MEETING

STATE OF CALIFORNIA

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

CALIFORNIA ENVIRONMENTAL CONTAMINANT BIOMONITORING PROGRAM

SCIENTIFIC GUIDANCE PANEL

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10:07 A.M.

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APPEARANCES

PANEL MEMBERS

Dr. Edward Moreno, Chairperson

Dr. Asa Bradman

Dr. B. Dwight Culver(via teleconference)

Dr. Marion Kavanaugh-Lynch

Dr. Ulricke Luderer(via teleconference)

Dr. Thomas McKone

Dr. Julia Quint

Dr. Gina Solomon

Dr. Michael P. Wilson

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

Dr. Joan Denton, Director

Dr. George Alexeeff, Deputy Director, Scientific Affairs

Mr. David Berger, Health Education Consultant, Safer Alternative Assessment and Biomonitoring Section(via teleconference)

Ms. Sara Hoover, Chief, Safer Alternative Assessment and Biomonitoring Section

Dr. Rachel Roisman, Public Health Medical Officer, Safer Alternative Assessment and Biomonitoring Section

Dr. Martha Sandy, Chief, Cancer Toxicology and Epidemiology Section

Dr. Lauren Zeise, Chief, Reproductive and Cancer Hazard Assessment Branch

APPEARANCES CONTINUED

DEPARTMENT OF PUBLIC HEALTH

Dr. Peter Flessel, Chief, Environmental Health Laboratory Branch

Ms. Diana Lee, Research Scientist

Dr. Michael Lipsett, Chief, Exposure Assessment Section

DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Dr. Myrto Petreas, Chief, Environmental Chemistry Branch

ALSO PRESENT

Mr. Davis Baltz, Commonweal

Dr. Randy Curtin, Centers for Disease Control and Prevention

Ms. Gretchen Lee, Breast Cancer Fund

INDEX

PROCEEDINGS

OEHHA DIRECTOR DENTON: Good morning to everyone here in Oakland and down in Los Angeles. My name is Joan Denton and I'm the Director of OEHHA. And we appreciate you being here. And for those individuals in Los Angeles, we appreciate you attending this meeting from that location.

This is unusual, and we're expecting this to be a one-time event, where we will have a meeting convened from two locations. The explanation for the meeting happening this way this time is that it wasn't until, what was it, three weeks ago that the budget was signed. So the meeting was off and on. And we couldn't really plan on it until the budget was signed.

Consequently, we didn't want to impose on the individuals from the south coast to be able to do traveling when we had an agenda for four hours. So we put together this meeting, in which we're here in Oakland and there are two of the Panel members down in Los Angeles.

And in just a minute, I will have the Panel members introduce themselves. In fact, that's probably a good idea right now.

So we'll start here in Sacramento. And, Marion, maybe we could start with you. Introduce yourself.

PANEL MEMBER KAVANAUGH-LYNCH: Sure. I'm Marion

Kavanaugh-Lynch. I'm the Director of the California Breast Cancer Research Program housed at University of California, Office of the President.

PANEL MEMBER WILSON: Michael Wilson, a research scientist at the Center for Occupational and Environmental Health housed at UC Berkeley.

PANEL MEMBER BRADMAN: Asa Bradman at the Center for Childrens' Environmental Health Research at UC Berkeley.

PANEL MEMBER QUINT: Julia Quint, retired from the California Department of Public Health.

PANEL MEMBER McKONE: Tom McKone with the University of California at Berkeley, School of Public Health, and also with the Lawrence-Berkeley National Laboratory.

PANEL MEMBER SOLOMON: Gina Solomon, a senior scientist with the Natural Resources Defense Council, and also on the faculty at UCSF in the Division of Occupational and Environmental Medicine.

OEHHA DIRECTOR DENTON: And you'll notice that Dr. Moreno did not introduce himself and is not here. He's expected to arrive probably around 11 o'clock. So after I make my introductory remarks, then I'll turn it over to Asa, who will conduct the meeting for Dr. Moreno until he arrives.

Okay. Dr. Luderer is going to be facilitating the meeting down in Los Angeles.

And could you introduce yourselves down there.

PANEL MEMBER LUDERER: Yeah. I am Ulricke Luderer. I'm at the University of California, Irvine, Center for Occupational and Environmental Health. And that's actually where we are sitting as we speak, not in Los Angeles. We're in Orange County.

PANEL MEMBER CULVER: My name's Dwight Culver, University of California, Irvine, Department of Epidemiology.

OEHHA DIRECTOR DENTON: Okay. So just a couple of things I want to mention before I turn it over to Asa.

First of all, I'm required to tell you if there's an emergency what you should do. And, that is, you should go out either door and look either right or left and there will be exit signs, and you follow people going to the exits. So that's your emergency information.

The restrooms are actually down here to the right, but you need a card. So you need to pick up a card from the back table. You go to the end of the hall and make a left and you'll see them right there on the left.

Okay. I just want to mention or just to remind you what happened at our last Science Guidance meeting and then tell you what our plan is for this Science Guidance

meeting. Again, it's scheduled to go until 2:30, with a break for lunch.

But at the last Science Guidance Panel, we had it here in Oakland in June, June 10th. And the focus of the meeting -- actually had a workshop the previous day followed by a Science Guidance Panel meeting the next day. And the focus of the meeting was on chemical selection and also laboratory capacity.

The purpose of this meeting is to get a program update, which will be the first item on the agenda, followed by a discussion and a presentation about sampling design. And then in the afternoon, we'll be hearing some updates about laboratory work. So that's what's going to happen this meeting.

The December meeting will be devoted to chemical selection. And will be a major, if not only, agenda topic.

So I think, at this point, I -- hopefully, everyone has picked up a copy of the agenda. And I think Dr. Asa Bradman here is going to go a little bit over the agenda, so I won't duplicate what he's going to say.

And I will turn it over to you.

PANEL MEMBER BRADMAN: First, I want to welcome everybody here on behalf of the Panel, welcome the staff and public participants.

Just to review a few of the plans for today and also some things to take note of in terms of this kind of unique meeting situation where we have people both in northern and southern California. One key goal is to make sure that the discussion here is audible to all participants. So if anyone has any trouble hearing at any point, particularly those in southern California, please speak up and let us know. In some cases, it will be necessary to pass these little mikes around so people can hear what you're saying. And, again, that's important.

Also, as part of that effort, please be sure to identify yourself before you speak. That's important for the person taking notes and also so we know who's talking.

There's a few points where we'll ask about whether there's any questions. And there'll also be several opportunities for public input during the meeting. Those will occur perhaps at the presentation on sample design in the morning and also after the laboratory update in the afternoon.

For those of you from the public who want to make comments in northern California, you can place questions on the card in the back room; and in southern California you can leave a card with David Berger. So if there's any questions about that, please let us know.

Dr. Denton mentioned the agenda, which most of

you have a copy of. We'll focus on the update on program activities, presentation of the sample design options, and an update on laboratory activities.

Everyone should have materials for the day. If you're a Panel member, you should have a packet. And for others, information is available on the website or in the back of the room.

We ask that you keep comments today focused specifically on the agenda today. We don't have that much time and there's a lot to cover.

There will be a lunch break, and there will also be a break at midday for lunch. And just a reminder, everyone's on their own for lunch.

So I think I've covered all the key points for today.

OEHHA DIRECTOR DENTON: Just one other thing to add, that the meeting notes, the meeting transcript will be transcribed and put on our website for the members of the public who are not able to attend this meeting.

And here in Oakland we have about 30 people in the room, including the Panel.

And, Dr. Luderer, do you also have members of the public in your location?

PANEL MEMBER LUDERER: No, we do not. There are only three of us here, David Berger and Dr. Culver and

myself.

OEHHA DIRECTOR DENTON: Okay. All right.

PANEL MEMBER BRADMAN: Well, with that, I would like to introduce Dr. Lipsett, who is Chief of the Exposure Assessment Section of the Environmental Health Investigations Branch at the California Department of Public Health. And he's been the lead on the California Biomonitoring Program and he'll update the Panel on program activities since our last meeting.

So, again, please let us know if you have any trouble hearing.

(Thereupon an overhead presentation was Presented as follows.)

DR. LIPSETT: Dr. Denton and Members of the Panel, good morning.

I wanted to start with a brief announcement; and, that is, that there have been a few minor changes that have been made on the presentations. So that what you're going to be seeing on the screen is a little bit different from what's in the handouts. But the corrected versions -- all the corrected versions will be posted on the web and available early next week.

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DR. LIPSETT: Okay. Could I ask a procedural question. Would the members who are down south -- will

they see as I switch the slides, or do I have to announce as I'm switching slides?

MS. HOOVER: No, you need to announce. Say "next slide."

DR. LIPSETT: Okay. I'm on the next slide that says budget status.

Okay. The current budget status for the program is that our Department has hired eight people for the program, OEHHA has hired two, and DTSC has hired two. The ongoing base budgets are listed there on the right-hand side of the slide: About 1.025 million for us; about .663 million for OEHHA; and DTSC, about 368,000.

Now, I guess the good news for the budget process is that we did not sustain any significant cuts to the budget. The bad news is that we're no longer on the General Fund -- although some people might view that as good news -- and we've been switched to the fund that is administered by the Department of Toxic Substances Control and it's called the Toxic Substances Control Account.

And as part of the budgetary process, the Governor issued an Executive Order that required all General Fund contracts to be suspended, which is what we did with the contracts that we had, for example, with the Centers for Disease Control. But this order was lifted this week, and so we hope to be able to continue to work

on these different projects with the CDC and with UC.

Next slide.

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PANEL MEMBER WILSON: Mike?

DR. LIPSETT: Yes.

PANEL MEMBER WILSON: Sorry for the Interruption.

Can people hear in the back Michael's presentation?

MS. HOOVER: Project, Michael.

(Laughter.)

DR. LIPSETT: All right.

Okay. I'm on the next slide that says Program Activities. Our department has been working continuously with the CDC on issues related to the statewide sample design. It's an ongoing iterative process that we are relying very heavily on the expertise of the CDC in their NHANES program. And we're going to hear a little bit later today from Dr. Randy Curtin, a senior statistician with NCHS, who's played a pivotal role in helping us with a number of the design issues.

One of the things that we would like to ask the Panel, however, in this regard -- I'll just put this out now, maybe you can discuss it later -- is that we would like to have a small work group of Panel members similar to the Chemical Selection Work Group to be interacting

with us periodically as we're going through the design, either for a statewide sample or, what is more likely in the shorter term, for community types of smaller scale studies.

So I just want to put that request out there for now, and maybe we can discuss it a little bit later.

Now, in terms of the questionnaire development, we have been working on specific modules for questionnaires that will be used for either a statewide sample or community types of studies. We're focusing on demographic medical history and specific chemical groups that we think are going to be included within the Biomonitoring Program. And so we've started focusing specifically on flame retardants and questionnaires that might be related to exposures to flame retardants.

Then we've also been working on developing field protocols and specifically a cost model with the CDC about what kinds of expenditures and resources would be needed in order to be able to, you know, collect field samples, administer questionnaires through the recruitment. And this cost model is something that could be applied to estimate the costs that we'd need both for doing community types of studies as well as the statewide survey. And, again, this is an iterative type of process where the design of the survey dictates to some extent the costs

that are going to be incurred. And our budget, in turn, will restrict what we can -- what it is that we're able to actually undertake in the field. And Dr. Curtin is going to talk about these sorts of trade-offs in his presentation.

And in terms of laboratory activities, this is the subject of this afternoon's discussion. So I'm going to postpone that for now.

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DR. LIPSETT: And then, finally, in terms of chemical selection, at the June 2008 meeting, the Panel named eight chemical groups -- I'm on the next slide, for you in southern California -- the Panel named eight chemical groups to investigate as potential designated chemicals; and also identified some chemicals for further investigation, including common household products and NDMA. And with the Chemical Selection Work Group, our staff have been meeting pretty regularly, and we hope to discuss these issues at great length at the December 2008 Panel meeting.

So I think with that -- I don't know if the Panel members have any questions about the program at this point.

PANEL MEMBER McKONE: A brief question. Since there was a stop-work order in place from roughly end of

July, has that -- so that you couldn't work with the CDC particularly. How much has that set things behind, or has that really been able to be worked around?

DR. LIPSETT: Well, probably you could say maybe about a month and a half, something like that. But we did have some work with the CDC that was ongoing where some of the members of the work group there, who are not specifically funded through this contract but who are full-time salaried staff, were willing to work on this anyhow. So we didn't have the full complement of people, but we had a subset of those working on this during that period.

PANEL MEMBER BRADMAN: Just a reminder, Tom. Please identify yourself for the record.

PANEL MEMBER McKONE: Right.

PANEL MEMBER QUINT: I'm Julia Quint.

I am curious about the new funding source. Is that a revenue-generating source from DTSC or what -- the toxics, the new switch from General Fund to --

DR. LIPSETT: It's a fee-based source.

PANEL MEMBER QUINT: Fee-based.

DR. LIPSETT: Right.

PANEL MEMBER QUINT: Okay.

DR. LIPSETT: It is fee-based. And the way it was set up is that both OEHHA and CDPH in principle would

be able to directly access that fund to support our activities.

PANEL MEMBER QUINT: Okay.

OEHHA DIRECTOR DENTON: This is Joan Denton.

It's a fee which is placed on generators of hazardous waste.

PANEL MEMBER QUINT: Oh, okay.

PANEL MEMBER WILSON: This is Mike Wilson.

As a related question, do you have as a --

MS. HOOVER: Hang on, Mike.

PANEL MEMBER WILSON: Oh, okay.

Okay. Mike Wilson. And is that -- do you see that as a more or less stable funding source, as --

(Laughter.)

PANEL MEMBER WILSON: -- vis-a-vis the General Fund, I guess, question?

OEHHA DIRECTOR DENTON: I think one thing to be said is that TSCA is a DTSC fund. And DTSC -- was there people here from DTSC? But it's a fund which is, you know, maintained by DTSC and they control the fund. I think the thought has been that that -- I mean, I don't know any excellent funding source at this point. And it has not been thought that that fund is all that stable. So I don't know if you want to -- but DTSC is really the -- that is the agency that has that fund and could

speak more to it.

DR. LIPSETT: Yeah. And my understanding from talking to some of the DTSC managers is that they view this fund as declining in revenues as well over the course of the next few years. So from the standpoint of, well, is this a growth fund? No.

(Laughter.)

PANEL MEMBER QUINT: That's a good thing. It means less hazardous waste, so that's good.

MS. HOOVER: Check with southern California.

PANEL MEMBER BRADMAN: Are there any questions or comments from the people in southern California?

PANEL MEMBER LUDERER: Yeah, hi. This is Ulricke Luderer.

I have just a question about the questionnaire development. And Michael mentioned that questions are being developed about demographics and medical history and some --

PANEL MEMBER BRADMAN: Hello.

MS. HOOVER: Hit "mute" on ours while she's speaking.

PANEL MEMBER LUDERER: Can you hear me?

PANEL MEMBER BRADMAN: We can now.

PANEL MEMBER LUDERER: Hello.

PANEL MEMBER BRADMAN: If you could repeat your

question.

MS. HOOVER: Yeah, you've got to unmute --

PANEL MEMBER BRADMAN: Can you repeat your question.

PANEL MEMBER LUDERER: Yes, I will.

I just had a question about questionnaire development. And Michael mentioned some categories that were currently being worked on in terms of the questionnaire. And I was wondering, is there going -- are you planning on having a meeting of the Scientific Guidance Panel that will be devoted more to really focusing on the questionnaire and the types of questions that will be asked or is that something that will be discussed potentially more today or at the December meeting?

DR. LIPSETT: Asa, I'm unmuting it -- it's unmuted now.

(Laughter.)

DR. LIPSETT: Yeah, we're having a dueling muting thing up here.

(Laughter.)

DR. LIPSETT: I think what we would like to do is with a work group from the Panel -- well, this is one aspect of the study design that we would like to work with a smaller subgroup on initially and then bring this to the

Panel perhaps for some of the meeting in December. But certainly this is the kind of thing that we would want your input on.

PANEL MEMBER LUDERER: Thank you.

PANEL MEMBER McKONE: Are we on? Never know.

DR. LIPSETT: You're on.

PANEL MEMBER McKONE: Remember, you had talked about setting --

OEHHA DIRECTOR DENTON: Tom, you want to introduce yourself.

PANEL MEMBER McKONE: Oh, I'm Tom McKone.

You had talked about setting up another sub-panel. About what timeframe are you thinking of doing that? Before the next full meeting, or would that be an activity in December that we would plan for, you know, to set up a -- or to discuss the formation of a subcommittee? Or is that something we should do today, actually talk about a subcommittee for the strategy of data collection and sampling?

DR. LIPSETT: Well, we were hoping that you would take some time today to discuss it. And hopefully we'll have at least a couple of volunteers.

PANEL MEMBER BRADMAN: So any comments -- any more comments related to this presentation?

Any discussion on Michael's points or requests at

this point?

I guess we'll defer discussion about the small work groups until later today.

DR. LIPSETT: All right.

PANEL MEMBER BRADMAN: So I think, at this point then, we're ready for Dr. Curtin's presentation.

Dr. Curtin, are you there?

DR. CURTIN: Yes, I am.

PANEL MEMBER BRADMAN: Okay. Are there -- I assume there's a presentation linked to that?

MS. HOOVER: Yeah, in southern California they should load.

PANEL MEMBER BRADMAN: In southern California you should be loading up the PowerPoint presentation for Dr. Curtin's talk.

And all of us should mute our phones during the presentation.

MS. HOOVER: But not yet.

PANEL MEMBER BRADMAN: But not yet.

DR. LIPSETT: Not yet. I wanted to just introduce him briefly.

PANEL MEMBER BRADMAN: Okay. Go ahead.

OEHHA DIRECTOR DENTON: Good idea.

DR. LIPSETT: Okay. So does the southern California group have Randy's slide show up yet?

PANEL MEMBER LUDERER: Yes, we do.

DR. LIPSETT: Okay. So I wanted to briefly introduce Dr. Randy Curtin, who is a senior research statistician in the Office of Research Methods in the National Center for Health Statistics.

Randy has played a key role in the development and refinement of sampling designs for a variety of national studies, including the NHANES study, the National Health And Nutrition Examination Survey. And more recently in the National Children's Study he has played a very important role. He's extremely knowledgeable and we've found his input to be very helpful and enlightening for us in this whole process.

So, Randy, you want to take it away. And we're going to go on mute right now.

(Thereupon an overhead presentation was Presented as follows.)

DR. CURTIN: Okay, yeah. So what we should have up on the screen right now is the overall title screen, which says California Environmental Contaminant Biomonitoring Program. Hopefully there's no questions with that slide.

So we'll go onto the next one --

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DR. CURTIN: -- which is the presentation

overview.

I'll be breaking the presentation up today into three different sections:

Some of the basics of sample design.

Then a little bit about implications for a statewide study for California.

And then the third will be designing a community study, which is also sort of part of the net to structure the statewide study as well.

In between each of these, I'll give a moment for questions and then there'll be questions at the end.

I'll probably apologize in advance a little bit. I'm never sure with the type of audience whether I'm doing things too simplistic or too complicated. But hopefully on the average it will be okay.

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DR. CURTIN: On the next slide -- okay, let me just -- I messed up my thing, so let me go back into it and make sure.

The next slide is: Is a probability sample really needed?

And for many people this isn't really an issue. But a lot of times in observation epidemiology studies there's other ways to do patient enrollment -- or participant enrollment. And so it is best to address the

issue right up front as to whether or not a non-probability or convenience sample could be done either at a statewide or community level. Typically, these types of studies are easier to conduct, they're cheaper, and they do have a great amount of internal validity to them.

However, the problem is that the results cannot easily be generalized to a larger population. And there's a potential bias in selection bias and specific populations be excluded. And unfortunately in non-probability samples, you really can't ascertain what that potential bias is to a great extent.

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DR. CURTIN: So the next slide says: Well, what about a probability sample?

The interesting thing about probability samples is they all have some aspects of randomness of selection to them, which helps you protect against these uncontrolled sources of variation. But you can also control other sources of variation in a probability design. So if you're concerned about a certain demographic group, you can design the sample to ensure a certain population size for that demographic group.

Typically, from a probability sample, you can make a valid statistical inference and compare across the population. You survey the entire population. If there

is some non-response bias, you have some information and you can ascertain to a great extent the level of that non-response bias and correct your estimates for it.

The most important thing is these types of studies are often under a great deal of scientific scrutiny of the results. And having the probability sample really aids in defending the results of the study against outside criticisms.

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DR. CURTIN: So the next slide starts with: Sample Design is part of the overall Total Study Design. And what I'm trying to get across here - and, you know, most of you who have been in studies realize this - there's a large number of issues in coming up with a study design, and sample design is only part of it.

You have to determine the population, the type of survey objectives you have, the mode of data collection, how you're going to measure these things. So sample design is just a part of this.

And you heard Michael speak in general about the iterative nature of sample design. And I'll be coming back to that over and over again. Because as you do these sample designs, it impacts upon the study itself, and often the trade-offs come and you may have to change content, you may have to change your objectives in order

to keep the whole thing within budget.

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DR. CURTIN: So what are the basic steps in sample design? The next slide you'll see that this is -- basically just about any study design has these types of basic steps. You start with the study objectives. What is the content? How are you going to measure these objectives? What is your target population? Is it the total population in California? Is it just a county in California? Is it just a small domain? Is it some sort of group that crosses like immigrant workers -- immigrant farm workers? So you define your target population for the study.

Somewhere along the line you make statistical considerations. What exactly are you going to measure in terms of a statistic? Are you generating means, proportions, percentile distributions? And what kind of precision do you attach to that? What kind of past statistical power do you want to compare groups?

Those types of statistical considerations then lead to the analytic sample size that you need. So that gives you the total sample size you need. Then you have to design a sample to come up with that total sample size.

And the sampling statisticians will drive you crazy coming up with design option after design option

after design option. You usually end up with more design options than you have sample people in your study. But somewhere along the line you narrow them down and get focused in on a couple of key issues.

For a contaminant biomonitoring type study, one of the major considerations is the data collection mode. If you're going to be collecting blood and serum for people, obviously a mail survey or telephone survey is not a very feasible mode of data collection. You're going to have to go out and either go to those people's homes to collect the information or bring them into some sort of clinic or examination center to do the blood draws.

When you discuss design operations then, you'll have to keep in count all the costs associated with each stage of the selection, whether it's fixed costs or variable costs, and then how that impacts upon the reliability or the variance at each stage of the selection.

So these things become very complicated. And even though in classical sample survey textbooks there's some nice equations, in practice those nice equations don't hold very well because the cost models or the variance models aren't as simplistic as they use in the traditional textbooks.

There's always practical and operational issues

to deal with. And the biggest thing that you're obviously dealing with in many of these studies are budget restrictions. You probably talked about the laboratory data. Even after you collected the data itself from the individuals, the processing of the information through the laboratories to get these measures can be very expensive, unless they impose a restriction upon the overall study design.

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DR. CURTIN: So next, what are some of the basic characteristics of a sample design? Well, what you could try to do is control the selection for a number of items, a number of characteristics. You want to be able to get at whether the population is urban or rural perhaps. You may want to get at minority populations. You may want to get at different types of age groups. So, if you do a simple random sample, those characteristics are coming in at random and at the level they are in the population.

Many times you want to have more -- say, you have 10 percent in an age group. Maybe for the analysis you need 20 percent in that age group. So you have to have some mechanism of over-sampling for that age group. And that's the whole purpose of sample design then, is to take that total sample size and start breaking up into an allocation by sample of units and size of units and number

of people that you need.

Ultimately though when you have these multiple-stage-selection-type probability designs, the actual selection itself is at random. And this is what protects you from an inferential standpoint and this allows you to make inferences to the general population.

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DR. CURTIN: So the next slide is this little diagram. And for your purposes, instead of looking at this as the United States as stage 1, you should look at it -- it's about the map of California. The way multi-stage-area-of-probability designs work is you take your state or your area and divide it up into smaller areas typical of primary sampling units. For California you could have the primary sampling units being the individual counties in California or they could be census tracts within the counties. There's a lot more census tracts than there is counties.

But also you then choose a set of those primary sampling units as your first stage of selection. Then within that first stage, you get down to lower and lower levels. You create segments. Maybe segments have a hundred households in each segment. And maybe you select 20 of those households into your sample. And then out of each household you select the study participants.

And one of the key things that you'll need to discuss is whether you want to select one person per household or more than one person per household.

But this is a little schematic that shows the stages of selection that you divide into smaller and smaller areas, until finally you get down to the participants. Each stage has a certain probability of selection attached to it. You can control the selection so that even though these areas themselves may be different size, you can control this so that every person in California has the same probability of being selected into the sample at least at the start of the study.

Onto the next one.

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DR. CURTIN: The sample design trade-off that we're most concerned with, that comes up all the time of course, is cost versus statistical precision. Typically, to get a decrease in variance or better precision for your estimates, you're going to have to have a larger sample size. And so this is kind of the trade-off as you go through sample design, is trying to make your design more efficient so that for the same dollars you're getting more analytic sample size, but at the same time some of the operational aspects that say you have to cluster the sample or stratify it in a certain way might be working in

the opposite direction. So bottom line is that fixed budgets tend to fix the sample size that fix the content.

So it just gets back to the iterative nature of sample design. Once you design something, if it's too expensive, you have to cut it back. And that may be cutting back on the content because it just may not be feasible to measure certain items if you don't get sufficient sample size for your fixed cost.

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DR. CURTIN: The next slide talks about two terms of immediate interest. You're probably all familiar, at least these days, with these voting polls that go out and they talk about their level of errors, plus or minus 2 percent. Well, that's typically what's called the standard error. And it gives you confidence intervals around the estimates, some degree of precision.

But in sample design work you're more concerned with the square of that standard error, or the variance. So I'll be using terms like "coefficient of variation" quite a bit, because that's what you're really focusing on is a variance. And then when you get down to analyzing it, you need the standard error.

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DR. CURTIN: So the next slide is the key kind of concept in sample design. When you do these types of

probability designs, you're not getting in the same type of variance that you would get out of the simple random sample. There's something called the VIF, the Variance Inflation Factor or the design effect. And this is defined as the larger variance you would get under the complex design divided by the hypothetical variance you would get as if you could do it as a simple random sample.

Now, keep in mind your probability -- that the probability is that you can't do a simple random sample, because otherwise you'd have interviewers going all over the country, it'd be very inefficient, and you'd get so much smaller sample size for your cost.

So the complex design allows you to actually increase the sample size. But some people mistakenly interpret this as design inefficiency because the variance is larger. But when you really consider based upon fixed costs, it's design efficiency.

The impact of weighting and clustering. Typically, you have to group people into small clusters. And that has something called the intra-class correlation coefficient. It means people of similar clusters have similar measures. And the more they're similar, the more -- the less sample you get out of a cluster. Now, this is the same thing you get in multi-stage clinical trials as well and multi-center clinical trials. All

clinical trials are now analyzed as cluster-based randomization procedures.

The effect of differential weighting. Differential weighting comes in when you try to over-sample groups. You may sample people at different rates in order to increase the sample size for specific domains. Typically, that increases your sampling variance, you know, somewhere in the order of 6 to 8 percent. So that's not a major factor.

The more major factor in increasing the design effect really is this intra-class correlation coefficient. So what we do is we look at past studies and use those past studies to estimate the intra-class correlation coefficient for an environmental exposure and then apply it into the sample design work for California to come up with the overall effective sample size.

Now, again, if you're used to doing types of studies, you know that you come up with a sample size for your statistical precision as if it was a simple random sample. But what happens in complex surveys because you have these Variance Inflation Factors, these design effects, if you go out and collect 150 people, but the design effect is 1.5, you really only have the analytic power of the sample size for 100.

And so there's two sample numbers you have to

keep track of here. One is the actual number of people that you're bringing into the sample. And the other is the actual analytic sample size or effective sample size that you have to do your analysis.

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DR. CURTIN: Now, the next slide is kind of a scary slide. This shows the design effects for some of the laboratory data collected in the NHANES survey. And I wouldn't be too concerned about this. From an analysis standpoint, what you're really concerned with is the relative standard errors associated with these, the precisions of these estimates.

The design effect in this case is actually somewhat of a misstatement, because that variance for a simple random sample is hypothetical and there's certain assumptions that go along with that that are violated in terms of these actual design effects. What these design effects are useful is for comparing alternative sample designs. So if I have three or four different types of design options, I can get these design effects and even though they're not appropriate from a simple random sampling standpoint, they are appropriate for comparing designs. And I can see if one design, it increases from 9 to 10, or decreases to 8, et cetera.

So two things to keep in mind, it's really the

relative standard error, that's a precision measurement, that you're really interested in ultimately from the sample design standpoint. These design effects are most useful for comparing relative designs, not so much from the analysis standpoint.

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DR. CURTIN: And, again -- next slide -- I didn't put real variables down here because I just wanted to illustrate a point on design effects by age. What happens is typically you have various sub-domains. And the design effect within the sub-domain can be pretty reasonable -- 1.2, 1.1, those types of things. But the biometric measurement may be differing by age, may be increasing with age or decreasing with age. So when you combine it in that fashion, you get these design effects that appear to be much larger. In one case, it's 2.6, another case it's 9.5. That doesn't really reflect a problem in the design. That reflects the heterogeneity of the estimate of the variable you're dealing with by age.

So, again, it's of interest from a specific standpoint in the design of the study; it's not that much of interest to the total population. That's why you see these total design effects very large that have to do with heterogeneity, not design.

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DR. CURTIN: So how do we do sample size?

Well, obviously you start with some sort of statistic, some sort of measured reliability about that statistic, and convert that into the analytic sample size you need. You then inflate it by the expected design effect for your sample design.

So if you design -- the analytic sample's 100, you inflate it by 1.5, it's 150. Well, you know that when you go out there, not everybody's going to respond to your study. So you inflate that by the expected response rate and you come up with a sample size of 200 that you need.

Often you'll need several domains. There'll be males and females, you'll need minority groups. So there's K domains of interest. So your total sample size will be that 200 times K. It's a very simplistic way of doing sample size. In fact, you're a little bit more complicated. But this gives you the general idea of having an analytic sample size, you inflate it by the design effect because of complex design, you inflate it by your expected response rate, and then you come up with the total sample size.

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DR. CURTIN: One of the key considerations for a California study or even a community study is that you're having these multiple objectives. And one size does not

fit all. The design you do for persistent organic pesticides may not be the best design for flame retardants. They have different sources of variability associated with them. They have different intra-class correlations associated with them. So the sample size is not the same for every objective.

To make the design efficient overall, then you have to sometimes have a slightly larger sample size for the multiple objective study than you would have for a similar single objective study. You would have different stratification variables for one set of objectives versus another set of objectives.

So when you design these multiple objective studies, you have to kind of go for the overall efficiency. And it may not be most efficient for any one particular variable.

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DR. CURTIN: The other aspect is that there's a big difference of whether you're designing a single, one-time survey versus a continuous survey. When you have the continuous survey and you know that you can combine more than one year, then you can get by by having smaller sample sizes for each year.

So a lot of times when people have expensive studies, they can't get all the budget for one year to do

that study in one year, they'll take that study out over several years, divide the budget over several years and divide the sample size over several years, and you have to accumulate sample over time in order to meet all the analytic objectives.

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DR. CURTIN: So in the next slide, sort of summarizes the iterative nature of sample design for these multiple objective studies. You start out by stating all the objectives, translating statistical measures, coming up with sample sizes, looking at designs, coming up with a cost and budget. And then when you're done you have to go back and either implement the design or start revising things. Maybe you have to decrease the sample, to decrease the cost. Maybe you have to change your statistical requirements on reliability. Maybe you have to drop components, because it's just not feasible to measure them. Or maybe you have to change the timeline in which to get your data. Maybe instead of getting it in one year, you have to get it in two years.

So you go back and forth on the objectives, the reliability measures, the sample size and the cost until you've finally come up with something that is in some sense optimal across all the different objectives in the study.

So that's the basic sample design part of it, just a very basic sample design.

I can take a quick break here for questions or we can just move onto the statewide survey if you want.

MS. HOOVER: Unmute and ask your questions.

DR. CURTIN: Okay. Well, hopefully I'm still on the line.

PANEL MEMBER BRADMAN: Gotcha. No, we're just demuting you.

We do have a question.

Go ahead.

PANEL MEMBER McKONE: I have a couple of questions. These are actually not broad, but a little bit technical.

Going back to slide 8. The implication of this is that area is used. But actually it would seem that it's some sort of trade-off between capturing the right population as much as the area. I would guess this is more focused on populations, that you used geographical segments really as sort of a tool for finding people, but ultimately you're driven more by getting the right types of people, that is, urban or gender or age or something else as more important, so that the -- the system is really never designed to get a geographical component. Am I missing --

DR. CURTIN: Well, yes and no. There's different -- what I didn't go over is there's different types of what's called sampling frames. You could have a list of all 36 million people in California and just draw a sample from the list. In a telephone survey you have a random-digit-dialing-type frame that pulls people in off of that. So you can have different ways of coming up with your sample.

What happens in these environmental studies is typically you have to have a group that's rather clustered, a group of households all together. And then you -- so you need an area probability design, so you're selecting groups of households. And then you backtrack from that.

Now, for the State of California, you can still ensure geographic representativeness by dividing the sample of the strata composed of north, middle, south; or urban, rural; or west coast, east coast of the state. So you can set in advance the type of stratification variable that will ensure representation by those characteristics.

PANEL MEMBER McKONE: Okay. We probably could discuss this more later.

The other ones are a little more technical. On slide 10 and 11, where you're using the coefficient of variation. I mean the definition on slide 10, isn't that

CV squared?

DR. CURTIN: Probably.

PANEL MEMBER McKONE: Right. CV is the standard deviation over the mean, whereas the CV squared is variance. Because the way you're using it in 11, it almost has to be defined as CV squared on 10.

And then this is another question -- probably interpretation we have to think about, is the Relative Standard Error as you show it in slide 12, that relates to the mean. I think we have to be careful that when we're looking at other percentiles -- and I see this mistake quite frequently -- is that you can't use the Relative Standard Error about the mean as a way of expressing confidence about a high-end exposure, for example, or high-end individual, because it doesn't play out the same way if you look at the statistics. So if you wanted to make it 5th percentile, you'd have to do a different exercise to get the standard error.

DR. CURTIN: Right. Actually, percentile estimation is pretty complicated. It's not what's called a linear statistic. It doesn't come out real quickly and easily from standard software packages.

There's something called the Woodruff technique that was developed. And without getting too complicated, you have to calculate the empirical distribution function,

go back and do the inverse of that to the proportion, calculate the -- around proportion and do the inverse TDF and come up with the confidence interval for the percentile.

So, yes, the percentile is not, strictly speaking, out of this. And if you look at, say, the environmental report cards that NCEH does, those are not symmetric confidence intervals that you get about that. And the definition of standard error is a little bit more complex for percentile.

PANEL MEMBER McKONE: Thank you.

CHAIRPERSON MORENO: Other questions?

PANEL MEMBER WILSON: Sure.

Randy, Mike Wilson. Thank you for your presentation so far. And two questions.

One is, if we know enough in the biomonitoring arena to understand the differences between inter- and intra-personal variability in these data, and so in other words as -- do we know enough if we are tracking a single individual over time what the variability looks like in those measurements versus different people at the same time?

DR. CURTIN: Right. The information so far is rather limited. The NHANES survey is conducted on an independent sample each year, so you'd have independent

people each year. So you don't have the longitudinal studies on every individual person.

Now, there might be some small longitudinal studies for some specific ones that track the within-person variation. But that kind of depends upon the geographic area they're in and their exposures and what they're dealing with there. So it's not often easy to extrapolate those to a more statewide population.

So you're kind of in an area here where you're a little bit in the dark. You can get the between-areas and within-areas, but the within-person is not well known at this time.

PANEL MEMBER WILSON: Okay. And I guess the second question is about -- you know, that you introduced at the very beginning, the question of if you follow the path of a convenience sample, that you then have data that are not generalizable. And yet on the random samples -- on a random sample design, we end up potentially washing out or losing the effect of highly exposed subgroups.

And I guess this is a -- maybe this is a question that's better toward the end of the presentation, but I'll pose it now. And that's just asking you sort of your judgment on what is appropriate for a State to be embarking on. If we should be, you know, attempting a random sample or if we should be really trying, based --

you know, looking at the constraints of a State, if we should really be focused on what we would judge to be highly exposed subgroups. So you don't need to answer that I guess now if you don't want to. But I want to pose that to you as you're proceeding.

DR. CURTIN: Well, ultimate I think that's up to Michael and you guys to kind of determine what the emphasis should be. Now, in the national study, we're interested more in sort of the baseline across the United States and what a reference population might be in an estimate for the United States, as opposed to an estimate for an area with a high exposure.

This comes up in the Children's Study all the time, because there we selected the areas at random. But each site has some impact upon how they're doing their within-PSU design. And a lot of people, a lot of the investigators want to select areas that they know have high exposures. And there's a very valid reason for doing that obviously. I don't have to go into that. But there's very valid reasons for doing that. And convenience samples, if you're looking at something that is a purely biological model that has no variation by other factors, then you can get by with doing that.

But, again -- this comes up in other countries as well, whether you have to -- or whether you should be

doing it, and especially when you're getting started, and looking at just high exposure areas and trying to determine the impacts without those high exposure areas. You can do it either way. But it's really up to the people who are responsible for the content of the study to make that decision.

PANEL MEMBER WILSON: Right.

Thank you.

OEHHA DIRECTOR DENTON: This is Joan. I have a question.

We have built this program on the concept that we would have 2,000 samples for the statewide survey. So if you take into account all of those factors that you whittle down to get, I guess, your effective sample size, say we just -- I don't know, theoretically we have -- with 2,000 samples we would have an effective sample size of 1,250 or something like that.

So looking at a statewide survey with that kind of effective sample size of 30 million, could you predict what -- what, will we see a lot of variability in the samples or -- I mean, what is your judgment as far as that effective sample size being able to tell us about statewide biomonitoring concentrations?

DR. CURTIN: Keep in mind that for the NHANES, the national study, we sampled 5,000 people per year and

release the data in two-year data cycles, so release it on 10,000 people for a national sample. So 10,000 people are representing close to 300 million people.

However, because these environmental laboratory measures are so expensive, we limit our age range and take only about a one-third sub-sample to do the environmental testing.

So our sample size is for the environmentals. For the national study, as far as raw sample sizes, range between 1,200 and 2,000 as it is. So if you just make a very heuristic argument that a sample size of 2,000 has given you national estimates pretty well, then you can hopefully think that a sample size of 2,000 is going to do pretty well at the State level as well.

Now, I can get more precise with that and I can actually, you know, generate estimates with expected relative standard errors once we get a little bit further into the sample design.

CHAIRPERSON MORENO: All right. Any more questions from Oakland?

OEHHA DIRECTOR DENTON: As you can see, Dr. Moreno has joined us and has taken over the job as Chair.

CHAIRPERSON MORENO: And thank you for chairing in the interim.

PANEL MEMBER BRADMAN: You're welcome.

CHAIRPERSON MORENO: Dr. Luderer, are you there?

PANEL MEMBER LUDERER: Yes, I am.

CHAIRPERSON MORENO: Are there questions from southern California?

PANEL MEMBER LUDERER: I have a question of Dr. Curtin.

My question has to do again with the stage -- you know, the slide that's dealing with the different stages of sampling. And so there's this discussion of talking about, you know, a completely random sample, and the problems with that being that you might not get enough of a representation of particular subgroups that you might be interested in. And so then I just wanted to sort of clarify this idea of a control selection or the multi-stage sample design.

So when you're going for an example, you have Stage 1, Stage 2, et cetera. So in my understanding, then each of these stages the sample size could be either random or you could have some kind of an over-sampling within each of those stages as well. If you're, you know, interested in, per example, if the first stage is counties, then you could decide that you're going to have a certain proportion of, you know, urban and rural counties ahead of time rather than just doing a completely random sample of all the counties.

Am I understanding that correctly?

DR. CURTIN: That's correct. And I actually have some slides -- I have some more on the other stages of selection and showing how sample size works through there and how you get to the over-samples. So I should be answering that question shortly.

PANEL MEMBER LUDERER: Okay. Thank you.

No more questions on this end.

CHAIRPERSON MORENO: Okay. We do have another question here in Oakland.

PANEL MEMBER SOLOMON: Yeah, this is Gina Solomon. Thanks for the presentation so far.

And I got a little stuck on slide 12, which has the design effects within the NHANES study for '99-2000.

DR. CURTIN: Right.

PANEL MEMBER SOLOMON: And I guess, you know, the design effect concept is where I'm not familiar with. But it did strike me that it seems like the most powerful design effects are for some of the electrolytes, like calcium and chloride, that really don't vary a whole lot across the population.

And so how could -- and you pointed out that this clustering effect that affects -- you know, the people who are sort of clustered look more similar in terms of their biomonitoring results. But it wouldn't seem to me like

that would explain what's going on here. And so I was wondering if you could just sort of walk me through the slide a little bit more so I get the idea.

DR. CURTIN: Yeah. And I actually -- at some point, I hesitated to show that, because I didn't want to get too hung up on how design effects are calculated. Because from the standpoint of the sample design itself, we're more concerned with measures that have design effects around 2 and 3 as far as design sample. These measures -- when you see design effects of 34 and 25, these are somewhat spurious relative to the design. It's because it's -- even though it's a variance under the complex design divided by a hypothetical variance under a simple random sample design, the variance of the simple random sample is not actually constructed correctly, because it doesn't really reflect what's going on in the population.

And that's what the hang-up there is. And we actually, a couple years ago, looked into the components of that design effect and determined that it really wasn't designed per se. It was more related to the measurements themselves and laboratory error, et cetera.

PANEL MEMBER SOLOMON: So should we be paying attention to the design effect number or not?

DR. CURTIN: Well, yeah, that's an interesting

question. You need to be paying overall questions about the design effect relative to some of these basic measures. But some of these laboratory measures, if you start seeing these very large design effects, you have to take pause and say, is that something that's really related to the design or is that really related to just how they're defined? Okay?

And what we do is we sort of break it up into those variables where we know that it's design specific versus those where it's definitionally specific, and focus it on that.

So what you have to be concerned with, I believe, is the overall impact upon clustering to determine whether you want very small, compact clusters or to spread it out a little bit more to know whether you want 10 areas within a county or 20 areas within a county. That's what you're really looking at. And so you're looking at the key variables that are affected by that. These things like calcium and -- no matter what the design, they're still going to come out that high. They're not just going to vary that much by the design, because it's something not related to the design.

PANEL MEMBER SOLOMON: Part of what made me nervous is that right below chloride and calcium are mercury and lead, which are fairly likely to be part of

our biomonitoring study; and, you know, there's an order of magnitude there. So if we have a sample size of 2,000, are we really going to gain effectively 200, which is beginning to seem small, or is that -- you know, can we perhaps consider those spurious as well?

DR. CURTIN: Well, those in particular, lead and mercury, vary quite a bit by age and sex. And so when you're doing estimates within age and sex domains, the design effects for those are actually much smaller. It's when you combine them for the total population and that heterogeneity has been taken care of in that definition.

So that goes back to the next slide, what I had by age. That's sort of like the example you see, the Variable 2 with the overall design -- the total design affecting 9.5 with the -- specific ones down around 1.5. That's the situation with lead and mercury.

PANEL MEMBER SOLOMON: Got it.

Thank you.

CHAIRPERSON MORENO: Yes, another question.

PANEL MEMBER QUINT: Yes. I have a question.

You talked about geographic clustering, you know, by households. What about the overlay of occupation on top of that? Suppose, you know, if you sample by counties and you have certain people living in a certain area but they have exposures through work that could be quite

variable, is there a way to -- how do you account for that?

DR. CURTIN: That's a lot more complicated, because the occupations are very diverse; unless you have an occupation like migrant workers that's very -- you know, kind of defined and geographically defined. If you're talking about occupational exposures in various industries, they're somewhat scattered around different areas.

Now, if you could identify strata that's at -- you know, all of these types of segments, all these types of areas are going to have where all my chemical companies are. Therefore, chemical workers are there and I can look at that way. Then you can do it.

Otherwise, you have to go with something that's called a multiple frame study, where you have one frame which is the area frame and another frame which you would do from a list of occupations, a list of businesses, and then you would sample the businesses, and within the businesses -- you'd sample people within the businesses.

PANEL MEMBER QUINT: Thanks.

CHAIRPERSON MORENO: Okay. It looks like that's it for the questions. So shall we continue with the presentation.

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DR. CURTIN: Yeah. Now, I'm probably -- the next slide where it says questions is now getting started on the sample design for CECBP. And, again, I'm probably going to go into Red Bull overdrive now --

(Laughter.)

DR. CURTIN: -- and decide to do this rather quickly, because we've answered some of the questions, but you're also limited in your time today. And I don't want to spend too much time on this other than to give you an opportunity to ask questions on it.

So let's go to the start of the design, talking about characteristics of California, maximum capacity, and a sample of the sample design.

So, first of all, the next slide --

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DR. CURTIN: -- is goals objectives for this study. The key thing from a sample design standpoint is that legislation calls for this study, for the California aspect of it, to be a representative sample with respect to age, race, ethnicity, and income. So those are types of things that will have to be controlled for in the selection to make sure you're adequately represented with respect to those.

And I also note that collection of the information will involve biological specimens which drives

you to one of these area frame cluster designs.

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DR. CURTIN: Under the next slide, the things to consider -- I've talked about this already -- it's just related to all these, target populations, precision, potential stratification variables. Then it goes down to the level -- the actual State design.

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DR. CURTIN: So the next slide is actually some information on California. It's the race/ethnic distribution. And what you would get was an equal probability sample of 2,000.

So in this slide, you see that there's 6.7 percent of the California population -- actually, I forget what year I used this on. So it may not be 6.7 today. But whenever I looked at it, it was 6.7 percent. But that would give you a sample size of 133 out of the sample of 2,000 and is what's called an equal probability design.

The Asian population -- and, again, if you're talking about the Asian population, you may have people who say, well, that's not one population. It's really Chinese Americans, Japanese Americans, Korean Americans, et cetera. But as an entire group, you'd end up with 244 in a sample size of 2,000.

Things like Hawaiian and American Indian, with an

equal probability sample, you're just not going to get that many into it and something special would have to be done.

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DR. CURTIN: In the next slide you see what we do in the NHANES in terms of all of our stratification and over-sampling and screening that we do there increases our sample size from 12 percent Black up to almost 23 percent in a sample.

Mexican Americans, as a whole, across the nation are much more geographically clustered. You can increase it by a factor of almost 4 to get that.

So this is just an example, given the domain of interest, how you can actually get more in the sample than you have in the population. But there's a trade-off, as you see in the age grouping. If you're going to get more people less than 20, you're going to get less people age 20 to 39, something along those lines. So whenever you over-sample one group, you're disproportionately undersampling another group.

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DR. CURTIN: So the next slide is what are the pros and cons of over-sampling. Well, unfortunately, because of the geographic clustering of some of these characteristics, sometimes in order to over-sample a

particular sub-domain, you may be going into highly urban areas and you lose a lot of the rural sample. Or you may be going to certain geographic areas in southern California and you might be losing northern California.

So you have to be really concerned on the trade-off here between the overall geography, other issues like urban and rural, when you're doing this over-sampling.

And, because you're over-sampling, not all the controls are for stratification. Typically, you have to add more households in there than you want and screen them. And that causes increased costs. In the NHANES survey, we screen about four households in order to select one into the family.

But you do get better precision for sub-domain, and you can do statistical testing on disparities in this way.

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DR. CURTIN: So the next slide is how a disproportionate sample might work for California. And you could actually -- since you have five race/ethnic groups here, you could put down an unequal probability sample that's 400 in each group. But it would be very difficult to do that because of the way the American Indian population, for example, is clustered in

California. So you probably couldn't do that.

So this is just an example. Instead of getting 244 Asians, you could, in theory, come up with 400 Asians in a sample; instead of 133 blacks, you could come up with 400 blacks in a sample.

But there's a relative weight. Then each black person represents 6,000 Californians, each white non-hispanic person represents 26,000 Californians. That's not a big issue for some people. But for other people, they get concerned about it. And it does slightly increase your overall variance for the total population, but you're improving the precision for the race/ethnic sub-domain. So it can be done.

Going to the next slide.

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DR. CURTIN: Again, talking about California, how would you possibly do 2,000 people in a year? And this is just a method of operation, a mode of operation. We said, well, suppose we had 50 weeks per year to move these people around the country collecting the data -- excuse me -- moving these people around the state collecting the data. There's downtime between every community that you sample where they have to pick up their equipment and travel. People are limited to five working days per week. And then the key assumption here is that, given your

content, given your questionnaires, given the burden that you're imposing upon people, you could probably examine 12 persons per day. Given those constraints, you could then have eight primary sampling units per year, 34 weeks of data collection, could come up with 2,000 sample persons per year.

So these are the constraints and the operations that would allow you to come up with 2,000 sample persons per year and gives you 8 -- if you define counties as primary sampling units, you could do 8 out of 58 counties every year in California.

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DR. CURTIN: The next slide is actually a map of a selection that I did. And I want to warn you that this is really not a highly stratified -- I didn't impose all the control in this. So please you do not ever want to use this as a sample. I did this when I did the Children's Study. I designed a sample forum as a sample and they took it and they ran with it. But this is not what I would consider a final sample design for California.

It is a sample of a sample. It shows you how the counties would distribute. And this passes that statistical criteria called the look test. This looks like it might be representative of the State of California

because it has the nice geographic spread to it.

But go to the next slide.

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DR. CURTIN: And this is another realization of that type of sample design. And now all of the sample seems to be more or less in the center of the state. And, you know, you have a large population in Los Angeles, Orange, and San Diego, and they're not very well represented in this sample. This is just part of the vagaries that you get in probability samples. You can get outlying samples that don't pass the look test.

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DR. CURTIN: The third map, which says the third two years of the CECBS design, again looks a little bit better. It still has some geographic variation.

Now, what I did for these three maps is I assumed that there would be a continuous survey over six years. Obviously, you may not have the budget to do that. But what I wanted to illustrate was that if you design a sample this way and you don't get the budget, that first year or first two years is still a statewide probability sample. By designing in advance, you have the ability to roll these samples and combine them.

And, in fact, the fourth map --

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DR. CURTIN: -- which is all in red there, if you combine this as a six-year data set, figuring that you have -- you're spreading your budget out over six years and you're collecting this information, you basically would cover about 85 percent of the population in California through such a design.

Again, this is just a sample of the sample design. And in working through the cost model and the budget expectations, maybe California will be able to do eight areas per year. Maybe they can only do six. And maybe you won't have six full years of data. But each of those previous maps is a representative sample of California. But I did not tightly control the selection.

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DR. CURTIN: Okay. The next slide just talks about this cumulative sample over time. This is something that you're going to have to consider in terms of doing this, whether you want to design a sample for one time only, and then get budget, design another sample independently. The problem with that is you might actually select the same area in two consecutive samples, which doesn't give you quite as good coverage. The advantage of selecting a sample over several years is that you can always cut back and not do the later years of the study and you still have a representative sample for those

that you can afford.

And, again, cumulative sample over time, you can get to more rare events, you can calculate out of percentiles for some of these estimates that you might not be able to do in a single year. If the sample sizes are not large enough for some, maybe combined years gives you the necessary sample size.

And you can also increase the demographic detail that you're dealing with for smaller and smaller sub-domains when you combine it over time.

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DR. CURTIN: So that was just a very brief first stage of how to do a sample design for California.

The next group talks about the within-PSU design, the within-community design, and gets into issues of segments and households and everything like that. But I'll take a quick break here to see if there's any questions on the overall concept of this first stage design.

CHAIRPERSON MORENO: Yes, we have question in Oakland.

PANEL MEMBER McKONE: Tom McKone.

It appears that the primary sampling units when you -- you said that, for example, we have eight that they were -- that you selected counties randomly until you got

a good, as you say, quote, look for the state. Or is there some other process?

DR. CURTIN: Well, again, what I wanted to show was a map with eight counties on it to show how samples can look geographically, just to give you an idea of how they look geographically. If you were actually to do this, what you would do is you would stratify -- and we've looked at this. I had other samples, designs done as well that looked at the 58 counties in California divided into air basin strata by level of air pollutant. I also looked at a map of pesticide exposure in California and where the higher areas of pesticide exposure were, plus the lower areas of pesticide exposure, that comes off of one of your websites.

In an actual design, those are the types of pieces of information we use to stratify the sample to ensure that you're covering those degrees of variability in your sample design. The only thing I wanted to show was how they might look on a map.

PANEL MEMBER McKONE: Just kind of thinking out loud. But as an alternative, couldn't -- I mean the counties of California are pretty lousy at capturing anything actually. And as an alternative, couldn't you do this by census tract, which would then have population density, so much built into it, and then reorganize it

into eight primary sampling units? So in other words, you would -- instead of starting with counties, you would start with census tracts, random -- go through some sort of random selection process, and then see what kind of coverage you have and then cluster it into -- because they would -- you know, several of them would be close enough that they could be lumped together, but you wouldn't aggregate them. You would just aggregate them in terms of going out to collect the data. You know, you'd set up your sampling station in an ideal location for a cluster of selective census tracts.

DR. CURTIN: Right. No decision has been made yet on how to define what would be primary sampling units. They could be counties. But as you say, there's certain issues with counties. The aggregate measures for counties aren't very good because there's so much variability within some of the larger counties.

You could have census tracts. The way -- for people not familiar with it, the United States -- every state is divided into counties, every county is divided into census tracts, every census tract is divided into a group of census block groups, and every census block group is divided up into blocks.

So you can build up these geographic units by looking at census tracts or combinations of block groups

or combination of blocks. So you can geographically build any sort of building block you want that captures the variation.

The amount of information you have is sometimes questionable, because when people collect data, sometimes they only collect it at the county level. They might not have it geo-coded down to the census tract level, so you may not have some information you need to do the design. But other -- you know, if you only have county levels for air pollution data, for example, it's tough to apply that then back to every census tract within the county.

But certainly it is feasible to use smaller units for primary sampling units as opposed to counties. It's certainly feasible to do that.

OEHHA DIRECTOR DENTON: Randy, I have a quick question.

In one of your earlier slides, did I hear you correctly? You mentioned that if you over-sample within a domain, say, the racial domain, that you would make that up in the age domain? And aren't those separate domains?

DR. CURTIN: Well, I had the -- I was using two different points to illustrate here. You do have to be a little bit careful, because there is some demographic difference in age structure between Mexican Americans, blacks, and whites. Not a lot, but there is some.

But the way that particular design was set up, there's actually 72 sub-domains by age nested within race/ethnicity. And so that has allowed us to aggregate the data in that way. Okay?

So the actual design was far more detailed than what I showed there. And the one I showed was only the margin for age and the margin for ethnicity.

So the answer I think is you don't necessarily impact the age structure by over-sampling for race/ethnicity. We did it separate -- we did it for both of them at the same time. And that's why it came out that way.

OEHHA DIRECTOR DENTON: Okay.

PANEL MEMBER BRADMAN: I just have a quick question.

Joan, you mentioned -- this is Asa Bradman -- you mentioned earlier that the program was built around the idea of 2,000 measurements. And I just want to clarify the timeframe for that. Measurements per year?

OEHHA DIRECTOR DENTON: A person can't hear in the back.

PANEL MEMBER BRADMAN: I'm sorry.

I was just asking about the scale of the program. And Joan had mentioned earlier that it's built around 2,000 -- potentially 2,000 participants. And I wanted to

clarify the timeframe for that population. That's 2,000 over two years?

OEHHA DIRECTOR DENTON: Yeah, maybe we could direct that to Michael.

Is that every two years, or is that --

DR. LIPSETT: Well, we were initially constrained by the laboratory capabilities where the labs thought that they couldn't process, especially for the persistent organic pollutants, more than about a thousand samples a year. And so we're thinking about two-year cycles with about 2,000 people.

But our thinking about this has evolved somewhat. So that we might do analyses say at our labs for the nonpersistents, for example, and the metals, for a larger sample size. We're thinking now somewhere on the order of 2,000 to 3,000 people per cycle over each two-year period.

CHAIRPERSON MORENO: Okay. Other questions?

Dr. Luderer, do you have questions down in southern California?

PANEL MEMBER LUDERER: Yes. I have a question relating to the idea of a cumulative sample over time. So one of the benefits is that you can get a larger sample size by doing this cumulating of the sample over time. But then one thing that seems to me that might be a possible trade-off was that depending about -- well,

depending on the duration of time that you're cumulating over, couldn't you be getting into issues relating to population trends -- or I mean trends over time in the exposure? You know, so the exposure's changing over time, and then having to deal with that. Or, in addition, also that your population could be changing over time. So population movements and, you know, growth or loss of population in parts of your sampling area.

DR. CURTIN: Right. The bigger problem is if you're dealing with an exposure that's rapidly changing over time, then you don't particularly want to cumulate over time. And what you're getting is sort of the average or the midpoint of that time interval. And if you're really interested in measuring the trend, then that's not going to be very well measured when it's changing over time.

So if you've got exposures that are fairly constant over time, you can accumulate over time. If you've got something that's changing rapidly, then all's you're going to get is the midpoint of that, not the actual trend.

PANEL MEMBER LUDERER: Thank you.

PANEL MEMBER QUINT: I have a question.

So one of the issues also with the cumulating samples over time is if you publish the data more recently

than, you know, the intervals in which you're collecting samples -- well, I guess I'm confused.

When do you actually publish the results of the sampling data? Because what I'm thinking is that once you publish the results of the biomonitoring data, there may be a call for policy change or, you know, intervention in terms of decreasing the exposures. So it would sort of affect, you know, the -- you know, some of what you could say about the kind of cumulative sample, if you understand what I mean. You know, do you wait until the end to publish the results or are you publishing the results every two years, every year, or whatever during that interval of the cumulative sampling or, you know, storing of the samples or whatever?

DR. CURTIN: Well, that will be up to Michael and his group to determine the interval for publication. What it means from a purely statistical standpoint is that maybe two years of data you could provide estimates for Mexican Americans in total, but with four years maybe you can do eight groups within Mexican Americans. So sometimes it's just a level of demographic detail. More years, you get better detail.

If you've already seen a marked difference in something, a marked disparity, you bring it and then they start doing policy and changing exposure levels, the

advantage is then that you're in the field over a period of time and perhaps you can pick that up. This is what happened when they took the energy crisis several years ago and gasoline usage went down and we saw a drop in blood lead levels in the national data, which indicated that the lead gasoline was an issue. So sometimes being in the field and monitoring this can actually measure the impact of the change.

CHAIRPERSON MORENO: Any other questions before we move on?

PANEL MEMBER LUDERER: Yes, there's a question here.

PANEL MEMBER CULVER: This is Dwight.

If you're doing cumulative studies, can you build in a nested control for those studies?

DR. CURTIN: Okay. I'm not sure I got quite the question. Could you repeat that?

PANEL MEMBER CULVER: Just whether you can build in a nested control for those cumulative studies?

DR. CURTIN: If you have sufficient sample and -- and when you talk about a nested control study, if those sources of variation in that control study are adequately measured in the sample itself, you can impose a quasi-experimental design and get at the information if the information's there to begin with.

So you have to be careful in your questionnaire development to have all those sources of variation asked of the participants.

PANEL MEMBER CULVER: Thanks.

CHAIRPERSON MORENO: Any other questions from southern California?

PANEL MEMBER LUDERER: No more questions.

CHAIRPERSON MORENO: Okay. Before we move on with the remainder of this presentation, I just want to remind the audience that there will be an opportunity at the end of this presentation for anyone in the audience or public to ask questions. If you do, you want to ask some questions, we have some forms. I think there are blue cards in the back. And please be sure to fill them out. And then we'll get to your questions after the completion of the remainder of the presentation.

Okay. Thanks.

DR. CURTIN: Okay. I only have, you know, maybe five or six more slides to just really touch on some of the issues in a community or within PSU design.

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DR. CURTIN: So if we go from the slide that says "Questions" into "Design Issues for Communities".

Again, this sort of gets back to the issue of how you define a primary sampling unit, how do you define a

community. You know, is it a contiguous group from a geographic standpoint? Is it a dynamic group that crosses the entire state line, but it has some sort of primary definition to it? And, in particular, once you define these communities, how are you going to select them? This hits back to the issue that was raised, well, maybe what we want to do is select at the start some communities with very high exposures. And that's fine. You can generalize that to other areas with similar high exposures, but you can't generalize it to areas with low exposures. But that's why that may be what you have to do at the start of the study.

So in any case, in a State design, the communities are selected at random. Whereas, if you just get started, you might actually select each community with more purpose and less at random.

Now, once you get to that level, the community and PSU are sort of the same thing as to how you do the within-areas design. So for within the design, once you select an area, whether it's a county or census tract or whatever, you start defining smaller areas. And you have to have all these sample size considerations: How many segments do you have? What are the size of the segments? How many households do you have per segment? How do stratify those segments? What's the number that you

select? What's the number of households per segment that you're selecting? And a very key consideration, as I mentioned, is the number of persons per household.

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DR. CURTIN: For many types of things, two individuals for the same households are going to have the same type of exposures. You don't want to do this. For other reasons, for other exposures, maybe they are highly different and it actually helps your response rates to have more than one person per household selected. That's a sample of design trade-off.

As you get into these designs, all of these sample size numbers have to be figured out how the sample gets allocated across segments, across households, across PSUs. Those are all variables in your design that you have to nail down. And depending upon how you allocate it, it has different impacts on variance and different impacts on costs.

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DR. CURTIN: So since I don't have a design in place for California, the next slide shows how this is done for NHANES, where we have, in this particular time, 27 areas represented these 3,143 counties in the United States. We had an average of about 24 or 25 segments per each of these PSUs for a total of about 700. We screened

about 23,000 households for characteristics. So only about 6,000 of those households are actually entered into the sample because of their characteristics.

We selected on the average of two per household, so we ended up with 12,000 samples. Out of that, almost 10,000 agreed to be interviewed. And most of the people that agreed to be interviewed then went on to complete the MECs -- where overall response rate was 76 percent.

So this gives an example then we were screening households at about a 4-to-1 ratio in order to over-sample age domain, in order to over-sample race/ethnicity domains.

The next slide.

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DR. CURTIN: Again, segments are typically groups of census blocks. One household per segment is what we use at NHANES. The Children's Study actually uses household size of about 1,200 households per segment, but that's a very special case. We sampled more households per segment than we need because we want to -- because of these environmental exposures, we want a little bit more spread. Rather than to just have 25 clustered households all together, we select a hundred and then take a one-fourth sub-sample. And then that gets -- the set spreads out the sample a little bit more. So we end up

with about 14 people per segment.

So even after you do this large study, you're getting down to these very small areas and only selecting maybe six households into the sample.

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DR. CURTIN: So that -- the next slide is impact of fixed to variable costs. But before I go on to that, the whole issue then and within community sampling is to set up smaller and smaller areas, to allocate samples across those areas, and to do it in such a way that you're providing coverage for the area at minimum cost, because that's the key thing in sample design for within PSU selection or within community selection.

Now, there's another slide I put in here, Impact of Fixed to Variable Costs. This is actually kind of interesting from a planning standpoint versus a budget cut standpoint.

In doing these types of studies you have a large fixed cost in order to buy equipment, to gear up to do it. And then you have the variable cost associated with each sample person. And this particular example, which is totally fictitious -- this is not related to any cost estimates whatsoever for your study, this is just to illustrate again, -- if you have $4 million in fixed costs at $1,000 per person, then for $5 million you can do a

study of a thousand.

You can then argue to your budget people that, "Gee, for only a $1 million increase I can collect" -- "I can increase the sample size from 1,000 to 2,000." And you might be able to make that case and get the extra budget you need, because it looks like you're doing so much better in efficiency to have just a relatively small increase and double the sample size.

Unfortunately, if you design a sample size of 2,000 at $6 million and then you're told to cut the budget, you may have to cut the sample by 50 percent in order to get down to that small budget cut because so much of the costs are fixed costs.

So something to keep in mind when you're planning to study is that a lot of the costs of doing these things are in the fixed costs, the infrastructure costs, the upfront costs. The actual cost of doing the sample is marginally less than that.

And then the cost that I did not put up here, that Michael mentioned earlier, was the whole processing costs, the laboratory costs after you collect the data, how to process it through the labs and come up with a final data set.

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DR. CURTIN: Finally, ultimately then we come

down to the final design parameters that are going to be required to do any study. And this just circles back to where we started.

You're going to need the content, the types of statistics you're interested in, the desired level of statistic reliability of those, and the sub-domains of interest.

There's going to have to be decisions made on whether you want an equal probability sample with respect to age, race/ethnicity and sex, or whether you want to over-sample particular groups.

There's going to need to be a decision whether you want to control the geographic spread of this in urban and rural or specific counties.

And then you're going to have to calculate for all of the -- and actually then what I do is turn around and I provide design effects by stage, cost factors by stage to efficiently design a sample to meet those design parameters.

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DR. CURTIN: And the final slide is from Dilbert. And just gives a little indication about the accuracy of numbers. And you can't read it. It says, "I didn't have any accurate numbers, so I just made this one up. Studies have shown that accurate numbers aren't any more useful

than the ones you make up." "How many studies showed that?" "Eighty-seven."

(Laughter.)

DR. CURTIN: So I'll open up now to any additional questions.

CHAIRPERSON MORENO: All right. Thank you for the presentation.

Questions?

Yes, Tom.

PANEL MEMBER McKONE: This is Tom. I hate to probably be leading off. But this is very interesting, Randy. I think you've brought up some great points.

One of the things that came up, when you were talking about the segment size and cost and, you know, translating this to problems we have in California, it looks like, you know, for California we may not be able to afford, for example, more than 25 samples within our households within a segment, or blood samples, say, within a segment. But actually it doesn't cost that much more to take 100 blood samples maybe. But it doesn't even double the cost.

Has anyone done a study where you'd do something like get 100 households or individual blood samples, split them and then -- for later, but then pool them together? So you take four and mix them to get, you know, 25

samples. Does that cause confusion or does that help out? Because then you'd have a design where if you're pooling the blood and you get a really high one, you do have the option of going in and taking the four that were in that high pool and looking at them in more detail.

DR. CURTIN: Yeah, actually, I just gave a presentation last Friday to the Joint Canadian, U.S., Mexican Group on Human Biomonitoring about the issues of pooling samples. And there are a lot of statistical issues involved in what you can estimate once you pool samples and whether the underlying distribution is normal or log normals, because you're dealing with geometric means as opposed to arithmetic means. So there are a lot of statistical issues in pooling samples. But it's also driven by not only this kind of concept you had of sample size, but sometimes you have a limited detection issue. And for the volume that you've taken, some of the dioxins, for example, 85 percent are below the limited detection in the national database. So the concept is to pull the samples, get additional volume and at least get a measure for that 85 percent.

So I'm trying to jockey it around, because this is probably a two-hour or a three-hour conversation. And we're actually scheduled to go down to the Center for Environmental Health next month to talk to our friends in

Atlanta about issues of pooling samples, and we'll bring that discussion back to Michael at some point.

CHAIRPERSON MORENO: Okay. Any more questions?

Okay. Dr. Luderer, do have questions in southern California?

PANEL MEMBER LUDERER: No questions here.

CHAIRPERSON MORENO: Okay. We're back to this group.

No more questions?

If not, I think this is the time to go to the public, if the public has any questions or comments they'd like to share.

You can come to the mics.

DR. ALEXEEFF: The best way to do this -- it's almost easier sitting down.

Hi. This is George Alexeeff from OEHHA. Thank you very much for the presentation. I have a question, and I'm trying to formulate it properly in my mind. I appreciate your example, which you said was fictitious, where you had a fixed cost and a certain number of samples. I guess one million for an additional 100 samples or an additional 1,000 samples.

But I'm trying to -- I'm wondering if there is a way of estimating it, what if you had a severe budget cut?

So --

(Laughter.)

DR. ALEXEEFF: -- obviously there's a certain fixed cost that you have to pay for equipment, you know, various specific equipment just to measure things. But is there a way of estimating -- I know that the requirement is for a representative sample. But if there are insufficient funds to actually conduct a representative sample, which we are presuming was 2,000 -- if there was insufficient funds to do that, is there a point you can calculate and say, you know, unless we had this amount of funds we could not do a representative sample? And then can I ask another question, is a focused sample or a community-based sample substantially less expensive.

I don't know if I've presented it well. I'm just wondering if that is something that one could calculate or estimate based just upon funding.

DR. CURTIN: Well, we're in the process now -- we, CDC and Michael's group -- of putting together some very detailed cost models, which look at the different aspects of the data collection, the different details of what goes into those cost models. And then these cost models then form the basis of looking at various design options. So that type of option could be examined in that context. Just a -- now, a community study is probably going to be about the same cost as a PSU in a state study,

because you're still doing the same type of things on the same sort of number of people.

But the major difference -- and I'll give you an example of what's happened in the past at the national level. Suppose you're rolling along and you collected half a year of data and then all of a sudden you're told to stop the data collection. Well, you don't really have a representative sample, where you needed a full sample to make a representative. So you have what's left over. And the question always becomes, "Can I do anything with this? What sort of analysis can I do with this?" And the answer is, you can still do something with it; there's still some types of inference you can make from those partial samples. There's obviously not as much as you would like to be able to do, but you don't really lose everything. You lose a lot, but you don't lose everything.

So severe budgets are going to cause severe problems.

But, Mike, I don't know if you want to talk anything about the cost model itself or just save that for some other time.

DR. LIPSETT: Yeah, I think we'll probably save that for another time, because we don't have materials to give the Panel that they can look at.

But I think suffice it to say for now, when Randy

said it was really detailed, he was not exaggerating. Yeah, it's a very detailed cost model, including going down to the costs of disposable supplies and everything, meaning for sample collection and costs of transporting the samples. And very, very detailed operational costs.

One thing I wanted to mention before the public comments, I wanted to raise this again --

OEHHA DIRECTOR DENTON: You're going to need to speak up.

DR. LIPSETT: Oh, I'm sorry.

One thing I wanted to mention again is we would like to see if there's any interest on the Panel of having a small subcommittee to meet with our staff on issues related to study design. And this would include not only some of the trade-offs that Randy is talking about in terms of over-sampling and the effective design effect and analytical sample size, but questionnaire development. And as you're going to hear later this afternoon, the labs are in the process of undertaking some pilot studies. So we want -- we'd like to have a couple, at least two to three members of the Panel who would be interested in meeting periodically with us, probably by conference call or perhaps in person, to discuss some of these issues as we progress through them.

PANEL MEMBER BRADMAN: Michael, are you -- this

is Asa Bradman. Are you talking about two or three different subgroups?

DR. LIPSETT: No, one.

PANEL MEMBER BRADMAN: Just one. And this one would focus on questionnaires, laboratory, and design issues?

DR. LIPSETT: Well, mainly design types of issues. But I'm lumping the questionnaire design as well within the overall study design issue.

And then with respect to the lab pilot studies, it would be like what kinds of processes the labs would be needing to pilot test; what are the criteria that we should apply, for example, with respect to this Request For Information that's going to be discussed by the labs later in terms of our analyzing archived samples, because the laboratories are going to be up and running before the rest of the sampling design is. So we would have kind of a broad scope of coverage, this particular -- I mean, we could have several committees. But that -- I mean, considering the size of the Guidance Panel, that's really not going to work.

PANEL MEMBER BRADMAN: I'll volunteer.

DR. LIPSETT: Thank you.

That's one.

CHAIRPERSON MORENO: Okay. We have one

volunteer. Dr. Bradman.

Others interested?

PANEL MEMBER KAVANAUGH-LYNCH: (Hand Raised.)

CHAIRPERSON MORENO: Two, Marion.

CHAIRPERSON MORENO: Others?

PANEL MEMBER McKONE: I'm quite interested in the sample -- I mean the statistical design and, you know, what it represents, the population modeling and segmentation.

I can't help too much with the questionnaire though.

CHAIRPERSON MORENO: Okay. And the staff is recommending four Scientific Guidance --

MS. HOOVER: Four total, maximum.

CHAIRPERSON MORENO: -- Panel members. We have three volunteers so far.

PANEL MEMBER CULVER: This is Dwight Culver. I'm interested in the questionnaire design.

DR. LIPSETT: Okay. So we've got four. That's the max that we can have.

Okay, great. Thank you.

CHAIRPERSON MORENO: Thank you.

Thank you, Panel members.

Okay. I'm going to ask -- oh, here we go.

MS. HOOVER: Any other -- no.

PANEL MEMBER McKONE: Just a comment.

You may want to consider splitting it into questionnaire versus sample design. Aren't they quite different? In my mind, they are. I mean -- then you'd have two and two. And, you know, when you're working on the questionnaire, I don't think I can help much.

DR. LIPSETT: Well, I think -- why don't we start for now with the four, and then we can -- we may want to split into two smaller subgroups that would be, I'm assuming, Dr. Kavanaugh-Lynch, Bradman and Culver, and then the other group would be Dr. McKone.

(Laughter.)

PANEL MEMBER McKONE: Less than four.

(Laughter.)

PANEL MEMBER SOLOMON: If you'd split that way, then I'd -- you know, I'd be happy -- I'm not fabulous at study design, but that's the side that I'm more interested in.

PANEL MEMBER KAVANAUGH-LYNCH: And I'm actually interested in both.

DR. LIPSETT: You're interested in both. Okay.

PANEL MEMBER McKONE: Could have it three and three.

PANEL MEMBER SOLOMON: Staff can --

PANEL MEMBER McKONE: We'll go whatever way you

think is best.

CHAIRPERSON MORENO: Would you prefer to have one initial meeting and then go from there?

DR. LIPSETT: Yes.

CHAIRPERSON MORENO: Okay. Of the four?

DR. LIPSETT: Yeah. And then we can talk to Dr. Solomon. After that, if we decide to split it into two groups, then --

PANEL MEMBER SOLOMON: Right. I mean, if you decide to split into two groups and you're looking for additional folks for one of the subgroups, consider me, you know, backup. But if -- I mean, it seems like you've got a good subgroup now. So if you keep it as one, that's fine.

DR. LIPSETT: Okay. Thank you.

CHAIRPERSON MORENO: All right. Then I'm going to -- I'm going to move forward with questions from the public. We do have one submitted - Davis Baltz.

Welcome back.

MR. BALTZ: Thank you.

Is this the --

CHAIRPERSON MORENO: State your affiliation, please.

MR. BALTZ: Yes. Davis Baltz from Commonweal.

Is this also the place to offer a public comment

on everything we've heard today or just on the presentation?

CHAIRPERSON MORENO: I think this is a good time to do it, yeah.

MR. BALTZ: Okay. Well, first of all, thank you, Director Denton and members of the Panel, Dr. Moreno.

MS. HOOVER: Speak up a little.

MR. BALTZ: Okay. I appreciate the chance to be with you again.

A couple comments on the presentation from Dr. Curtin. I mean obviously a probability sample would be preferable so that we have the scientific rigor to back up policy proposals that might stem from the study. And so to the extent that those are possible, as a member of the public who's going to -- has and will track this carefully, we'd really like to see the results of the program be statistically strong enough that then proposals that come forward can have strong backing from across the spectrum. I think that probably goes without saying.

And then a comment that Dr. McKone suggested, pooling samples to try to save money. Obviously, we'd need to try to conserve resources. Although, we need to remember that the statute does provide for individual study contributors to receive individual results. So if you pool the samples, you may have to go back and do them

again anyway, unless you knew that the people who were agreeing to have their samples pooled knew they didn't want their individual results. So, in fact, you would probably have to do it twice anyway.

But all of it comes back to the budget. And Dr. Lipsett gave the overview slide. I think given the uncertainty that we have with California's budget situation -- and I know that the staff of the program have talked about this -- I think it would be very valuable for the program to try to generate some data this year that could be published. And even if it doesn't have the kind of statistical significance that we would ideally like, it would really be valuable for the program to publish some results and -- particularly if it focused on some communities of concern, so that we could demonstrate to the Legislature and to the Governor that this program really is something that the public is interested in. And that may lead to some opening where additional funding can be provided so the program cannot only stay at base level funding, but actually have some increases that will enable it to get back on its original schedule to publish a statistically significant study every two years.

Right now we're sort of behind schedule, we all know that, and we all know why. Everyone is willing to be patient. But with the budget situation as it is, it would

just be a shame if the program sort of withered on the vine because there wasn't sufficient public understanding of its value.

And a final short comment on the budget situation. The DTSC Toxic Substance Control Account from which the program is to be funded this year, you know, maybe that's going to be the better solution over the long haul than a General Fund line item. We don't know how this account is going to fare this year and into the future. So on the surface, the General Fund sounds like a better bet.

But one thing about the DTSC fund is that -- as we know this program is a collaboration of three different agencies and offices, two of which are in Cal/EPA and one of which is Department of Public Health. So I have a lot of trepidation about the Department of Public Health having to rely on a Cal/EPA, a DTSC account for its funding, and is there going to be, you know, the potential for roadblocks to be put up for the Department of Public Health to receive the funding that they need to keep the program on track?

So thanks for the chance to comment.

CHAIRPERSON MORENO: Do Panel members have any questions or response to the public comment this morning?

Anyone in southern California?

PANEL MEMBER LUDERER: No.

CHAIRPERSON MORENO: We have one comment here.

PANEL MEMBER WILSON: I just have a question now. Mike Wilson.

Davis, your suggestion was to try to generate initial data, and focusing on, you know, community of concern of some kind. And I'm wondering if there is -- if you have suggestions about what that community would look like. What would be a reasonable focus?

DR. LIPSETT: Before Davis responds to this.

You are going to hear this afternoon about this Request For Information that the labs have put out, where we do want to have the labs analyze some archived samples from an ongoing epidemiologic study. And that because the labs are going to have their new equipment installed and ready to go, hopefully within the next few months, that we do hope to generate some results within a year after that. That may not be quick enough for Davis, but -- I don't know. Davis, do you want to say anything more about it?

MR. BALTZ: Yeah. I mean, it's a little bit of a tricky question, because the program wouldn't want to be perceived as, you know, cherry-picking a certain community and prioritizing it over another community that might also be, you know, very valuable to have a look at.

And a small study, we probably wouldn't have

statistical significance either.

But one idea that I would have would be in the same way that the program is putting out a request for collaboration with people who might have samples that could be biomonitored. The program could potentially put out a similar sort of, you know, request for interest from communities who would like to be biomonitored. So I, you know, would be interested to see some occupational exposures looked at in more detail for an example. I think there's a number of Environmental Justice communities in California who might step forward and have a geographic focus as a fence-line community, would be another possibility. Or, you know, certain groups who have a common disease burden might be another idea.

PANEL MEMBER WILSON: Thank you.

CHAIRPERSON MORENO: Is that it?

OEHHA DIRECTOR DENTON: I think that's it.

CHAIRPERSON MORENO: Okay. Well, I'm looking at the agenda for today. And if there are no more questions from the public and the Panel on this last presentation, my recommendation is the Panel could break for lunch. It's noon now.

We have a presentation starting at 1:15?

MS. HOOVER: Yeah.

CHAIRPERSON MORENO: Is that the time that's

recommended that we come back?

MS. HOOVER: 1:15.

CHAIRPERSON MORENO: 1:15. All right.

Any other announcements before we break?

No?

All right. Thanks.

(Thereupon a lunch break was taken.)

AFTERNOON SESSION

CHAIRPERSON MORENO: Let's get started, everybody. Welcome back.

Do we have southern California on the line still?

Southern California, are you still there?

Dr. Luderer?

PANEL MEMBER LUDERER: Yes, we're here.

CHAIRPERSON MORENO: Great.

Okay. We're back at about 1:20. We're going to get started again.

And, at this point, I want to introduce Dr. Michael Lipsett.

Dr. Lipsett.

DR. LIPSETT: Okay. Thank you, Dr. Moreno and Panel members.

This morning we heard about a number of the issues that we've been grappling with with respect to study design. And this afternoon it's going to be a briefer, pretty non-didactic session with the two lab chiefs about where the labs are in this whole process. They're further along really than the rest of the program. And they're going to be giving you kind of a progress report, and then discussing as well this Request For Information that we have distributed or disseminated to the research community to try and identify potential

university collaborators, so we can analyze some other types of samples.

So making the presentation for Department of Public Health Laboratory is Dr. Peter Flessel, who's the Chief of our Environmental Health Laboratory Branch in Department of Public Health; and Dr. Myrto Petreas, who is Chief of the -- she's not the chief. That's right, Bruce -- her supervisor's the Chief of the Environmental Chemistry Laboratory.

DR. FLESSEL: And he's here.

DR. LIPSETT: He's here. So --

(Laughter.)

DR. LIPSETT: Oops.

(Laughter.)

DR. LIPSETT: Dr. Myrto Petreas will be making a presentation for DTSC.

(Thereupon an overhead presentation was Presented as follows.)

DR. FLESSEL: Thank you, Michael and distinguished Panel. Thank you for having us back.

I have to say, I don't know how you feel about this, but -- what about this? Does this go in? I hope so.

Every time somebody says the labs are further along, I kind of have this little chill.

(Laughter.)

DR. FLESSEL: But we feel like the increments are important. What we're here to do today is basically update you on the things that have been happening in the laboratory. It may not seem all that different than what you've heard before, but we've been working very hard. Just the process of getting equipment purchased, huge effort. So we're eager and we're moving on.

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DR. FLESSEL: Just to remind you, that we are fortunate to have two labs involved in the program. Our laboratory in the Department of Public Health will focus on the nonpersistent organics and the metals. Because we're looking at nonpersistence, we'll typically be looking at urine specimens. That's the best way to look for those kinds of chemicals. And we'll look for metals best tested in blood.

Our lab also has the responsibility for processing and archiving the samples. So we'll have a bio-bank eventually within the Department -- within the program.

And then Myrto's lab will focus on persistent organics, which are best tested in blood and serum because they are less water soluble, more fat soluble.

So we have made progress -- next slide, down

south. We're on slide 3 now.

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DR. FLESSEL: We've been able to hire our staff in both of the departments. There are five in the Department of Public Health and two in DTSC that are devoted to this and supported by this program.

And we have undergone some remodeling to accommodate the new lab equipment. And that's almost done. And here, these slides probably don't impress you the way they ought to. But right --

(Laughter.)

DR. FLESSEL: -- right behind Dr. Moreno there is a space -- a blank space. And if you look very carefully, you see it's a little different color on the floor. There used to be a lab bench there, and we got it cut out. And that was a major step forward. As well as the materials that you see that are going to be installed, ventilation material.

So it's going -- and, in fact, I should tell you that one of the -- one small impact -- large for us, but small for the program - of the budget impasse was that in our lab at least the Department of General Services stopped work without the budget. And they were the contract that we're bringing to do this.

But in a certain way, it helps us, because we had

originally thought that we would have the lab completely renovated and ready to go when the equipment came in, and then we would just drop it in and go on from there.

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DR. FLESSEL: Actually, it helps that the equipment is coming in at the same time, because it's easier to make the renovations when you have the piece of equipment sitting on the bench. You can know exactly where it's going to fit. So, in a sense, we lucked out.

We have been able to purchase the major pieces of equipment. They're either arrived -- they've either gotten here -- here you see some boxes. Proof that at least one of the instruments has arrived in our warehouse. This is our new ICPMS. Others will be arriving soon. We have delivery dates for most of the equipment now.

And then we have finished our Memo of Understanding with the CDC. We signed it just a few weeks ago. And you have a copy in the -- in your packets, the Panel does. And I think there are copies on the back table.

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DR. FLESSEL: The MOU describes the lab support that CDC will give to the California Environmental Contaminant Biomonitoring Program in two areas: One, CDC will provide lab training. They'll also provide analysis

of samples for us.

The training has to do with learning how to do their methods at CDC. So we'll be sending staff back to do that.

And, in addition, the process of sample collection and processing and shipping is complicated. And having a model to use and getting training from CDC in those steps is immensely helpful to us, so we don't have to start from scratch.

And then CDC has told us that they will do a number of kinds of chemical tests for California's program. First of all, they'll prepare QC samples and help us with our quality control by providing samples that have target values, and see how well -- they'll send it to us blind, and we'll see how we match up with that. That's very, very valuable.

They'll be willing to -- in fact, they have provided us some expensive standards already for certain -- from the OP metabolites. We received some specimens from standards from Dana Barr's lab a couple of weeks ago.

And they'll continue to do that as they're available, because standards are enormously expensive. You could spend your whole -- if you wanted to make them yourself, you could spend your whole life making them. Or

if you wanted to buy them, you could spend your whole budget on that.

They have agreed to do a -- support a community study involving 500 samples for the range of CDC panels. In other words, CDC's got 10, 15, 20 panels of chemicals. And as needed, they will do 500 samples. And they'll also support a one-chemical study that will involve measuring one specific chemical, PBEs, lead, whatever, in 200 participants. And they'll also do for us something that they'll -- they've always been willing to do this for California and anybody else -- any other state -- assist with exposure incident response. So if we had a major industrial accident, a rail car derailment, something like that, where there was major community exposure, California needed some quick assessment of what might have occurred; tire fire in Fresno, whatever, they're willing and able to do that.

Now, I should give credit where credit is due. Behind me sits several people who are much more responsible for items 2 and 3 under that second bullet.

The willingness of CDC to help us with community studies came out of an initiative that was driven by the NGOs, which resulted in a letter from Nancy Pelosi to the Director of CDC, Julia Gerberding. And it was in Dr. Gerberding's response that she said basically that they

would do these things. And so when we sat down to write the MOU with them, we incorporated those items in. And, of course, CDC was fully committed to do it.

So, again, thank you.

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DR. FLESSEL: Lab challenges remain.

You hit me when I'm supposed to pass it over to you.

(Laughter.)

DR. FLESSEL: We, in the Department of Public Health, still do not have operating funds for running the lab. Chemicals, standards, solvents, glassware, et cetera, we don't have any in our operating budget.

And Myrto's lab has only two staff dedicated -- supported out of the Biomonitoring Program. And this is well below the critical mass to really drive much progress.

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DR. FLESSEL: Next steps. I mentioned we're in the process -- almost in the process of setting up the new equipment. Followed hard on that will be training of staff, both with the vendors as well as at CDC. We will be seeking to develop and validate our methods to meet the high QA/QC standards that you have to have for this kind of a program.

We'll be sending staff to CDC to get the training. And we'll be beginning our process to develop a plan to manage samples and think about how we can increase throughput.

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DR. FLESSEL: One small initiative in terms of actual testing that we've begun to plan for, this is a collaboration with a health tracking study. Those of you who have gone back through the story on health tracking -- I know several of you were on the 702 panel -- I emphasize the need for in the early stages -- health tracking and biomonitoring should work together. And in the legislation, in 1379 it says the same thing.

So we feel comfortable in responding to an initiative from the tracking program to assist them with a pesticide drift study out in Tulare County. This is a study that has the involvement of local health and community clinics out there. It's designed to see whether you can get some information about exposures in these buffer zones around the fields where there are lots of people. So the requirement for the study, which came along before us, was to do very sophisticated GIS mapping all over California. This is what the tracking program is so great at. And they were able to indicate where people are and where pesticides are used.

And so, at that point, there was interest in having the laboratory sit down with them and think about, "Well, could you do this in so many samples for us," and so on, as a way of maybe developing better buffer zones around the fields that are sprayed with pesticides. So that's where we're trying to plug into that small program.

We'll be able to test the collection and transportation of specimens, in this case urine specimens, from the field to the Richmond Lab.

And then sometime in 2009 -- I can't really tell you when, but I'm confident we'll get them some results in the next calendar year -- we will analyze samples from 30 participants that will actually be probably something like 100 specimens all told for the metabolite chlorpyrifos.

DR. PETREAS: This morning we heard about the complexities of choosing the proper sample design and the resources, and the time it would take to get to the proper design for a statewide survey as per SB1379.

On the other hand, our labs work on a parallel track trying to build capacity and capability to analyze the chemical classes that the program would want.

And as we get ready and we get our equipment and we have our methods fully validated, then we would like to have some real samples so we can produce some real results. And we have three ways to get -- to work with

real samples. And Peter already talked about the health tracking, one small study that his lab can handle.

Last June, we talked to you about obtaining approval from IRB to conduct a pilot study to test the laboratory components of the study. And that involves from selecting the samples, shipping them, labeling them, making sure the samples arrive to the lab intact. And then we do our methods and QC and produce valid data.

So our project was started with the phlebotomist. We didn't have any interest in that project on who the donors are. So, at this point, -- and Michael referred to that -- we started to develop criteria on selecting donors, that maybe then the data will make some sense. And that's where you're invited to help us with this selection criteria.

And we'll talk more about this in December. So I'm just mentioning this here.

Now, a more direct way to get samples directed to the lab is to go to the freezers. So we want to find collaborators who already have collected samples and work with them.

So in your packets, you have this copy of the RFI, the Request For Information, that we sent out. And in the next slides we'll take you through that.

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DR. PETREAS: So basically the goals that we described in the RFI is that we want to use the archive specimens collected in the last few years from California. We want to use our new equipment and our new validated methods to produce real data that we can share and see where we are. An important thing is to see what to expect when we do the real study, the big study. For the labs, it's very important to know so we can optimize our equipment, to make sure we can measure what we need to measure.

So just assessing the ranges of certain chemicals is very important. And, of course, by doing these collaborations, we'll be adding value to the ongoing -- or the original study of the collaborator with whom we're going to work.

Next slide.

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DR. PETREAS: So the RFI describes the criteria -- objective criteria hopefully to select among the respondents for one or more collaborators. Basically, the chemicals that our collaborator would like us to use to analyze for should be compatible with the ones that the program wants. And I think it's on page 3 of the RFI packet we list what we can do now in terms of classes.

The samples are very important. What type? We

are focusing on urine and blood, because these are the samples that we'll be using in the program. And from, again, a lab's perspective, switching matrices and going to different material is very distracting, and I don't think it will help us. We really want to stay with blood and urine.

Another important factor is the condition of the sample, whether it was collected properly for what we want to use it. There are proper tubes, the proper storage, handling. So making sure that it was not cross-contaminated and then the valid samples were analyzed. That's very important.

Of course, population. We assume that the basic demographic information will be shared with the collaborators so we can know what to infer. And it's very important to use a -- or select a population that we can make some inferences on. So that we want basic criteria when we judge the proposals.

It has to, of course, have sufficient volume to allow us to do the analysis. But also it has sufficient sample size -- samples from the sample size to make some useful, more valuable information.

Again, we want to have recent California samples, taken maybe the last three to five years. And we would prefer to work with children or pregnant women or other

high interest, high-risk groups.

Funding, at least partial funding, is one of the key criteria here. As you heard, we have very limited resources. So if someone comes with funding, it's a plus.

And as with any collaboration, we need to be up front about data ownership, how we can use the data and co-authoring papers.

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DR. PETREAS: And, again, the RFI timeline -- next slide. Yes, next slide.

This is again from -- this is from the RFI. So in September we sent out the Request For Information. And we sent it to everyone we could think of: Academicians, university researchers, the EPA, the CDC, any contacts we had, even vendors of equipment and the standards so that they can spread the word. And, hopefully, we will reach everyone who may have an interest to respond.

So far we haven't had any response yet. But we still have until November 1st to get the submissions.

And then we envision, some time by January, we should have selected collaborators and start talking with them. And in February finalize and negotiate and execute the materials transfer agreements.

With a plan that in the spring -- we say March here -- maybe we'll push that later -- the samples will

come to the lab. And the intent is to have approximately 200, 300 samples which we'll analyze. And within a year, we should have data so we can go back to the Legislature, as we have to do by 2010 with the first report, and show something to keep the program alive and keep the interest. That you heard this morning that we'll have some real data.

Next slide.

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DR. PETREAS: So, in summary, we've heard the initial hiring has been completed. We're making progress with renovating the labs, procuring the equipment, setting them up. We have a plan and so forth.

But we still have problems. DPH lab has no operating money and we have no staff.

So with the current resources, we can only do, as we say, small collaborative studies to test a limited set of chemicals in small numbers of participants. And examples we gave is the health tracking, the collaborations as a response to the RFI, and the pilot that we can talk about, you know, in December.

So in order really to do the statewide or any large scale study, we need more resources.

And that's where we are.

CHAIRPERSON MORENO: All right. Well, thank you

for the update on the laboratory progress.

At this time, any questions from the panel or speakers?

PANEL MEMBER BRADMAN: I have a question. Asa Bradman.

Is part of the criteria for responses to the RFI be that collaborators can return results to participants in those freezer-drawn samples?

DR. PETREAS: If it's compatible. If the RFI isn't compatible, you have to talk about that. There are many things to explore.

PANEL MEMBER BRADMAN: But that's not a criteria.

DR. PETREAS: We would like to, but it's not an absolute -- it's not a deal killer.

CHAIRPERSON MORENO: We have a few more questions here.

PANEL MEMBER QUINT: Yeah, Julia Quint.

I guess I'm a little confused about the budget situation. This morning it sounded more optimistic, I guess because I heard what I wanted to hear.

(Laughter.)

PANEL MEMBER QUINT: But it sounds now that we -- with the presentation by CDC, we don't have the capacity budget-wise or, you know, resource-wise to do anything other than this very limited sort of study based on

existing samples. Is that not correct?

DR. FLESSEL: Certainly, that's correct.

PANEL MEMBER QUINT: So -- how do I ask this question? Because I had the impression with whatever has happened in terms of releasing -- changing funding sources or whatever, that there was more optimism about budget potential or resources. But now I'm hearing that that isn't true. I'm just a little confused.

OEHHA DIRECTOR DENTON: Well, I can just -- maybe I can just cut to the chase. We are lurching from year to year on this funding. And right now the baseline, which includes the resources Michael mentioned, we have to make sure that we know that baseline is protected. And then that doesn't include potential growth. We've gone through all of the internal State procedures one does to increase the funding and the funding source. But given the state of the budget, we just -- it's an uncertain time for us, I guess would be the nicest way to put it.

DR. LIPSETT: Julia, can I respond to your question?

PANEL MEMBER QUINT: Yes, please.

DR. LIPSETT: One of the things I said this morning was that there was some good news and that we were -- our budget was maintained. We were facing a 10 percent cut. In fact, we have had to put in for a 10

percent cut as long as we remain part of the General Fund. But because we did not -- did not stay on the General Fund, we were not subject to that 10 percent cut.

Now, we're looking at a scenario where we -- we had a new program just getting started and our budget's hacked by 10 percent if we stayed on the General Fund. That didn't happen.

But the fact remains that the current base budget does not include operating expenses for the DPH labs. And the reason for that was that the laboratory people were trying to be conservative and budget-conscious in their first budget, because they knew that they would have equipment that would take awhile to order and be built and have it be installed, and they were not likely to be operating the equipment during the first fiscal year. So they did not include that. They were assuming that they would get funding for it in the next budget cycle, which turned out to be an erroneous assumption.

So that's why Peter was talking about that really severe kind of constraint on what they can do at this point.

DR. FLESSEL: I'll give you one other positive aspect of this funding switch. The Governor when he signed the budget said, "I'm going to take 400 million out of general operating in the State." And so that trickles

down to various units and divisions and so on.

Being over in the DTSC funds this year, we don't have to deal with those drills, which are coming down all the time, where they're asking us, well, project what -- I want another 10 percent, another 15 percent.

I had the same reaction that Michael had when we first heard about this. Oh, my gosh, this is a sort of replay of something that happened 15 or 20 years ago going over there. But short-term we feel good.

PANEL MEMBER QUINT: Right.

DR. FLESSEL: It doesn't build us. But it's relative, right? It's been down so long, it looks like up to me.

(Laughter.)

PANEL MEMBER QUINT: Right. And I haven't been out long enough to not appreciate what you're talking about.

(Laughter.)

PANEL MEMBER QUINT: So the bottom line is we need to do these short-term pilots to establish and maintain interest in biomonitoring. So that's imperative, it sounds to me.

DR. PETREAS: To keep the program alive.

PANEL MEMBER QUINT: To keep the program alive. It sounds like keep hope alive, but --

(Laughter.)

DR. LIPSETT: We don't want this to have the same fate as the hydrogen highway that was so high profile a couple of years ago.

PANEL MEMBER QUINT: Exactly.

CHAIRPERSON MORENO: Mike and then Gina next.

PANEL MEMBER WILSON: Mike Wilson.

Yeah, I just -- first of all, just commend you for working with what we have rather than sort of saying, you know, well, the Bill stipulates we have to do a representative sample; we don't have the funding to do that, so we're stuck.

That leveraging the CDC and leveraging these other sources and what have you, I think it's just really commendable and creative.

And I guess -- and my question is, if you think that -- how confident are you that there are samples out there in the community that we will be able to draw on? I guess the question is, do you have an indicator that we have -- that the samples are there?

DR. PETREAS: The samples are there. Whether they're -- we know many resources who have samples there. Whether they're compatible, whether they want to work with us, we don't know. Nobody has submitted anything yet.

DR. LIPSETT: Although, we've received a number

of inquiries from people who are potentially interested, but we haven't had any formal submissions.

DR. FLESSEL: It's a new concept.

PANEL MEMBER BRADMAN: You'll get a couple by the end of the week.

(Laughter.)

CHAIRPERSON MORENO: All right. Gina.

PANEL MEMBER SOLOMON: So I guess I've heard really four different kinds of study designs that are really being discussed right now. One is what we heard about this morning, which is obviously sort of what we're aiming for in the longer term.

And then the others include a CDC community study of 500 people that they've committed to. And another being a one-chemical study, which might or might not be sort of part of the same study that CDC is committed to. And then the other being these sort of methods development pilot studies that are the subject of the RFI.

And so this morning we created a subgroup of our Panel to think about that big longer term set of study design questions. But I guess my question is, since, you know, we do have these other at least three kinds of things that are happening and that we -- you know, that seem more feasible in the near term, should we actually be throwing some more of our resources as a Panel into trying

to really help make those as strong as possible, help, you know, offer ideas and suggestions for those pieces?

DR. LIPSETT: Well, actually, that's what we had in mind for this Panel, that we would be considering all these different things and not just the statewide one. We wanted to surprise you this afternoon.

(Laughter.)

CHAIRPERSON MORENO: So I have a thought, I guess. My thought was that the -- this is Ed Moreno -- the big study that the group will be working with staff on in the design is one thing. But that the subcommittee would consider the community study, because in some way they need to be linked. And I think that -- my thoughts are that the population that defines this community study and the chemicals that are tested in this community study would also be the same chemicals that are tested in the larger Biomonitoring Program so the comparisons can be made in the future.

And then as far as the chemical study, it sounds like that's a study in response to an exposure event of some sort?

DR. FLESSEL: That's not really a study. That's an emergency response which CDC would make.

CHAIRPERSON MORENO: Okay. And so --

DR. FLESSEL: But that's different than the four

that we've just described, that Gina just reviewed.

CHAIRPERSON MORENO: Then as far as this chemical study, it's a response --

DR. FLESSEL: It's an incident response, not a study.

CHAIRPERSON MORENO: Incident response. Thank you.

But there will be some sampling done? CDC will come out to provide some sampling among the exposed population?

DR. FLESSEL: No. But we should -- I thought about not even putting it into my slide. But --

CHAIRPERSON MORENO: If there's no sampling, then okay.

DR. FLESSEL: The sampling would be done locally typically. Somebody -- if it's a train car wreck in your town, your public health people are probably -- and your hospital people are probably collecting the samples. And CDC then takes them home and analyzes the population that you tell them is probably at greatest risk for exposure.

CHAIRPERSON MORENO: Okay. Well, then just --

DR. FLESSEL: Different topic completely.

CHAIRPERSON MORENO: Okay. Then perhaps the guidance panels and the programs could maybe keep track of exposure events as they occur and have an idea of which

types of exposure events would trigger a call to CDC, because the exposure was to chemicals that are also being tested under the Biomonitoring Program. Then you can make -- because then you can compare that to the baseline that's been collected over time.

DR. FLESSEL: My response would be that that activity is completely separate from the biomonitoring work that we are collaborating on. That is a kind of -- emergency response would occur every once in a while.

Dunsmuir: Kid brings a jar of mercury to school, drops it, and it goes all over the floor. And you've got a bunch of kids potentially exposed. They want to know quickly if there was exposure. CDC will help. But that's not, I think, what we're doing, so it wouldn't matter.

CHAIRPERSON MORENO: I know it's not the same.

Okay. Those are my thoughts. Thanks.

PANEL MEMBER QUINT: This is Julia. I have a question about the CDC's, you know, commitment to doing a community study.

Does that mean just doing the samples or actually doing all of the sort of collection of the samples and all the front part of that part of the study?

DR. FLESSEL: We would be involved in the front-end.

PANEL MEMBER QUINT: Right, because that's a big

difference. I mean analyzing the samples is a huge commitment, and that's great. But it sounds like we don't have money right now to do the front-end of that kind of a study. Am I not correct?

DR. LIPSETT: You are correct.

PANEL MEMBER QUINT: Okay.

DR. LIPSETT: Yeah. No, the MOU is between our laboratories and the CDC laboratory. And, you know, they'll be responsible for the analysis, but not for the field logistics.

PANEL MEMBER QUINT: But we still need the questionnaires, the door-to-door, whatever else would be involved in that kind of a study?

DR. LIPSETT: Right.

CHAIRPERSON MORENO: Okay. Other questions from the Panel here in Oakland?

Yes.

We need a microphone next to her.

PANEL MEMBER KAVANAUGH-LYNCH: Yes. I'm just brainstorming here. So you've come up with an RFI to try to take advantage of researchers' resources and their access to funding as a way to pilot the screening methods.

Could we also possibly take advantage of community interest and community resources and their access to funding to start to develop and pilot the

recruitment and sample collection and maybe even testing for community studies? And I'm kind of thinking of the idea that Davis suggested of some sort of RFP out to communities to say, gee, are there communities out there that are interested? And just like you did to researchers, you said there had to be funding available, you know. So we -- in RFPs to communities and say if you can come forward with interest and expertise and funding, we want to partner with you on -- in doing biomonitoring in your community.

DR. PETREAS: We only focused on the laboratory here. So the researchers, we have to go to their freezers -- from their freezers to our freezer. So we bypassed other equipment and so forth, which takes resources and --

PANEL MEMBER BRADMAN: But in --

DR. FLESSEL: And we're so limited. We're just thinking small. Definitely your idea's a good one.

PANEL MEMBER BRADMAN: But in a way, you are doing that with the chlorpyrifos project in Tulare county.

DR. FLESSEL: Well, that's true. But we came in at the end. We didn't go to them and encourage them. They came to us and encouraged us.

DR. PETREAS: So they were going to do it anyway?

DR. FLESSEL: They were going to do it. And they

weren't sure how they were going to get the samples analyzed.

DR. LIPSETT: Yeah, I think that's a very interesting idea. And you're certainly right, that a lot of NGOs and CBOs could access foundation funding money that we would not be able to access as State organizations.

So I think this is one -- this is an idea that we could certainly discuss in the smaller work group too about how something like that would work, what it would look like and timeframe and the kinds of objectives. I think it's a very good idea.

CHAIRPERSON MORENO: Julia, did you have any other questions?

PANEL MEMBER QUINT: Well, I wanted to just agree with that idea, because having talked to a lot of groups, I think there's wellness and maybe other funding out there that the State -- we wouldn't be eligible for. But what would be important is the expertise of, you know, the researchers and folks here to help -- you know, that would have to be sort of an in-kind, I would think, in such a study. I'm not sure how many community groups have, you know, the kind of expertise that would be needed. But I may be wrong in that.

DR. LIPSETT: Well, another potential hybrid

would be to have community groups partnering with the academicians --

PANEL MEMBER QUINT: Right, that's true.

DR. LIPSETT: -- to help design that to respond to such an RFP.

PANEL MEMBER QUINT: And we're considering that. I'm on a work group for the PRHE, the Program on Reproductive Health and the Environment. And we are actively looking for those sorts of collaborations right now. So I think that's an excellent idea.

DR. PETREAS: The way we put the RFI was to try to get samples sooner, because any kind of recruitment would take funding, would take time. Because we want to get something within a year.

PANEL MEMBER QUINT: Right. I think a parallel course. Not either/or but parallel.

DR. LIPSETT: Yeah, I think that Dr. Kavanaugh-Lynch was intending for this to be a way that we could help the program grow, given the constraints that we have right now fiscally. And it's not something that would intrude on the RFI at this point.

DR. PETREAS: But the bottom line remains, that the labs can only handle so much. So we can't have both based and the other and something else.

PANEL MEMBER QUINT: No, I understand.

CHAIRPERSON MORENO: Okay I'd like to ask Dr. Luderer if there are any questions from southern California.

PANEL MEMBER LUDERER: We have two questions here.

PANEL MEMBER CULVER: Not so much a question as -- this is Dwight Culver -- as a comment.

I am somewhat familiar with two fairly large biospecimen banks. And I know that the people that are responsible for them are very, very stretched for funding. And to ask them to go into their banks and pull out specimens -- prepare specimens for shipment, it's going to cost them money. And they don't have the money to do that. And so that may be one of the reasons why you're not getting much of a response with your Request For Information.

CHAIRPERSON MORENO: Any comments?

DR. PETREAS: We still have a week.

(Laughter.)

CHAIRPERSON MORENO: Okay. Other questions?

PANEL MEMBER LUDERER: Yeah, I have kind of a related question, kind of getting back to the RFI and kind of -- also I think related to Dr. Kavanaugh-Lynch's suggestion for maybe trying to think of additional creative ways to partner with researchers and community

organizations. And, that is, you know, I understand that the way -- with the RFI currently, you'd like to have samples that are already collected, you know, preferably where there's funding, also currently already available. But I'm wondering whether it would be possible to, you know, partner with researchers in terms of maybe developing proposals, which could then be committed to actually fund -- you know, to help fund the analyses, and whether that's something that you might be willing to consider. Obviously, that's not something that could be done in a one-year timeframe. But, you know, potentially in a two-year timeframe something like that might be possible.

DR. FLESSEL: We're definitely interested in that, sure. The lab certainly is. The program is, right?

DR. LIPSETT: Yeah, I -- again, I think this is something that our new work group would be discussing as well, because what you're describing would require, you know, another RF -- either an RFP or an RFI in order to be able to do something like that.

CHAIRPERSON MORENO: Further discussion?

PANEL MEMBER WILSON: I want to -- sorry.

Thanks, Sara.

Mike Wilson. I'm just picking up on Dr. Culver's point, that I could see how that would be the case in the

lab -- in samples that we had worked with in Kathy Hammond's lab, that, you know, you get your samples and you catalogue them and store them and it's all laborious.

And so extracting those and then releasing them to an agency would be a large -- it would be a lot of work and uncertainty, I think, there. So I'm worried that this idea, which I think is really creative and could be really helpful, will fail because there won't be a response.

And so I guess my question is if it would make sense, just in thinking about my own experience -- if I was asked to produce samples, one thing that might be encouraging for me would be if there was a -- somebody from the laboratory that would actually come out and help me do it.

(Laughter.)

PANEL MEMBER WILSON: And just, you know, catalogue the samples and ship them. And I guess if that's within the realm of possibility for the laboratories, they have to take that on.

DR. FLESSEL: Actually, I think an epidemiologist could do that too.

(Laughter.)

PANEL MEMBER WILSON: Is there an epidemiologist in the house?

DR. FLESSEL: I think that's -- we'd have to come

to some kind of middle ground on that. But, yes. As Gina said, we can get students to do things like that too.

PANEL MEMBER WILSON: Uh-huh.

PANEL MEMBER BRADMAN: I related the issue -- and I think also it might be part of the reason why we haven't had so many responses, the interest in, you know, having some financial contribution from other researchers. I understand the need for that. I know in our situation, you know, we don't have a line item for that in our current budgets and we couldn't -- we couldn't do that without some sort of change with the agency - and, you know, there's a lot of issues involved, -- or a separate funding for that.

So there is kind of -- there could be some tension over that if that's a key criteria. And I know, of course, that everyone is strapped for cash right now.

DR. FLESSEL: Well, it is for us because we don't have an operating budget.

DR. PETREAS: Or staff. So we're --

PANEL MEMBER CULVER: This is Dwight Culver.

CHAIRPERSON MORENO: Yes, go ahead.

PANEL MEMBER CULVER: Blood banks sometimes get rid of out-of-date blood. Can you use any of that for initial pilot work?

DR. PETREAS: How much demographics will there be

with a blood bank?

PANEL MEMBER WILSON: What is the question?

DR. FLESSEL: Why don't we use blood from outdated blood bank specimens?

From a laboratory perspective, we don't know the difference. Yeah, there may be some program considerations.

CHAIRPERSON MORENO: I think one of the questions that was brought up was how much demographic information comes with the sample.

DR. PETREAS: From the blood bank.

PANEL MEMBER CULVER: Probably not much.

DR. LIPSETT: In addition, we would want to make sure that the samples were collected and stored in a way that would not promote any contamination with chemicals that we would be interested in analyzing.

PANEL MEMBER McKONE: PVC bags.

DR. LIPSETT: Yes, for example, right. There may be problems with phthalates.

CHAIRPERSON MORENO: But thank you, Dwight. Keep the ideas coming.

PANEL MEMBER KAVANAUGH-LYNCH: Well, I think there'd be serious IRB issues with that. I don't think you'd -- generally when people are donating blood, they're not consented for research uses for their blood.

PANEL MEMBER BRADMAN: If it's being thrown away? Different standards if it's anonymous.

CHAIRPERSON MORENO: I believe Julia has a question.

PANEL MEMBER QUINT: No, I just wanted to say I worked for many years in a lipoprotein research, and we used blood bank blood all the time. I don't think there was an IRB issue. It was -- you know, we isolated lipoproteins from blood bank blood serum. So I think there are researchers -- and I'd be happy to contact the ones I know who are actually using -- still using blood bank blood, and they may be able to contribute, you know, some part of their specimen. So I could at least look into that. I'd be happy to do it.

CHAIRPERSON MORENO: Gina Solomon.

PANEL MEMBER SOLOMON: So to be a little bit -- yes, Gina Solomon -- to be maybe a little obnoxious here. But, you know, like can the DTSC lab lend the DPH lab, you know, various lab materials that are needed for doing sample analysis and can the DPH lab lend the DTSC lab, you know, from time to time a staff person to help with some analysis? And are there ways that you guys can really sort of just throw -- you know, for example, if a batch comes in that needs to be analyzed, you know, in one lab or the other, to really sort of pool your resources to

get that batch of samples analyzed. And so that's one question. Because I certainly hope that can happen. That kind of collaboration should be great.

And then the other thing is, should we actually be talking -- identifying some specific researchers who we know have really nice, you know, samples in their freezers and start really bugging them? And is that something that you're thinking of doing? Should we be doing it as a panel? I've already, you know, been chatting with some people. And maybe that's something we should be doing, to just try to push them to make this a priority. Because I could see that some researchers may just sort of decide, well, it's a bit of a pain to do it and there's this whole form to fill out and it may not meet all of the criteria, so they just won't get around to it.

DR. FLESSEL: Well, I'd respond, first of all -- first question, not obnoxious at all. We've had those discussions. And, in fact, the first person who brought it up is Bruce. Where is Bruce La Belle? Bruce said, "Gee, we should be switching around however we can." Now, easier said than done. But in principle, we're committed to that. In practice, we'll see how it works. I mean, we just want to cross-train in our own lab, and then we'll think about cross-training in --

DR. PETREAS: And we do talk to each other and we

do have this --

PANEL MEMBER SOLOMON: Yeah, I know.

DR. PETREAS: But primarily focusing on certain instruments and certain matrices, it's more efficient this way.

CHAIRPERSON MORENO: This is Ed Moreno. A follow-up to that thought.

Dr. Denton, there's no reason why Panel members couldn't personally contact other researchers and make them aware of the RFI that's out there and the deadline to submit?

OEHHA DIRECTOR DENTON: I think we would encourage it. Yeah, you bet.

CHAIRPERSON MORENO: All right.

PANEL MEMBER WILSON: Mike Wilson.

And if we were to do that, are you looking for blood or also for urine samples?

DR. FLESSEL: Both.

DR. PETREAS: Both.

PANEL MEMBER WILSON: Yeah, okay.

And then the second is if -- looking at these, you know, sort of under-resourced entities like researchers and blood banks and other agencies that would be out there, have you contacted, you know, for example, Kaiser or Catholic Healthcare West, these other -- you

know, hospitals essentially that would have, you know, staff and funding to do this? Are they part of the mix?

DR. FLESSEL: I don't -- we haven't actively solicited particular individuals or organizations. But I did, through a contact with the tracking program, did meet one of the senior epidemiologists at Kaiser, who said, "Oh, we have this huge bank and we" -- this bio-bank on the Hudson somewhere. And I said, "Well, are you going to submit this?" "You know, I saw their invitation, and I don't think we'll get around to it." But definitely they're aware of this interest. It's a question of getting the right people to sit down with us. So maybe we'd have to take a more active role in this.

MS. LEE: Let me just comment that --

CHAIRPERSON MORENO: Identify yourself.

MS. LEE: Sorry. This is Diana Lee with EHIB.

The RFI went out pretty broadly to maybe roughly a hundred individuals, organizations, including with a request also that it be forwarded onto people who may not know about it directly. So some people may have even gotten it more than once. And it did go to Kaiser, I know, for sure. I don't think it went to Catholic Healthcare West. But if you know of an individual in particular, we'd be happy to contact that person and send them something.

We did try to send it to heads of researchers or people who were kind of in that position, who were in a position to be able to distribute it broadly. But we certainly -- if you have individuals in particular you want us to contact directly, please let us know and we'd be happy to do that.

PANEL MEMBER WILSON: Okay.

PANEL MEMBER CULVER: This is Dwight Culver again.

How many -- what is the minimum number of samples that you need for the pilot study?

DR. PETREAS: For the frozen archive specimens, we estimated 200 to 300 individual specimens. And this is given the resources of the lab.

PANEL MEMBER CULVER: Have you thought of going to clinical laboratories and asking them if you could piggyback on their activities, getting consent from patients?

DR. PETREAS: One thing we want is to have frozen samples, not something ongoing. We don't want to rely on their recruitment process. It will take longer. So samples which have already been done. It's in the freezer.

PANEL MEMBER LUDERER: This is Ulricke. Just sort of two questions.

One is, are you looking for 200 to 250 specimens all collected on one study and basically under one protocol, or that's just the total number of specimens that you'll be able to analyze and they could be from multiple studies?

And the second question, whether the RFI was sent to the, you know, contracts and grants offices at all the, you know, universities in California?

CHAIRPERSON MORENO: We'll have an answer for you in just a minute.

MS. LEE: Hi. This is Diana Lee.

It went to the Office of the President at UC. There's a key person there who handles that kind of distribution of grants information. And the person escapes my memory -- the name escapes my memory. But my understanding is that she posted it to a UC researcher list serve, and it should have been distributed broadly within the UC system.

So I can get you the name of that individual directly, but I don't have it at hand right now.

PANEL MEMBER LUDERER: Yeah, because I don't recall seeing it. You know, we have a grant newsletter that -- it's an electronic, and I don't recall seeing that. And that would be something that would certainly be worth exploring doing that maybe more directly.

MS. LEE: Okay. We can get you the name of that person and check with her on Monday.

DR. LIPSETT: And to respond to your other question, Dr. Luderer, with respect to whether all the samples needed to be from the same source. I think the answer to that is, no, they don't need to be. It would certainly be more convenient if it were to work out that way. But we're not -- we don't have a requirement that they all be from the same group initially.

DR. FLESSEL: But, still, I think from a -- this is Peter Flessel. I guess my thought is that the laboratory wants to add value to existing epidemiological studies. So it's not like we're just looking for specimens to analyze. We want it to add to something that's going on. And therefore, a study design with some coherent question with a significant number of samples would make more sense to us. Although, as far as we're concerned, one sample looks the same as the next. But we want it to feed into the larger issue of the program.

PANEL MEMBER SOLOMON: This is Gina.

My sense is that there's just about half a dozen researchers in California that have exactly what you want, you know, one way or another. And so if we just -- you know, I think this is like six phone calls to get plenty of samples. And so I'd be happy to help with that and at

least give my 2 cents about who those -- you know, who the people would be.

PANEL MEMBER KAVANAUGH-LYNCH: I think the issue is they want samples and money.

PANEL MEMBER SOLOMON: Yeah, but I mean --

PANEL MEMBER KAVANAUGH-LYNCH: That's much more difficult.

PANEL MEMBER SOLOMON: Yeah, but I mean I think very clear that they want -- the lab wants money, but that it's -- that it is feasible to do this analysis without getting money from the researchers, as long as the samples are provided for free. Is that correct?

DR. FLESSEL: It's certainly negotiable.

PANEL MEMBER SOLOMON: I mean, you'd love to get money but --

(Laughter.)

DR. FLESSEL: Yeah, that's correct.

DR. PETREAS: But we can't do both the pilot and the archive and develop methods, and, and, and...

PANEL MEMBER SOLOMON: Right. I know.

CHAIRPERSON MORENO: Okay. I think the important thing for the program is to at least get some response. Because once you get some response, then you have a process to go through which may involve some negotiation, if necessary, to come to an agreement so we -- so that we,

from the laboratory, can get what it needs. So the response is the important first step before the deadline.

And I also understand though, if necessary, we'd like to meet the deadline. But deadlines for these can be extended, right --

DR. FLESSEL: Sure.

CHAIRPERSON MORENO: -- if necessary?

DR. FLESSEL: Yes.

MS. LEE: We have sent out a reminder.

PANEL MEMBER WILSON: So if we are going to involve ourselves in this, at this time, who's the appropriate point person that we would refer to?

DR. PETREAS: Marta -- Is it Marta?

On the RFI, we have another contact name.

PANEL MEMBER WILSON: Oh, it's on the RFI. Okay.

DR. LIPSETT: Yeah. In fact, that individual is here. She's waving her hand in the back. It's Marta Lutsky --

PANEL MEMBER WILSON: Yeah, okay.

DR. LIPSETT: -- who's a graduate student in the School of Public Health, who's working with us on this program.

PANEL MEMBER WILSON: Thank you.

CHAIRPERSON MORENO: All right. Any other comments or questions from southern California?

PANEL MEMBER LUDERER: No.

CHAIRPERSON MORENO: Julia here has a comment.

PANEL MEMBER QUINT: This is Julia Quint.

When do you think -- or what is the possibility of restoring an operating budget for the laboratory?

DR. FLESSEL: That will happen when we can successfully get a Budget Change Proposal through. And through, in other words in the basic core funding. If we were able to work with researchers or others to submit grants, a different story. But we don't have an operating budget in our current base. That will only happen when we're successful with a Budget Change Proposal.

CHAIRPERSON MORENO: Follow up on --

DR. FLESSEL: 2010 is the earliest possible.

CHAIRPERSON MORENO: 2010-2011 fiscal year?

DR. FLESSEL: Fiscal year '10-'11, right?

OEHHA DIRECTOR DENTON: How about nine?

DR. FLESSEL: Oh, sorry, nine. I'm living in the future.

DR. LIPSETT: Nine. And we'll have a -- Julia, as you remember from your years of service in State government, this is a period of time during which Department of Finance makes its decisions about various BCPs. So we should have a sense of that within the next couple months.

PANEL MEMBER QUINT: Right. Yeah, but it just seems -- I mean, I know for, you know, add-on program sort of thing. Operating budget for a laboratory sounds so basic, it just seems to me -- I don't know how you're operating without a budget to do anything, let alone biomonitoring. But how can you be a laboratory without an operating budget?

DR. LIPSETT: They do have an operating budget for other programs, just not for biomonitoring.

PANEL MEMBER QUINT: Oh, but not -- now I understand.

All right. It's been too long.

(Laughter.)

CHAIRPERSON MORENO: All right. Any further comments from Panel members in Oakland or in southern California?

If not, I'd like to open it up to questions or comments from the public. I have one blue sheet requesting public comment.

Are there others?

Anyone else?

By the way, anyone wishing to make public comment or questions from southern California?

PANEL MEMBER LUDERER: No, there isn't.

CHAIRPERSON MORENO: Okay. Then I will ask Davis

Baltz to come back and provide comment.

Thank you for the presentation.

MR. BALTZ: Davis Baltz with Commonweal. And thanks again for a chance to say another comment.

It's basically just that, you know, as cosponsors of this legislation with the Breast Cancer Fund, Commonweal is committed now and into the future to see this program not only get off the ground, but build to a point where it's generating biomonitoring information for the State on a regular basis in the same way that CDC does. So if some of these ideas about approaching CBOs and NGOs and accessing the community resources that we may be in touch with as well as maybe some funding sources, we're happy to pursue that conversation.

Of course, it's not something that is going to make this program what it could be over the long term. So as a stopgap measure, if it's helpful, I hope that we can continue that conversation.

And the only other thing I really want to say is just express my appreciation to all of the staff from DTSC and OEHHA and the Department of Public Health, who have bent over backwards. And I haven't even seen the extent to which they have done their acrobatics, but I know that they have really moved heaven and earth to really try to find solutions, and I just want to express my appreciation

to them.

And Peter Flessel I know is going to be retiring soon. And, Peter, maybe you could be called out of retirement to help catalogue some of those blood bank samples.

(Laughter.)

MR. BALTZ: You'll have a lot of time on your hands, I know.

So we look forward to being in touch with all of you as appropriate in the next meeting in December.

So thanks.

CHAIRPERSON MORENO: Thank you.

Any response from Panel members to public comment?

Okay. Well, I think that's -- oh, sorry, sorry.

Gretchen Lee with the Breast Cancer Fund, is that correct?

MS. LEE: Yes. I thank you so much.

Well, first I want to really echo my colleague Davis' appreciation to the staff of the Biomonitoring Program. You know, I think a lot of the work that they're doing is probably largely unfunded, and they're giving really voluntarily to make sure this program gets off the ground. So I really do want to congratulate them for their efforts on that.

And I really also want to extend my appreciation to all of you for your continued diligence and your offers of help today. I think that's fantastic.

I'm going to ask for one more -- I'm going to plea for your help in one other area, if we could. And the underlying, you know, problem with this program is the fact that we don't have the funding to get it off the ground. And we've all been through budget processes and we all know that they are highly political and contentious at times. And so I would just encourage the Panel to, whatever extent it's appropriate and to whatever extent you feel comfortable, and maybe slightly get out of that comfort zone, to help the advocates and to help the NGOs advocate to the Governor, advocate to members of the Legislature to ensure that this program does get the funding that it does need.

I think, you know, a lot of programs can get the funding that they do need if just enough people stand up and speak out for them.

It's very easy to rally people around legislation and to get a program up and running. It is very difficult to get people together to ensure that that program stays running.

So to whatever extent possible, I would like to be able to call on you as we go forward in the next few

months to ensure the program has the funding that it needs. And I would just encourage you all to help us in that regard as well.

Thank you.

CHAIRPERSON MORENO: Thank you very much.

PANEL MEMBER SOLOMON: Actually -- this is Gina. We had some discussions about this issue at the last meeting. So I just was a little curious as to where that stood. I think -- you know, speaking for myself as an individual, I'm happy to speak out on behalf of the program. I'm not quite sure where it stood in terms of our being able to say something as a panel.

CHAIRPERSON MORENO: I wouldn't mind -- I don't mind at all updating the Panel. There was a request -- what I recall, there was a request by the Panel that I and a group of Panel members -- I think the request was to approach the Governor or write to the Governor the importance of the Biomonitoring Program and funding for the program.

And so in reporting back to the Panel, I can tell you that what we did was we made some phone calls at the administrative level and some secretary in the Administration, and determined that I would -- probably the best, at that time, was to contact the Secretaries of the Agencies directly and meet with them and also write

letters to them and meet directly with the department heads. And so I did that and provided them in writing and in person -- or at least by telephone call what the Biomonitoring Program is, the mandate that exists, what its mission is, what we hope to obtain, and that we, as Panel members, would greatly appreciate knowing from Agency and from the departments what their budget process is, so that we can, in turn, be more effective at not just advocating, but intervening at the appropriate time and in the appropriate manner to try to convince at the Agency level and at the Department level the need for funding.

And so there was effort -- I can tell you there was a favorable response, an open response by Cal/EPA. I did try to meet with the Secretary of Health and Human Services. And, unfortunately, it didn't seem to work out. I did have a conversation though with Dr. Mark Horton, the Director of Department of Public Health. And I'm fortunate enough to meet with him almost monthly. But this was -- in particular this issue and trying to get to him while he was still creating his and getting ready for proposed Budget Change Proposals.

But I talked with the Panel members here and in southern California. Unfortunately I didn't -- I wasn't as -- I don't think I was as successful with that department in reaching him before Budget Change Proposals

were finalized to submit by that department.

So, at this point, I have got to -- what I'm considering is looking at the next opportunity to raise awareness and intervene as a panel to the Administration to try to get funding. And my understanding is the earliest time -- or next opportunity for us would be after the January Governor's budget comes out to respond to the budget and advocate for funding. So that would be as a panel.

Again, now understanding how the Administration's budget process was moving forward, that would still -- that would provide an opportunity to influence the amount of funding available for the '09-2010 fiscal year.

In terms of 2010-2011, we will need to -- as a panel, we would need to get back to each of the respective departments well in advance of, I would say, probably before August most likely to get Budget Change Proposals, our recommendations, in for budget for the Department to consider for the Budget Change Proposal for 2010-2011. I think we've got that right.

So those are the next two opportunities as a panel as far as I can see.

In terms of individual advocacy from Panel members, any time is a good time for that.

(Laughter.)

CHAIRPERSON MORENO: So that's my update.

OEHHA DIRECTOR DENTON: I think speaking for the departments, we applaud, we appreciate. It heartens us to see your support. It's very, very difficult, but, you know, it's worth fighting for. As we were talking over lunch, it took us four years to get the program started. And so, you know, it's something that we're all fighting for in our different ways.

CHAIRPERSON MORENO: Yeah. And I want to thank, I believe it was, Asa and Julia and Dwight who helped put that letter together. So I -- where I could, I hand delivered that letter in the office of the agency heads myself and sat with them and talked to them about this.

PANEL MEMBER SOLOMON: Thank you.

CHAIRPERSON MORENO: Um-hmm.

All right. I think we're at the point of the agenda where we've gone over. And we still have -- well, I was going to introduce, I think, George Alexeeff with OEHHA.

DR. ALEXEEFF: George Alexeeff with OEHHA. So I'm just providing a short summary of today's meeting.

Dr. Lipsett provided an overall update of the program's activities and budget. And Dr. Randy Curtin of CDC provided an overview of sample design issues.

The Panel formed a subcommittee, which was going

to look at the issues of developing a questionnaire and also study design. And the Panel members were Marion Kavanaugh-Lynch, Asa Bradman, Tom McKone and Dwight Culver. And once the subcommittee gets together and begins to work with staff, there will be some decision made as to whether this is a two-committee project. And, at that point, if it does break into two committees, Dr. Gina Solomon has offered to participate on the Study Design Subcommittee.

We heard an update from Dr. Myrto Petreas and Dr. Peter Flessel regarding the laboratory activities, the purchasing of equipment, staff that have been hired, and their ability to decide what types of analysis they can perform in each of the laboratories. They've completed an MOU with the Center for Disease Control regarding lab support for training and sample analysis. They've initiated some collaboration with the health tracking study, looked at a pilot study to test lab components and to analyze archive samples. And there was a discussion of a need to do some of these short-term projects to help develop methods to show incremental progress particularly with regards to sample analysis. And it was also brought up that probably study design could also be included in that.

And finally, there was some discussion regarding

the value of partnering with academic institutions, community group, and other organizations.

That's it. Thank you.

CHAIRPERSON MORENO: All right. Well, thank you.

Before we close, one moment.

All right, I just want to impose a little bit on each of the three departments, OEHHA, DPH, and DTS. If one of the representatives could just go quickly through the room and identify your staff who've been putting so much work into this program.

Would you like to start.

OEHHA DIRECTOR DENTON: Well, let's see. I'm looking at them right now. George Alexeeff, Lauren Zeise, Farla Kaufman, Amy Dunn, Gail Krowech, Sara Hoover, who's the lead under Lauren for this group. And then I think our newest hire is Rachel Roisman.

Do I have anybody else?

MS. HOOVER: David Berger in southern California.

OEHHA DIRECTOR DENTON: David Berger, of course, is in Orange County.

So that's OEHHA's staff.

DR. LIPSETT: Okay. From our department, actually Peter -- oh, up to the microphone.

MS. HOOVER: Got to let everybody hear the whole meeting.

DR. LIPSETT: Okay. Peter Flessel expressed an interest in identifying the laboratory staff. So I will just identify non-laboratory staff who are from --

(Laughter.)

DR. LIPSETT: Not very good with these logistics.

So from our department, people in the Environmental Health Investigations Branch who were funded solely with biomonitoring money are Diana Lee and Robbie Welling. You want to -- just a second. I want you to raise your hands. And Philip Gonzaga at the back. And then others who are, I guess, contributing time include myself, Sharon Lee, Lori Copan, Sandy McNeel, and Marta Lutsky.

DR. FLESSEL: So we have three of the four --

CHAIRPERSON MORENO: It works.

DR. FLESSEL: Three of the four laboratory staff supported by the program are here. Jianwen She, right there. Next to him, Paramjit Behniwal. And right behind Paramjit is Bob Ramage. Frank Barley is in Portland, Oregon. But he's here in spirit. And then the one member of the staff who supports us is a staff services analyst by the name of Meralda Rafol. She's not here.

DR. PETREAS: From DTSC, the two funded staff, Miaomiao Wang and Yunzhu Wang, are in the lab working.

(Laughter.)

DR. PETREAS: And not in the laboratory, Dr. Bruce La Belle and I, who contribute our time here.

CHAIRPERSON MORENO: All right. Well, thank you very much for that. And I appreciate all the work that goes into these meetings. And I'm sure the Guidance Panel greatly appreciates the opportunity to come in and get down to business as a panel to work with you.

At this point, I was asked to remind the Panel program and the public that we have a meeting in December. And I believe it's been decided that it will be a half day meeting December 4th, which --

MS. HOOVER: Yes, December 4th.

CHAIRPERSON MORENO: And then followed by a full-day meeting December 5th, on a Friday. And that the Panel members should have received an Email to make -- or a suggestion of where to make hotel reservations.

And that the focus of the meetings will -- I believe the December 5th focus will be on chemical selection. But there's going to be continued discussion on the day -- prior day, December 4th, some follow-up on today's activity and hopefully some -- maybe some reports back on the committees that have been formed and the activities of the committees.

DR. ZEISE: And it'll start around 2 on the 4th.

CHAIRPERSON MORENO: Okay. So December 4th

meeting starts at 2.

DR. ZEISE: In Sacramento.

CHAIRPERSON MORENO: In Sacramento. I'll be there.

(Laughter.)

CHAIRPERSON MORENO: And I think that's it.

So if there are no -- are there any other comments by Panel members, program staff?

If not, I believe that that's it for the meeting for today.

Thank you, everyone.

(Thereupon the California Environmental Contamination Biomonitoring Program Scientific Guidance Panel meeting adjourned at 2:37 p.m.)

CERTIFICATE OF REPORTER

I, JAMES F. PETERS, a Certified Shorthand Reporter of the State of California, and Registered Professional Reporter, do hereby certify:

That I am a disinterested person herein; that the foregoing California Environmental Contamination Biomonitoring Program workshop was reported in shorthand by me, James F. Peters, a Certified Shorthand Reporter of the State of California, and thereafter transcribed into typewriting.

I further certify that I am not of counsel or attorney for any of the parties to said workshop nor in any way interested in the outcome of said workshop.

IN WITNESS WHEREOF, I have hereunto set my hand this 10th day of November 2008.

JAMES F. PETERS, CSR, RPR
Certified Shorthand Reporter
License No. 10063