, you would be expected to put together a subcontracting plan that we would negotiate and include in the contract when it would be awarded.

The subcontracting plan is basically one tool that is used to encourage small business participation. So we will either try to get small business participation as prime contractors or, if not, then we will encourage small business participation at the subcontract level. And that includes small businesses, small disadvantaged businesses, women-owned businesses, historically black colleges and universities, veteran-owned businesses, and some additional categories.

Then we also have a section of the RFP covering representations and certifications. And the government has moved to some online representations and certifications. So there is a Web site that is provided for that.

Then we have a very important section in the RFP called "Instructions to Offerors." That is section L. So I would encourage you to pay particular attention to that as you are preparing the proposals as well as pay very close attention to section M on the evaluation factors for awards. And I will have a few more things to say about the evaluation factors a little bit later.

Another feature that we have turned on on the Web site, fedbizopps, is called the interested vendor list. When we issued the first amendment to this RFP, we turned on a feature that enables companies to basically sign up and indicate that they are interested in this acquisition. This is one of the tools that enables people to then view that list and perhaps get in touch with one another for the purpose of subcontracting opportunities.

So next time you have a chance to check the fedbizopps Web site, you might want to take a look at that feature. It's something that I have been

encouraging our staff to try to make available for our acquisitions.

Okay. Again, we have released the RFP. A very important date is the proposal submission date, which will be June the 21st. And the time on June the 21st will be 2:00 p.m. So don't think that it's close of business. It's 2:00 p.m. on that date.

Okay. After we have received your proposals, we will basically go through those proposals and make sure that they have met the minimum criteria or mandatory criteria for eligibility. And those that have met that mandatory criteria for eligibility will then proceed into technical evaluation using a team that we will put together.

In addition to the technical evaluation occurring somewhat simultaneous with the technical evaluation, we will begin review of your business proposal, including the cost elements and some of the other factors.

In section M of the RFP, some of the factors that are mentioned are past performance. So that is something that we will be looking at concurrent with the technical evaluation. Also, small disadvantaged business participation, there is pretty lengthy information in section M about that evaluation

factor. And that is sort of a subset of the subcontracting plan. One of the evaluation factors that we consider is small disadvantaged business participation.

And then two other evaluation factors that are sort of on a pass/fail basis have to do with use of human subjects, such as during your clinical trials; and then also animal welfare. We want to make certain that the contractor or contractors who are selected have acceptable approaches to both of those last two topics.

After we have done both the technical evaluation and the evaluation of these other factors, then we will try to aggregate those results and I will take a look at those results to then determine who I believe are the offerors who are in the competitive range. In other words, who are the offerors who have a likelihood of getting an award out of this acquisition?

At the current time, we don't know how many offers we are going to get, but we do at some point have to narrow that range down to those that we believe are likely to get a contract award. At that stage, then we will notify those offerors that are outside of the competitive range. So that's one of

the opportunities to notify the unsuccessful offerors.

When we provide that notice, we will also provide the opportunity for you to choose either a pre-award debriefing if you would like a pre-award debriefing or you may wish to wait and ask later for a post-award debriefing or you may not want to ask for a debriefing at all. That is fine as well.

If you ask for a pre-award debriefing, then we are limited in terms of what we can tell you. We can't tell you about the other offerors that remain in the competitive range, but if you were to ask for a post-award debriefing, then we would have additional information later in terms of who the award had gone to.

Even if you ask for the pre-award debriefing, there is a later point in the process, after contract award, when you can get the information about who was awarded the contract or contracts.

During the negotiation phase, after we have established who is in the competitive range, then we will come up with some questions that have resulted from our technical evaluation and also from our evaluation of other aspects of the business proposal and the cost proposal, maybe questions of past performance.

So we will put together many of the questions that have come out of the evaluation. We will communicate those questions to you to try to give you enough time to consider our questions.

Also, with many of our acquisitions, we will schedule a pre-award site visit. I don't know how likely that is with this particular acquisition because in many cases, there will not be the manufacturing facilities already set up for use under this since we are at a much earlier stage. So at the moment, I cannot predict whether or not pre-award site visits would be very likely, but it is something that we reserve the right to schedule: a pre-award site visit.

We also in many cases if we are dealing with a company that is very new will have a pre-award site visit to make sure that they have adequate facilities and adequate accounting to be able to carry out the contract.

We also are likely since the RFP talks about a cost reimbursement arrangement to schedule an audit using the services of the Defense Contract Audit Agency. They would be basically coming out after they have looked at your cost proposal. They would be coming out and trying to verify some of the

information that you had provided in your cost proposal. For example, you might have certain indirect cost rates that you have included in your proposal. And they may want to come out and do an audit to try to verify those rates.

Under cost reimbursement contracting, we do try to identify what are going to be the billing rates during the contract performance. And those are the billing rates, for example, for indirect costs.

We need at the outset to be able to establish that we are entering into a cost that is fair and reasonable to both the government and to the contractor. And so we need the assistance from the audit agency to help us arrive at a fair and reasonable cost. And we will try, to the best of our ability, to work with you in terms of scheduling any of these on-site reviews.

With the schedule that we have laid out, it would have the proposals coming in June 21st. Our goal for awarding the contract or contracts is October. That was identified in the RFP.

So it's somewhat likely that if we're going to do an audit, mid to late July would probably be the earliest period that we would be doing an audit. You know, it could be that we would be

scheduling that sometime in August. And if we run into delays, if we have more proposals than we would anticipate, then it could be a little bit later. But that's pretty much the best time frame that I can estimate at this point.

Once we have gotten some information back from the auditors in terms of the costs that have been proposed and once we have given you the opportunity to consider the questions that we have posed to you, we will then enter into some discussions or negotiations, where we can get some answers from you in terms of those questions and we also can indicate our position with respect to certain issues in the acquisition.

Maybe we have had some questions about your costs in some areas and didn't understand or didn't understand the rationale for costs being what they were. So it gives us an opportunity to have some exchange of viewpoints on your proposal.

Then at some point, we will call a cutoff to those discussions or negotiations. And we will ask you to revise your proposal. And this will be referred to as the final proposal revision. And we will give you a deadline by which you have to submit that final proposal revision.

Then we will do some additional analysis

or evaluation of that final proposal revision. And we will make the source selection. You know, we will decide who the contractor contracts will go to. And at that point, then we will award the contract or in this case perhaps multiple contracts.

After contract award, then we have the contract administration phase, a very important phase and in this case a phase that will last three to five years. So we will be having both project staff and contracting staff involved in working with you during contract administration and management of the acquisition.

Another aspect of this acquisition is that it's incrementally funded. We have the funding spread out over more than one fiscal year. And it's a little bit difficult for us to anticipate since we don't know if we are going to be making one contract award or maybe more than one contract award.

You know, it's a little bit difficult for us to anticipate how much funding will be available up front for each contract. But after we have received proposals, we will be able to get a better idea of how that funding may be spread over the contract or contracts, though, that we have in mind. And we will be able to give you a better indication, perhaps

during discussions or negotiations, as to how much funding is going to be available in the first fiscal year.

Okay. So we are about ready, then, to go into the question and answer phase of our session. We had questions, again, that you had submitted. We had asked for questions to be submitted by, I think it was, May the 10th.

Unfortunately, we gave you a pretty short deadline because we needed to have some time to review those questions and research the answers. We have gotten some questions after that deadline.

And we do encourage you that as you identify something else that you think you need to ask a question about, please send that to us. Even though we had that initial deadline, we are still open to additional questions. And we will be open to additional questions until June 21st at 2:00 p.m. and perhaps even after that point.

Those initial questions we have some answers today that we will be discussing this morning. And we will also be posting those answers on the Web site.

And then, again, today is the opportunity. If you have questions written out on index cards, we

will be collecting those in a few minutes. And then after this conference, if you have questions -- and I know that many of the answers that we give you might lead to more questions -- simply send those to us.

We will be posting, as I said, the questions that we have already provided answers to or developed answers to. You know, we will try to post those by Monday. We will have other questions that we will try to group them and have another posting, maybe about a week after that. And then if there is a need to, we will have posting of additional questions and answers as the acquisition progresses toward June the 21st.

Before we launch into the question and answer phase dealing with the substantive questions, does anybody have a question of more of a logistical nature or administrative nature about how we are going to proceed for the next two hours? We'll open it up just in case there is some burning question. Yes?

PARTICIPANT: I had one about the conflict of the page numbers. Is that a question for timing now or later?

MR. BECK: You could put that about the page number. Yes, if you could jot that on an index card, yes, that would be very helpful. You know,

unfortunately, even though we spent hours and hours, you know, reviewing the RFP before we sent it out, you know, we still missed a few things. And it's very helpful with questions that you had provided about that.

Other questions of an administrative nature, logistical nature?

(No response.)

MR. BECK: Okay. Rodney is in the back of the room. Those of you who have written out questions on your index card, if you can pass them toward the center aisle, then Rodney will come down and collect some of those questions.

Once he collects those index cards, he will try to sort them out. And Robin will answer some of those later. And then I will answer some of the other ones. And if you need more index cards, let Rodney know, and Rodney can bring some more index cards in, I think.

Any other questions that people have written out already? Yes?

PARTICIPANT: Just one question. Post-conference questions that you may have --

MR. BECK: Yes?

PARTICIPANT: -- do they get sent to Mr.

Early?

MR. BECK: Yes, please. Yes. Please send post-conference questions also to Mr. Early. His contact information is near the end of this briefing.

PARTICIPANT: Okay.

MR. BECK: I guess Rodney has all of the initial questions. So we'll let Rodney sort those out.

Oh, a few more questions here. And, again, if we don't have a chance to get your questions at this break, then at the end of the session, if you have additional questions on the index cards, you can leave those with Rodney on your way out.

There may be one more up here. Okay. That's excellent. So what I will do is I will let Robin come back up. And he will spend some time going through some of the questions that you had submitted by May the 10th and maybe a few days after that date.

DR. ROBINSON: Question number 4 of 61 that had been submitted previously, are the clinical sites outside of the United States excluded from all phases of clinical development? The answer to that is that the clinical development plan may include foreign sites, but the pivotal clinical trials really do need to be in the United States for FDA licensure.

Certainly we want you to be aggressive and to use sites all over the world that you have engaged before or in the future, but the clinical trials that are really for the pivotal trials -- and, as far as we know, the FDA is going to ask for cell and recombinant, that an efficacy study be done and that they be conducted in the United States to support your BLA.

Question 5, a candidate vaccine from a non-U.S. site for use in clinical trials be employed in the development plan. The answer is yes. If you have facilities that are making the vaccine in another country and they can be used during the clinical development period for clinical studies and at the end when your facility is licensed, then we would love to see that material also go into clinical trials here in the United States.

Is it your expectation the offeror be in a position to submit a BLA within the three to five-year period covered by this RFP? We would hope that everyone was in the stage that that could happen, but we certainly realize that you are in different stages of development for your vaccine products.

And if it is within that period of time, the three to five-year period, window that you are

going to be submitting a BLA, then that is great. But we don't expect you to do things that are really impossible. And if you are in phase I right now, you may not be there in five years. So we would rather you be very rational about this and to project what really can be done.

Question 23, what will determine the length of the contract? Again, that depends on what stage of development you are for your product. So that's, again, driven by your contract, driven milestones.

The next question is, is the target capacity for the commercial facility expected to be 150 million doses or 300 million doses? For this RFP, we ask that a minimum threshold be 150 million doses of monovalent influenza vaccine over a year.

Next question, should offerors also indicate whether they can achieve the capacity for up to 600 million doses? And the answer to that is simply whatever you think your surge capacity can be, you should put that in there, but you also need to provide the support of why you think that is true.

And we ask that to make a level playing field, that you compare it to a 15-microgram dose of hemagglutinin in the licensed vaccines now. So

whatever way you can calculate that as equivalent, then you need to do that to calculate your entire surge capacity.

The next question has to do with biocontainment. The BSL-2 requirement on page 6, does this apply to the production of recombinant hemagglutinin? This appears to be overkill since we and presumably others do not work with live viruses.

The answer is that BSL containment levels should be abided by those that are provided by CDC, WHO, and USDA. If you are not dealing with a live virus and you are having your genes synthesized and so forth, then you are not going to run into that. But you will at some point be dealing with virus at some point, assays or in some of your animal studies and challenge animal studies. So abide by the most recent guidelines.

I know that the WHO has an interim guideline for avian influenza vaccine manufacturing. Those are being revised now. So probably by the time that before you submit your proposals, you might look for a revision of those to be posted by the WHO. Basically they will say that you have to have BSL-2+ viral containment facilities for direct contact with the live viruses.

Next question, can you please confirm the BSL-2+ requirement will apply only to those parts of the manufacturing process where live or otherwise potentially dangerous viral materials are involved?

The answer is yes. And those areas that we see, of course, will be the virus C production areas, upstream processing, some areas of downstream processing, and the QC test labs where they will actually be working with virus need to be BSL-2+ or even 3 levels of containment depending on the virus strain and the specific characteristics of your virus reassortments.

Next question, can you be more specific about what types of items might be appropriate for milestone 6, contractor-defined milestones? As I pointed out earlier, these are activities that can go from the IND submission all the way through BLA submission and your clinical manufacturing; clinical studies; the validation of your facilities, systems, equipment; your process; your product assays; the facility design itself; and, of course, even the BLA licensure, but we will not consider the costs for actually building the facility. We will not consider costs for the HVAC systems or the WFI water supplies. Those would be consistent with the facility that could

be used for other things. And I will address another question I'm on about what equipment would we consider.

Next question, does the definition of recombinant DNA-based influenza include vaccines based on DNA? And how does the DHSS, which is what was put in here, envision purchasing vaccines in these two scenarios?

Yes, plasmid-derived or vector-derived influenza vaccines will be considered. So DNA vaccines are within the scope of this provided that they can accomplish these things.

Again, this is for advanced development. If you are at a point where you are still doing animal studies and you don't foresee being far enough long by the time you submit the proposal, then we recommend that you still seek funding from the NIH. They certainly are considering those proposals.

And, again, if you have a recombinant DNA, as with any other type of influenza vaccine we are looking for, we want plans for both inter-pandemic and pandemic vaccines.

Next question, does the DHS envision annual inter-pandemic vaccine from the facility being sold on the free market or by means of state

contracts? Certainly inter-pandemic vaccines, that is a decision is for each company to decide whether they want to market it or not.

The scope of this RFP is not acquisition of the vaccine. It's to facilitate the development and licensure of recombinant and cell-based vaccines.

Next question is, will the government guarantee the purchase of any specific quantity of vaccine on an annual basis so as to provide less risk to the contractor in maintaining warm-based manufacturing capabilities? This again is not in scope with this RFP. And so we wouldn't consider that here.

Can you confirm that the definition of 150 million search capacity reflects the number of administered doses and not the population coverage; i.e., 150 million doses equals 75 million such that given prime plus boost construction?

The answer is that we envision that two doses will be needed for pandemic vaccine, as soon with inter-pandemic vaccine in children who have naive immune systems. That's the whole point of a pandemic, is that the entire world population will be naive for pandemic strains.

Next is, it is generally accepted that a

pandemic vaccine may require an adjuvant to achieve significant immunogenicity. Can you confirm that a cell or recombinant-based vaccine containing an adjuvant will be eligible for this RFP?

The answer is not in this RFP. There is another RFP, 0508, antigen-sparing, that will be posted I spoke of earlier. That would be the appropriate place for those proposals.

It is expected that the offeror consults in detail on the development plan with the FDA prior to response to the RFP or should that occur subsequently?

Preferably before the proposal is submitted so that you will have some guidance, in a pre-IND meeting or if you already have an IND filed with the FDA so you can get counsel from them, but certainly it is not a requirement.

Would DHSS facilitate and/or attend future interactions with the FDA? This is a good question. In this program and with other HHS agencies, we do not intercede on behalf of the contractors with the FDA, but we may attend the contractors' meeting with FDA provided that both the contractor and the FDA agree to that.

We may provide guidance to you as we can

with what FDA has already said about this, but we recommend that you talk directly to the FDA. If we think that there is some area in your regulatory plan that you should go to the FDA, we think that we would prod you to do that, but, you know, they're a different agency within HHS. We stay at arm's length so that we don't have a problem there.

The next question, can a proposal be submitted for both a cell and recombinant-based approach, either separate or combined? We would like you to put your best vaccine candidate out for us to review and to fund. If you want to take the chance of submitting them, submit them separately, but, again, we would like to see your very best one.

The next question is about U.S. vaccine manufacturing. And the question talks about the criteria here. And this says, "Please suggest what would be the appropriate content of the written state required to meet the criteria."

We won't write the statement for you, but what we would think that you would need to have in that is in the commitment letter is to say location; the feasibility; if you have partners, who they are and the relationship that you have with them; facility description; and the strategic business plan for

construction and product licensure, including both milestones and time lines. So, I mean, if you're going to go to that extent, you have a fairly big investment already there.

David, do you want to take the last one?

MR. BECK: Robin was just talking about the U.S. vaccine-manufacturing facility and, you know, about a firm written commitment. I would just remind everybody that offerors should ensure that when they're submitting a proposal, that it's submitted by somebody who has authority to bind the company. So if you're having a proposal submitted by somebody with the authority to bind the company, that helps in establishing the firm written commitment.

For question 10 having to do with -- we had several questions relating to cost. And the question was, what is the period included for cost recovery, such as for costs accumulated specific to a deliverable, before or after the contract date? Since this is a cost reimbursement contract, there is a requirement that all direct costs that are charged to the contract must occur during the contract period of performance. So that's the basically the answer that we are able to provide for that question.

The next question was, what is the

intention of HHS regarding the potential number and monetary value of contracts awarded? We have a few references here to sections of RFP where it's talking about the fact that HHS may award one or multiple contracts under the solicitation.

You know, part of that question talks about the monetary value of the contract. And we would point out that in April, I think it was maybe at the beginning of April, we had announced that HHS had awarded out of the Centers for Disease Control and Prevention a contract. And we've given the contract number here. It's 200-2005-11758. And that value of that contract was 97 million to Sanofi Pasteur, located in Swiftwater, Pennsylvania. And that was for an RFP that required similar services.

However, again, since we don't know exactly what you are going to propose, we don't know at this point how many contracts we'll award, it is difficult for us to predict the dollar value. So any contracts awarded under this RFP might or might not be similar in dollar amount to what we awarded in April. But at least the April award gives you some idea of what we had awarded for something that was similar.

Okay. Question 13 -- and, by the way, we sort of numbered these questions as we got them, but

for the purposes of this presentation, we have tried to regroup them into sort of similar topics.

Question 13 had to do with whether or not additional funds can be added after the contract begins based on the plans that were submitted for the milestones. And it points out that detailed plan preparation during the first year of the contract may uncover additional costs that were not predicted during the proposal period.

Certainly that would be a possibility for how things might progress, but we are requiring that offerors submit their total proposed costs for the entire requirement at the time of proposal submission.

Any unforeseen or unanticipated costs are going to be governed by the limitation of cost clause or the limitation of funds clause, which basically establishes a limit for the estimated cost.

And that limit limits the government's obligation. Our obligation is only for the funds that are provided in the contract at the time. And then any increase to this funding level has to be approved by the HHS contracting officer, in this case me.

So during contract performance, if you anticipated that the estimated cost was not going to be enough to carry out what the contract required,

there is an obligation under the limitation of cost clause or limitation of funds clause for you to notify us when you envision that there will be a need for additional funds.

That, then, gives us the opportunity to decide whether or not we want to try to add additional funds or maybe try to modify the contract to reduce its scope to stay within the funding.

Question 18 has to do with what is the detail that is required in the RFP for the cost of the subcontractors. Are letters of commitment appropriate at this stage or can the detailed costing structure; for example, the CMO, which might be costs by management objective perhaps, be provided at a later stage?

Basically, the estimated costs for all the subcontractors need to be proposed under the solicitation, must be included in the same level of detail as outlined in section J at the time of proposal submission.

So we are looking for the same level of detail in estimating the costs of your subcontract work as we are looking for work at the prime contract level.

Again, the government needs to arrive at

an estimated cost of the contract that is considered fair and reasonable. And we realize that after contract award, there can be things happen that might require you to reallocate costs within that overall estimate, but at the outset, having as much detail as possible is very helpful for us to make sure that we are entering into a contract that is fair and reasonable.

Question 14 has to do with the incremental funding nature of this contract. It's basically saying, will the costs that the contractor will have a right to recover under the cancellation charge provisions be in addition to the funds that have been allotted under the limitation of funds clause?

The answer to that is no. Whatever funding we allot to the contract has to cover both contract performance as well as the possibility of a cancellation charge being invoked.

A cancellation charge would only be invoked if we end up being unable to provide additional incremental funding. Then that is when we would use this cancellation charge to basically wind down the contract.

Okay. We have a lengthy question and answer here. And this question as well as the next

couple of questions have to do with property or equipment under the contract.

There was a question about what does the phrase "product-related equipment" cover? And the person asking the question had given some examples of wanting to know what was all covered by that phrase.

Robin had provided a very lengthy answer that identifies different types of equipment that would meet that definition of "product-related equipment." So you want to take a close look at that.

The next question talks about, is there a dollar limit for capital reimbursement? And basically we have not set in the RFP a dollar limit. That is going to depend on the nature of the work that you are proposing and the stage at which your company happens to be in developing these vaccines.

But the expenditures -- well, one thing that should be noted is that with those items that are charged directly to the contract, they will then become government-owned equipment under the government property clauses in the RFP.

The next question, again question 50, then, also asks some additional information about that. For the purchase of any special product-related equipment that the government funds as a direct cost,

the government gets title to the equipment. That's a true statement. Will that equipment be made available to the contractor on a rent-free basis for the purpose of manufacturing product for commercial sale?

At the current time, the answer that we have to give to that question is no. At the conclusion of the contract, we would anticipate that HHS would provide disposition instructions having to do with that equipment. And the instructions would likely be that the equipment that would be directly charged against the contract would possibly be returned to the government.

You know, that's basically the best answer that we can give at this time. It is difficult for us to foresee how our needs might change over the next three to five years during the course of the contract.

There is always the possibility that we may see the need to extend the contract, in which case the equipment could remain in place. There is also the possibility that the government might award other contracts to your company that would require use of the equipment.

There are also provisions under the terms of the contract as well as the Federal Acquisition Regulation part 45 for companies to request that they

be allowed to use that equipment in their commercial work. You know, we can certainly consider those requests.

You know, the government property area is one of the more complex areas of government contracting. And, unfortunately, right now at the outset of this contract, since we can't envision what our needs are going to be three to five years from now, the best answer I can give you is the one that we have provided here. But, again, if you have additional questions along that line, please submit them. And we will do our best to try to answer them.

For question 21, it had to do with the other two projects that were announced in the middle of March. And, once again, those RFPs have not been issued. But once we have them ready for issuing, we will put them on the fedbizopps Web site.

I guess before we go on to the next slide that we have here, we did have some questions that you wrote out on the index cards. Robin, have you had a chance to take a look at some of those questions?

DR. ROBINSON: Yes.

MR. BECK: Yes. Okay. So Robin will come up and answer some. And then I have some here that I will answer.

DR. ROBINSON: Okay. The first question is the answer to question number 20 talks about a dose at 15 micrograms of hemagglutinin. What is a DNA dose? And what is a DNA equivalent of 150 million doses?

That is for you to tell us. And, as I said before, you need to have some kind of equivalency or comparability of saying, this is what would be the equivalent of a protective dose. And you are in a better position to say how is that comparable to a license inactivated or live attenuated influenza virus vaccine.

So you should provide in your proposal how you arrive at that number of equivalency or comparability. And in your clinical studies, if you are doing that, then you show, explain how you are doing that, and the rationale for doing it. And certainly the question was, does this apply to the DNA vaccines? And certainly it does.

The next question is, when you say 150 million doses per year, do you mean 12 months manufacturing period or a typical annual flu season period?

This is for a pandemic surge capacity of 150 million doses per year. The realization is the

more you can produce each week during a pandemic, the more lives we hopefully will save.

Can you clarify again that this RFP is for pandemic cell and recombinant vaccine and not for trivalent epidemic vaccine? The answer is that it is for both. You need to submit a plan for the trivalent vaccine. And since that can actually be tested in efficacy studies, that you move forward with that.

In addition, what we are asking is that you also have a pandemic plan to make that vaccine. And, really, the reason for that is we want you to have experience at actually working with pandemic-like virus vaccines to get that experience because we may be asking you later on if you're close to licensure or far enough along in development to help us when a pandemic does arrive.

Will there be any preference and a scoring weight be given to the offeror that controls their own operating facility over those that opt for Com strategies? And will this be engaged in the context of experience and time line issues?

It will depend on the quality of the facilities that you owned and those that are contracted out and the performance of that forms the experience with the vaccines, with the biologicals,

with influenza vaccines. And that would be part of the overall look when you look at personnel, when you look at facilities, at how that is weighted, and also how those are integrated together, whether it is in a single company or a consortia or subcontractors with the prime.

The next one is section M.1 in general speaks of the need to provide documentation to demonstrate unencumbered access to intellectual property. What type of documentation is required or expected? And when must it be supplied as part of the mandatory criteria for eligibility? I will start with this, but I am going to defer to David to also talk on this.

A reality here is a reverse genetics of sorts will likely be in many of your proposals. What we would like to see is that there is some agreement, or at least in draft form, at a minimum, that if you are going to use reverse genetics of sorts, that has been addressed.

And for other recombinant systems, if you need to have unencumbered access to that IP, if you have a strong IP, then it is not a problem. But if you are licensing it from some other company, then you need to have in your appendices a copy of the

agreement or portion of that agreement that demonstrates that.

Dave?

MR. BECK: Yes. We had gotten a question like that that was submitted before the conference, today's conference. And Robin and I discussed that topic for a little bit, but we need to have some more discussion on the best way to try to answer that question.

There are a couple of places in the RFP that talk about intellectual property and what is needed before contract award or to be considered during the evaluation. And I suspect that we will need to go back in the RFP and amend some of that language.

So I would just suggest that we will have some additional information about that particular issue, hopefully not too long from now, maybe as early as sometime next week.

DR. ROBINSON: Relative to that, I think we want the projects to go as expeditiously as possible. And if there looks like there is going to be a patent interference issue later on or that you don't have an agreement with the patent license, then we would hate to see the project go down the tubes at

some point. So that is why we would want it up front that you would have unencumbered access.

The next question is the RFP states that product-related equipment costs can be included, along with facility design and validation costs. Is there a further explanation of product-related equipment available?

I am showing you a slide that David provided of a whole list of different product-related equipment; again, those that are actually in contact with the product that would be used specifically for your influenza vaccine, as opposed to be used and would be dedicated for that.

Where in the RFP could U.S. government-funded facilities costs be included does not appear to be a specific deliverable. The cost for the facility or the facility design and your mechanical engineer, your architectural firm, you should just put that in the milestone 3 for that.

And also it can be one of your contractor-driven milestones also and if you are doing it in-house or you are subcontracting and you wanted to include those costs and have support for those costs.

Does the clinical requirement for pandemic

stop at phase I or II? The answer is no. It depends on sort of where you are in development, but we would like to see it in your overall milestone 1 product plan.

You'd want to take it all the way to licensure but certainly as your contract-driven milestones, as far as you can take it within the time duration of the contract, which is five years.

So if you are already in phase II, then you can go through phase III and begin to license it, you need to put that in there. If you're in phase I, put as far as you think you can reasonably get in that time limit.

Next, if you are doing a cell culture-based pandemic program with NIH in parallel with this RFP, do you want it referenced and/or the protocol included? The answer is absolutely because we will have to talk with the NIH about where their funding stops and where ours would pick up.

There are two more questions here, and I am unable to read them. I will start the question. If you can recognize it, then you are welcome to stand up and ask the question so that I can try to answer it.

MR. BECK: Or if you prefer not to --

DR. ROBINSON: That's okay, too.

MR. BECK: -- you're also welcome to e-mail it to us.

DR. ROBINSON: This is regarding milestone 2 and the comprehensive product development protocol. Is the mandatory criteria -- and after that, I can't understand the question. So if you want to stand up and ask, it's fine or it can wait until you submit the question.

PARTICIPANT: The question is with regard to whether or not it is one protocol or multiple protocols we need in the mandatory criteria for that milestone.

DR. ROBINSON: For milestone 2, there would be whatever clinical protocols you would have that would be covered within the contract scope. In other words, if you are asking for us to fund phase I and phase II studies, then we would ask that you provide details in the clinical protocols for those.

The last one is, what is the lower age limit or to which age group does the government expect the pandemic vaccine to be studied in the clinical trials on this proposal?

Certainly the inter-pandemic vaccine would be in the age groups that are already first in the

licensed vaccines. But with pandemic, we would say down to six months at first blush. And we will consider this a little bit further. So we may have more clarification on that, your question, once it's posted on the internet.

That's all.

MR. BECK: I have about another half-dozen questions that were handed to us. I can probably provide answers to about half of them. And then I'll explain why I may need to research some of the others.

The first question is, the RFP states a five-megabyte limit for the technical appendix, which has 500 pages. How strictly will that be enforced? Five megabytes is not very much for the length of the document, especially if data other than text is to be included.

That is a very good point. I think we probably picked five megabytes because if the information is being e-mailed, sometimes a lot of e-mail servers won't let, you know, really large documents through.

So maybe afterwards, we will take a look at whether or not we can provide some instruction on maybe breaking up, you know, that appendix into five-megabyte chunks and maybe provide up to perhaps

four separate e-mail submissions. We will take a look at whether or not there is some instruction we can provide that will give you some additional flexibility.

Another thing that we will look at is whether or not we should suggest that you use some type of compression method on that document to try to compress it down to the five-megabyte limit, something like doing a .zip file.

Another question has to do with the human subjects and animal welfare and whether or not these materials could be included in just the appendix. We probably can go ahead and answer that and allow that, but we probably would want you to at least include in the technical proposal a reference to where that material can be found in the appendix. Otherwise, when we are going through 500 pages, it is going to take us a while to locate that information.

Another question has to do with, does Puerto Rico qualify as U.S.-based manufacturing? There are, you know, quite a few different definitions of the U.S. for different purposes. So I'll have to confer with -- you know, Robin is nodding his head yes. So I will go back, and we will try to verify that. But it is likely that we will be able to answer

yes to that question.

Clinical trial costs. Should these use government costs or commercial costs? For example, BTEUs charge less to NIAID than to commercial customers, how to get these costs. Since we are operating under, you know, cost reimbursement contracts and the cost principles that apply to that, which are out of Federal Acquisition Regulation part 31.2, you know, if I understand the question correctly, we do need the requirement that the costs be acceptable under our cost principles for our contract. So we haven't developed any exception for that.

But, again, that is a question I will try to research a little bit more and have you a written answer once we post the questions and answers that we receive today.

A couple of other questions having to do with some of the oversights that we had in proofreading the RFP. We initially had set a 25-page limit for the technical proposal. And then we decided that was too small. So we increased it in one place to 40 pages, and we forgot to increase it in the other places. So we will be issuing a correction for that.

Somebody else was very observant, and they

saw that when we were stating the size of the pages, we described it as 8 by 11 and we really should have said 8 and a half by 11. So we don't need people to buy special paper.

And then there is another question here having to do with the inside cover page. And I'll have to go back and research the RFP and give you an answer for that later.

That has gotten us through the questions in very good time. So we are well ahead of schedule. And I think it is still raining out there, unfortunately.

We are going to have to ask when we conclude the conference that those of you who are in here on a visitor's badge, we will have to get you down to the lobby and get you out to comply with the security protocol for the office.

If you have some other appointment in the building later, you will have to check with the guards about, you know, getting back up for the later appointments.

Let's see. Let's go ahead and go on to the next couple of slides here. Some of the key dates to remember are we have asked in the RFP that you provide a letter of intent to propose. This is very

helpful for us in trying to anticipate the number of offers that we are going to receive and helps a lot in our scheduling. And, again, we have a very aggressive schedule for trying to get this awarded by October. So by providing that letter of intent, that can help us out greatly.

The proposal submission date is June 21st, falls on a Tuesday. You know, for those of you who want to work over the weekend and FedEx it to us on Monday, you know, we chose a Tuesday to try to accommodate some of that. And, again, that's at 2:00 p.m. on the 21st.

And the primary point of contact for the acquisition, you know, is Andre Early. We provided his phone numbers and e-mail address. And then if you are unable to get in touch with him, I'll serve as a secondary point of contact.

On this next to last slide, we have given some of the Web sites. There is a lot of very useful information, provides background for the acquisition in terms of what HHS has been doing within this field. You will find that at the National Vaccine Program Office's Web site.

The office that Robin and I and Tom are from and Andre and Rodney, we're all part of the

Office of Research and Development Coordination. We have a Web site that describes the activities of our office.

One of the major activities there is Project BioShield funded under the Project BioShield Act. So you'll find a lot of information about those activities relating to that project, and then you will find some information I guess about the flu projects that we have.

And then the key Web site for you to keep in mind is the Federal Business Opportunities Web site, where we post any amendments to the RFP, along with the questions and answers; and then a couple of acronyms that we had used earlier in terms of our offices.

I guess we have the last one there. I guess since we are ahead of schedule, I'll go ahead and see if there a couple of other sort of logistical questions or administrative questions.

And, again, remember, if you need additional index cards, you know, please see Rodney. I think he has a stack of additional index cards. And we'll be happy to take any remaining questions that you have today and any questions that you e-mail to us later.

Any additional questions today, though, for administrative purposes or logistics?

(No response.)

MR. BECK: Okay. We hope very much that this has been of use to you and has helped in your understanding of this acquisition. We're very excited about it and about the possibilities for addressing pandemic flu and other instances of flu.

So we thank you very much for coming out on this rainy day. Hopefully it will clear up pretty soon. Thanks.

(Whereupon, at 10:39 a.m., the foregoing matter was adjourned.)