MEETING

STATE OF CALIFORNIA

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

ENVIRONMENTAL CONTAMINANT BIOMONITORING PROGRAM

SCIENTIFIC GUIDANCE PANEL

CAL/EPA HEADQUARTERS BUILDING

COASTAL HEARING ROOM

1001 I STREET

SACRAMENTO, CALIFORNIA

THURSDAY, NOVEMBER 8, 2012

10:10 A.M.

JAMES F. PETERS, CSR, RPR
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APPEARANCES

PANEL MEMBERS

Ulrike Luderer, Chairperson, M.D., Ph.D.

Asa Bradman, M.S., Ph.D.

Thomas McKone, Ph.D.

Julia Quint, Ph.D.

Michael P. Wilson, Ph.D., M.P.H.

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

Dr. George Alexeeff, Director

Ms. Carol Monahan-Cummings, Chief Counsel

Ms. Amy Dunn, Safer Alternative Assessment and Biomonitoring Section

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

Dr. Gail Krowech, Staff Toxicologist, Safer Alternatives Assessment and Biomonitoring Section

Dr. Melanie Marty, Acting Chief, Reproductive and Cancer Hazard Assessment Branch

Dr. Laurel Plummer, Associate Toxicologist, Safer Alternatives Assessment and Biomonitoring Section

Dr. Lauren Zeise, Deputy Director, Scientific Affairs

DEPARTMENT OF PUBLIC HEALTH

Dr. Michael Lipsett, Chief, Environmental Health Investigations Branch

Dr. Laura Fenster, Research Scientist, Environmental Health Investigations Branch

APPEARANCES CONTINUED

DEPARTMENT OF PUBLIC HEALTH

Ms. Lauren Joe, Research Scientist, Environmental Health Investigations Branch

Dr. Sandra McNeel, Research Scientist, Environmental Health Investigations Branch

Dr. Jianwen She, Chief, Biochemistry Section, Environmental Health Laboratory

DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Dr. Myrto Petreas, Chief, Environmental Chemistry Branch

ALSO PRESENT

Mr. Davis Baltz, Commonweal

Ms. Nancy Buermeyer, Breast Cancer Fund

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PROCEEDINGS

OEHHA DIRECTOR ALEXEEFF: Good morning. Let's bring the meeting to order.

Hello, everyone. I'm George Alexeeff, Director of the Office of Environmental Health Hazard Assessment. I want to welcome the Panel, the public, and the staff and the audience participating via webcast to the meeting of the Scientific Guidance Panel for California Environmental Contaminant Biomonitoring Program, also known as Biomonitoring California.

So again, I want to thank the Panel for taking time out of their busy schedules to come here to advise us --

I guess I'll start again.

I like introducing myself. I'll do it again.

(Laughter.)

OEHHA DIRECTOR ALEXEEFF: Hi, everybody.

I'm George Alexeeff, Director of the Office of Environmental Health Hazard Assessment. I want to welcome the Panel, the public, and staff and the audience participating by the webcast to the meeting of the Scientific Guidance Panel for the California Environmental Contaminant Biomonitoring Program, also known as Biomonitoring California.

I want to thank the Panel for taking time out of

their busy schedules to come to this meeting to advise us on this very important program. I have a couple of announcements. First of all, the restrooms, out the back door and then you go to the left. And then please notice the emergency exits, 2 in the back, and on the side and up here.

So this meeting is being webcast, so please be sure if you're going to speak to speak into a microphone, either at the front or a microphone if we're handing one around at that time. And the meeting will also be recorded, and transcribed. There will be a transcript of the meeting posted on the website in about a month after this meeting.

So just to refresh everyone's memory, I'll give an overview of the last Scientific Guidance Panel meeting. The last Scientific Guidance Panel meeting was held in Oakland on July 26th, 2012. And at that meeting, the Panel heard about the Program, the laboratory chemical selection updates and they provided input into these activities.

The Panel discussed and provided feedback on the issues interpreting and communicating biomonitoring results for chemicals with short half-lives in humans. And if you're interested in more information about this meeting, you can visit our website biomonitoring.ca.gov.

So now, I'd like to turn the meeting over to Dr. Luderer.

CHAIRPERSON LUDERER: Thank you, Dr. Alexeeff. I'd also like to welcome everyone, all the members of the public and -- can you hear me better now -- the Guidance Panel members and the Program staff.

I'd like to just briefly review what the Panel goals are for today's meeting. We're going to receive Program updates and provide input on the Program updates. We're going to hear some preliminary results from California Teachers Study, as well as preliminary results for the environmental phenols and polycyclic aromatic hydrocarbons from 2 other studies.

And in the afternoon, we're going to consider the group the p,p'-bisphenol As diglycidyl ethers of p,p'-bisphenol As as potential designated chemicals. And we're also going to be discussing synthetic musks for possible future consideration by the Program and provide input on next steps regarding synthetic musks.

And finally, we'll be providing input on the Scientific Guidance Panel agenda items for 2013.

So each presentation will be followed by an opportunity for questions from Panel members as well as a public comment period and then time for further Panel discussion and recommendations.

Just to remind everyone about how we'll be handling public comments. If a member of the public would like to make a comment and you're here in the room, then you should fill out a comment card, which can be obtained from Amy Dunn. She's holding up the purple comment cards. And also I guess there are also some in the back of the room as well on the table in back of the room.

And if you're participating in the meeting by webcast, then you could submit comments by email and we'll also read those during the public comment period.

To ensure that the meeting remains on schedule, at least somewhat on schedule, we will need to limit the public comments, so we'll be timing them. And we'll be giving everyone equal time to speak who wishes to speak.

So, again, please keep your comments focused on the agenda topics that are being presented. There's also going to be an open public comment period at the very end of the day, at which any issue related to the Biomonitoring Program can be brought up.

Also, remind -- I'd like to remind everyone to speak directly into the microphone and please introduce yourself before speaking. And this is for the benefit of people who are listening via webcast as well as for our transcriber.

So the materials for the meeting have been

provided to the Scientific Guidance Panel members, and the via the website to the public. And there are a small number of handouts on the table in the back of the room. And there's also a sample folder for viewing at the staff table in the back of the room.

We'll be taking 2 breaks today, one at around 12:30 for lunch and another one around 3:15 in the afternoon.

So now I'd like to move on to the first agenda item. So the first item will be a program update. Dr. Michael Lipsett from the California Department of Public Health will be updating us on Program activities since the last meeting.

Dr. Lipsett.

MS. DUNN: I just want to make a quick announcement, Michael, before you begin. We're going to be taking photographs today for our website. So if anyone would rather not appear in a photograph on our website, just please let me know and we'll make sure to exclude any photos that include you.

Thank you.

DR. LIPSETT: I'm in the witness protection program.

(Laughter.)

DR. LIPSETT: Hello. All right. There we go.

Okay, with all that elaborate preparation. Dr. Luderer and Panel members, I'll present a brief update of the program since the last meeting.

(Thereupon an overhead presentation was presented as follows.)

DR. LIPSETT: I'll be talking briefly about staff our ongoing field studies. I'm going to spend a few minutes talking about the Prenatal Screening Program as a source of samples for biomonitoring. The results of a survey that we did of the California Health Officers and Directors of Environmental Health, and a -- we're going to have an update on the development of our website. That will not be presented by me, but by Amy Dunn of OEHHA.

Okay. So in terms of staffing, I want to just say thank you and farewell to Danny Kwon whom several of you have interacted with. He has been instrumental in helping with our RFI projects and obtaining samples from -- the archived samples from ongoing studies. He's now working in the hazardous waste group in my branch. And then Dina Dobraca who's played an integral role in all of our field studies so far. She is having an extended farewell though, so she is still going to be involved with a number of programs. Although, this is not going to be her primary work anymore.

I want to welcome Ying Li to the Environmental

Health Lab. She has a degree in pharmaceutical science and has had many, many years in developing methods, and developing and validating methods for chemical analysis.

And Sara Encisco who is working in the Environmental Chemistry Laboratory. She has previously worked with CDC in the NHANES program and doing analysis of vitamin C and has a lot of experience as well. And we welcome both of them in the 2 laboratories.

At this point, we do not have a replacement yet for Dr. Das, but we are actively engaged in looking for that. Although, this is a personnel issue, and I can't talk a lot about this now, but we're hopeful we'll have somebody within the next few months, hopefully before the next Panel meeting.

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DR. LIPSETT: Okay. So for our Maternal and Infant Environmental Exposure Program, what the -- what has happened since the last meeting is we've returned the first set of results to the participants. And this was something that was -- took a huge amount of effort to undertake this, but it is -- they finally received them and the items in yellow that are ongoing.

The first set of results included metals, PFCs, triclosan and BPA.

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DR. LIPSETT: For the FOX study, the firefighters exposure -- occupational exposure study, the POPs analyses are now complete. Although, they haven't -- the results have not yet been returned to participants. And for the other analytes from creatinine on down, Dr. She will address those in his presentation.

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DR. LIPSETT: In the Biomonitoring Exposure Studies -- the Exposure Study that we're doing in collaboration with Kaiser Permanente, the analysis of the first set of analytes has been completed since the last meeting. Again, the other things that are ongoing are shaded in yellow.

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DR. LIPSETT: And something I did want to spend a little bit of time on now too is to just update you on the results of some of the laboratory data.

In March of -- in the March Panel meeting -- you know, this is really awkward having to hold up this microphone.

Can you hear me?

Thank you. That's much better.

Okay. So, in March, we presented some results to you that went into our data summary report, that went up our chain to be approved. It was finally approved. It's

now on the OEHHA website, but it's out of date. And so what I wanted to do for the next few slides is just indicate some of the progress that's been made since we presented these numbers to you previously.

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DR. LIPSETT: So in terms of looking at metals in blood, the numbers of samples now are getting up there, when in the last -- in the report that we presented before, say, for example, cadmium, there had been only 529 people who had had samples analyzed. And here this is the number of samples and not the number of people, but there's a few relatively small percentage of duplicates that have been done, so there's been a substantial increase in the number of metal samples.

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DR. LIPSETT: The next slide for the PBDEs, these have effectively doubled since the last time, the numbers that we have here. And this is -- these are from these various studies that are listed there from FOX, the San Francisco study and -- a couple of pilot studies as well.

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DR. LIPSETT: Next, the PCBs, it's the same -- basically the same thing. The numbers have doubled since the last time.

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DR. LIPSETT: And then perfluorinated compounds, we've seen the greatest progress. So, for instance, the top one there, there are 592 samples that have been analyzed. When we presented this to you before, there were only 203, so we are -- the laboratories are beginning to make substantial progress on this.

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DR. LIPSETT: Finally, environmental phenols, we had not had any of those at the last meeting, and now we're starting with those. These are some of the results also that were returned to the subjects in the MIEEP study.

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DR. LIPSETT: Okay. So I wanted to spend a few minutes talking about the Prenatal Screening Program that our department runs. So we have -- in California and Iowa are the only 2 states that run prenatal screening programs as part of Departments of Public Health. We have the largest one in the world in California.

They screen about 400,000 patients a year for neural tube defects and major genetic disorders. This historically has been with the second trimester samples. They've begun to look at first trimester samples as well. These are collected in 4 mL serum separator tubes. They're sent by mail, so it's at ambient temperature. So

for ones that are collected in the summer, for example, they're -- they can be in the mail for several days, even at pretty high temperatures, ambient temperatures.

But they go within 7 days to a NAPS lab, a Newborn and Prenatal Screening Laboratory. The residual sample in these labs, after the tests have been done, they discard them after 30 days. This is from 5 out of the 7 NAPS labs, two of the other labs, one in Fresno and in Long Beach.

However, they take the residual serum and pellet, they aliquot these to cryogenic vials and these are archived at minus 70 in a repository in Long Beach. Now, the screening process -- the ones that go to the repository, the women have -- are given an opt-out on the form if they don't want their samples used for research. The ones that are in the repository are ones that we can use for additional purposes.

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DR. LIPSETT: Like biomonitoring.

So, as part of this program, they also contain -- collect data on demographics and some aspects of the pregnancy, including the gestation -- estimate gestational age when the samples are collected. These data can be used both for stratification. So if we wanted to get a sample say only of women ages 20 to 25 of say Asian

descent, we could do that. We could specify this, put in a request to the Program -- to Genetic Disease Screening Program that they're the ones who run this screening, and they can send us these samples from the archive in Long Beach.

And, as some point later, because they -- these are part of a statewide program, they can be linked to a variety of these California databases, such as birth defects and cancer. That's not something that would happen in the immediate future, of course.

Sample acquisition cost is relatively reasonable. At this point, it's $37 per vial. We would have to pay additional fees for getting some of the demographic data. I don't know exactly how much that would be, at this point.

And these archived samples, the whole biobank archive that's been established in Long Beach is funded by NIH. They're finalizing regulations for researchers that want to use these samples for a variety of different purposes. In order for us to get them, we have to submit a formal proposal to them, that they have to approve. I don't think that would be a problem, but at this point, they're not available until after the regs are finalized. We hope that will be some time in 2013.

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DR. LIPSETT: Some of the problems with -- or limitations with this Program would be that there is a relatively small residual sample volume of around one half to 2 mL's. So we can't do the same extensive testing that we would do with large sample volumes. So we may need to end up pooling some of these samples in order to be able to look particularly at the POPs.

One other potential -- really significant potential limitation is that when they do the testing for these various markers like alpha-fetoprotein, these metal probes are inserted into these vials which can sit out on autosampler racks for up to 3 or 4 hours. So to the extent that there might be any dust particles with PBDEs or something like that, that could fall into one of these vials while they're open, that could be a potential problem.

So what we've done now is the lab, the ECL lab staff, has obtained some blank tubes for testing and they're going to be going through a series of QC tests to identify the extent to which this might be a problem in terms of contamination with artifacts.

And the other limitation that I didn't put up on the slide is that because these are serum samples, really we can only be looking at the POPs. You can't look at metals for which we require whole blood, and the

nonpersistent chemicals that might end up in urine that this is not a source for those kinds of samples as well.

But I've initiated contact with UCSF as a possibility. And I've mentioned this before about getting medical and nursing students to participate in this. It's going to be a long process, I can you tell from my initial response. I don't know if that's going -- this is going to work at all, but this is something I think would be very useful and interesting.

Right now, at UCSF, the medical students get 1 hour in their entire 4 years of instruction in environmental health. And possibly something like this might interest, you know, a few more students in this particular field.

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DR. LIPSETT: Okay. So we indicated at the last meeting that we would give you a brief review of the survey that we did of the local health officers and directors of environmental health in California. This is an electronic survey distributed via SurveyMonkey through our Director's office with input from our division and from OEHHA.

We received 47 completed surveys from individuals representing 40 health and environmental health departments in counties that include about 86 percent of

California's population. We're heartened to see that more than half had heard of the Program before. And one of the benefits of this was that we got 21 new people signing up for our listserve from these local health departments.

This is a map showing in green the counties that responded. So you can see that the mountain counties were not -- well, they're -- there are relatively few of them to begin with, but we didn't have a great response there, but we did throughout the rest of California.

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DR. LIPSETT: One of the things that we asked about was the kinds of resources that our Program could provide that they might find useful. So if you looked to the left of this graph about things that they would potentially distribute to their constituents or would use internally, you can see that there is interest in the chemical fact sheets, and in a pamphlet on reducing chemical exposures.

And internally, potentially about a third of them would be interested in having some sort of webinar, a written summary of the program, or a tutorial on biomonitoring.

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DR. LIPSETT: So that's all I wanted to talk about. Are there any questions for me before Amy takes

over with a description of the website update?

CHAIRPERSON LUDERER: Any questions from Panel members for Dr. Lipsett?

Dr. Wilson.

PANEL MEMBER WILSON: Thank you. Mike Wilson.

Michael, given the limitations that you've described for the prenatal samples, do you have a sense of what the potential is there for a number of samples that, you know, that could be analyzed for biomonitoring in the course of a year?

DR. LIPSETT: Well, I think it would really depend on what the capabilities are of the laboratories. And that will depend, in part, on both the funds that we have to support State staff and external funding like we currently have from CDC. But potentially, we could purchase, you know, hundreds, if not thousands, of these samples. And it's really going to be limited only by the laboratory capacity. And the lab directors I think could speak more knowledgeably about that than I could.

PANEL MEMBER WILSON: All right. Thank you.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: This is Julia Quint.

DR. LIPSETT: Your mic is not on Julia.

PANEL MEMBER QUINT: Okay, here we go.

Julia Quint.

I think the prenatal sample -- the possibility of doing biomonitoring on those is very exciting. And I was just wondering -- I know you're doing some testing on the tubes, and, you know, there may be some challenges in terms of how they're currently collected. Is there any possibility that should you find that the method -- you know, that the way they're collected, either the tubes themselves or the ability of dust coming into the tubes, that they could change their methods, so the tubes -- or, I mean, could that be negotiated in some way with the current practice in the labs for how they're doing this, or they have been doing this for a thousands years that way and no chance of changing the procedure?

DR. LIPSETT: I think we'll jump off that bridge when we come to it.

PANEL MEMBER QUINT: Right.

DR. LIPSETT: I suspect that it will be very difficult to make modifications, because they have their labs already set up with those autosampler racks. It would be something that is -- would require, I think, probably not just a change of their practices, but a change of their infrastructure, and their laboratories. So I think that the likelihood that that would happen, based on the request of this program alone, is probably pretty slim.

PANEL MEMBER QUINT: Right. But other people will be requesting -- I mean, after 2013, it sounds like other people will be interested in these samples.

DR. LIPSETT: There's already a queue.

PANEL MEMBER QUINT: There's already a queue, so power in numbers.

DR. LIPSETT: Well -- and it really depends on what other people are going to be requesting. I mean, in this prenatal program, they're looking for things alpha fetoprotein, human chorionic gonadotropin. These sorts of larger types of -- you're not really going to expect that to be floating around. It's not a significant indoor air contaminant, neither of these, to my knowledge.

And I think that most of the researchers are going to be looking for similar kinds of macromolecules as opposed to biomonitoring.

PANEL MEMBER QUINT: Yeah, which is very important. Yeah, exactly. Thanks.

CHAIRPERSON LUDERER: Dr. Bradman.

PANEL MEMBER BRADMAN: I have just 2 comments related to this QC issue. One, you mentioned here that the samples are sent by mail for several days to the NAPS lab. And perhaps another QA/QC check would be to take some samples and spike them and send them through the mail to perhaps your own lab, and then see -- and look at

analyte stability.

We've done that with our CHAMACOS samples for samples that need to be shipped unfrozen, and that way you get some sense of, you know, how stable the compounds are.

Another thing, would it be possible to work with some of the labs a priori to see if they can ship the samples by mail, but with ice packs, not on dry ice, not frozen, but could they at least be kept cool. And that's kind of related to Dr. Quint's comment.

It would be another modification, but perhaps in a special study that could be arranged.

DR. LIPSETT: Yeah. I think -- with respect to the earlier QC suggestion, I think this is something that Dr. Petreas can talk about. I think they were planning to do something like this, but using some of their bovine samples.

PANEL MEMBER BRADMAN: Exactly.

DR. LIPSETT: But she could speak more knowledgeably to that. With respect to their -- some of the -- these samples are collected by providers all over the State. And it's the providers who ship them then to the laboratories. So it would involve possibly working with, you know, one or more of the providers that do collect these samples to do that kind of shipment. And I think that that would be possible to do something like

that, but, again, it's the kind of thing that would -- we would probably need some substantial resources to persuade them that this would be something that would be reasonable to do and to provide the resources for them to do it.

CHAIRPERSON LUDERER: I'd like to actually thank you for sharing the new updated aggregated data with us. That was very exciting to see kind of how the results are accumulating from the Program.

And I also actually had a question for you. So it was great to see that that report also was posted on the website this weekend. I was wondering if you had an update on the status of the 2012 legislative report?

DR. LIPSETT: It's in our agency awaiting approval. I checked on that yesterday, and that was what I was told.

CHAIRPERSON LUDERER: Okay. Thank you.

DR. LIPSETT: Thank you very much.

CHAIRPERSON LUDERER: Amy Dunn will be our next speaker.

MS. DUNN: Good morning. So what I'd like to do is just briefly give you an update on what we've been doing with our website. As you see on the top right-hand part of the slide is an image of our current site, which has been serving us well during the last 5 years that the Program has been in operation, but we've also been working

over the last year and a half on developing a new site.

And the revised site will be designed to appeal to a wider audience. We hope to still make easily accessible the information that's been bringing people to our current site, which mainly is meeting related traffic, but we've added some new features to the upcoming site, which we'll be launching in the early part of 2013.

We'll be optimizing the site for hand-held devices, hoping to stay current with the technology. And the new site will also include interactive features and video, a lot of more visual impact, we hope, with this new site.

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MS. DUNN: So here's an example of one of the features on the new website. We call it an interactive brochure. You may be familiar with this hard copy brochure that we've had for a while, and we've been handing out. Well, this was the jumping off point for the development of the interactive feature, which is shown on the right-hand side of the slide.

It has several different chapters, 6 shown here. And these are based on the content that was in the hard copy brochure, but then we've been able to expand it, because of the capabilities of this kind of a platform, so people can get a simple explanation of things like what is

biomonitoring, and why is it important?

But then those who are interested can dig deeper into the content about that topic or related topics that we've included with links, and, in some cases, video and other kinds of content that, you know, is on our site that otherwise people might not easily find. So this is a way to kind of bring some of our interesting content up to the front where people can see it.

And it's also our web consultant, Studio Weeren, has been doing a wonderful job of making our content, which can be somewhat dense, easy to navigate through and good looking. And it's also fully accessible.

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MS. DUNN: So we're getting ready to launch the site, and we're using the site launch as an opportunity to reach out to new audiences. We're going to be testing the site both before we launch it and once we have it launched. And we're hoping to bring in some new people with the website launch. So we've been distributing information to new -- in a variety of settings, mainly conferences.

We have these postcards that we've been handing out recently at the American Public Health Association meeting. Also, down in southern California, there was a meeting of the Exposure Assessment Association, something

like that. And we're also going to be handing it out at upcoming meetings like the Society for Risk Analysis and other smaller meetings.

So what we're looking for is your ideas about other ways we might try to use the website launch as a way to reach out to new audiences to bring them in, especially now that we're starting to have some results on our website. And this is for the Panel and the public and certainly anyone through listening on the webcast, you know, we'd welcome comments either at the meeting or after the meeting via email.

And we've also set up, those who have been to our website recently, and see this banner that's on the slide, we've put on our Biomonitoring homepage, and people can actually just click right on the banner to get signed up to be notified of when we're going to have this launch. And we're going to have, as part of the launch, a survey, so people can give us feedback on the site. So we're trying to make this kind of splashy and a way to, you know, start building our constituency.

So that's it. And if people have questions, I'd be glad to answer.

CHAIRPERSON LUDERER: Great. Thank you, Amy. I know we'll all be looking forward to the launch of the website. Do any of the Panel members have suggestions?

Dr. McKone.

PANEL MEMBER McKONE: First of all, congratulations. That's great to do this. Even, I don't use brochures anymore. I can't even keep track of where they are. So everything -- you know, we're in a world where everything has to be accessible on your devices. They seem to be doing that.

I guess probably more than a question is in terms of how to share it better, I don't use Facebook, but I know so many people whose world is defined by what's on Facebook. And I don't know how -- you know, if you want to spread something around, that seems to be a very effective way to do it. I don't know quite how -- again, I'm not an expert on this, but it's something worth considering as a network of information.

Also, next week is the Society of Environmental Toxicology and Chemistry meeting in Long Beach. Historically, this has been more of an ecological type risk assessment and toxicology, but they're very much moving into human health. They even have now a working group on human health issues, which I'll be at. So if you give me a stack of these, I'll pass them out to everybody there and encourage people. It's a very different society, more broadly interested in the intersection of human and ecosystem health, but I think it's a perfect

opportunity.

MS. DUNN: Great. Yes, I have postcards I can give you today.

CHAIRPERSON LUDERER: Okay.

PANEL MEMBER McKONE: Yeah. One more question. One of the things that come -- I know, occasionally, I get people who call me with -- you know, they see our names associated with various things and say they're really worried about some issue, you know, they think their house is contaminated. I never try to respond to people like that, because -- I mean, I just tell them you have to -- you know, I'm not an expert where I can tell you, without looking, what's wrong with your house. Somebody called me about their car from Japan about whether it was radioactively contaminated.

But, you know, is there a way to expand this or is there a resource where people say, well, I'm worried about what's in my blood and I saw this Biomonitoring Program, who do I talk to? Is it set up to kind of provide some links like that or resource people?

MS. DUNN: We do have links currently, and we're certainly creating a space on our site with resources, both internal to OEHHA and CalEPA and also the Department of Public Health. But beyond that, so if you have resources that we could send people to. We do also get

those kinds of questions coming into our email. And I do my best to direct them to people who might have answers.

But one of the things that we will have on the new site is some information that's been being developed for our participants on how to reduce exposures to the chemicals that we're measuring. So there is some information like that that will be on the site.

But for people who have specific questions, it's nice when you have, you know, someone to send them to. So if you have suggestions of good resources, it would be nice for us to include on our site. I'd love to hear about it.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: I'm sure you probably have done a lot of this, but I'm always surprised when I work with different groups like Cal/OSHA or just different people within California government the extent to which they are not aware of programs like this one, and other programs going on, you know, the whole silo effect. So I was wondering if there -- you know a way to do outreach just get on some agenda to just briefly describe the new exciting website, so that people can be more aware of the work that's being done here, because, you know, the Green Chemistry Program within DTSC.

Everybody is looking at emerging -- not

everybody, but, I mean, you know, some of these programs are looking at issues of chemical toxicity and emerging chemicals and things like that, and a lot of the work here is very relevant to the work that they are doing.

So, however, you know, to -- you can reach out to them and then use the website as a way that they can stay in touch with the work of the Program, I think, would be excellent.

MS. DUNN: Thank you for that suggestion.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Thank you for that -- for the info here, Amy, and congratulations on taking this next step. And I had an experience a little while ago of running a workshop up in Martinez with the United Steel Workers Union on confined space fatalities. And chemical exposures that occur in refineries and so forth.

And in the end of that workshop, I did a little session on biomonitoring. And contaminants identified in umbilical cord blood and also the NHANES information. And when we did a little survey at the end of the workshop, without question the thing that was most interesting and most compelling to that room full of refinery workers was that information regarding umbilical cord blood contaminants and the NHANES biomonitoring information, which I was actually surprised and -- because, you know,

they have, you know, some very, you know, hazardous confined space issues as well.

And so I'm wondering if, you know, it would be helpful to -- for me and my colleagues to be able to point people, you know, workers who might be interested in this to the website. And if there was a place on the website that was something around resources for workers, it would -- you know, and start making those linkages between how biomonitoring relates to occupational exposures and, you know, healthy families and children and so forth, I think would be a great contribution. And I'd be happy to help in whatever way I could with that.

MS. DUNN: Great. Thank you.

CHAIRPERSON LUDERER: Thank you. Amy, I actually did have one other suggestion for another Society, which you may have already thought of, the Society of Toxicology, which has their annual meeting in March. So I don't know if that will be too late, but I think that would be another great place. There would be a lot of people that attend that conference that would probably be interested in --

MS. DUNN: And it might be that we could reach out to groups, you know, that -- you know, after the site launch, but also if we can find a way through a listserv, through, you know, someone who's in the society might be

able to get it in a newsletter or -- you know, some kind of thing that goes out to people.

So thank you.

CHAIRPERSON LUDERER: And then one final thought was we've had a lot of it at all of these different meetings that we've had of the Scientific Guidance Panel representatives from a lot of different community groups and other stakeholders. And I wonder -- I mean, I assume that many of those already subscribe to the listserv, at least some of their members, but whether we could use them to reach out to kind of their constituents, their membership to publicize the website in some way.

MS. DUNN: Yes. I'm certainly hoping -- well, we do have access to certain listservs, like the Cal/EPA Environmental Justice listserv. But those kinds of listservs could reach some people, but I am hoping that when the site is a little closer to actually -- you know, people can actually go there to have a link that people will then forward through their networks.

Thank you.

CHAIRPERSON LUDERER: Thank you very much.

All right. We'll move on now to the next agenda item. This will be Dr. Myrto Petreas from the Department of Toxic Substance Control who's going to be telling us about the preliminary results from the California Teachers

Study.

Sara, did you have a --

MS. HOOVER: Sorry, I wasn't -- did you call for public comment on Item 1?

CHAIRPERSON LUDERER: I'm sorry. Thank you for reminding me.

Amy, do we have any public comments on that last item?

MS. DUNN: There's none by email, but it looks like there's one in the room.

CHAIRPERSON LUDERER: Or 2? Are there 2?

And my apologies on that. I was wondering why we were ahead of schedule.

Yes, please. And could you please introduce yourself, since I don't have the card.

MS. BUERMEYER: Absolutely. I'm Nancy Buermeyer with the Breast Cancer Fund. And I just want to continue to say how much we support this program and all the work that it does.

And in thinking about other places to get the word out, it's certainly helpful to our advocacy efforts if this program is better known and the value of it is better appreciated. So one thing I would suggest is reaching out to the CHANGE Coalition, the Californians for a Healthy --

MR. BALTZ: And Green Economy.

MS. BUERMEYER: -- and Green Economy.

Thank you, Davis.

And we could probably help with that. And the other thing I would like to think about and work with the Program on is how do we get this out to the State Legislators, the people who actually hold the purse strings for this -- or at least 1 or 2 of the purse strings for this Program. How do we find a way to highlight the Program and its accomplishments to the State Legislature?

So I will happily work with Michael and Amy on those things. So thanks again for all your work.

CHAIRPERSON LUDERER: Thank you very much for those comments. And we also have comments from Davis Baltz from Commonweal.

MR. BALTZ: Thank you. Good morning, everyone. Davis Baltz with Commonweal. I'd also like to congratulate the Program on the ongoing work that they're doing with, you know, as we've known from the beginning, less than the full funding that they need and staffing changes. And for the past few months without a director, and I know they've been working hard to find someone.

The presentation Michael -- Dr. Lipsett was very informative. I just wanted to comment on a couple of

things. I was, you know, pleased to hear that you got quite a bit of interest from county health officers and other county officials who are in charge of environmental health. And I'm just wondering if it would be worth it to also reach out to cities that have, you know, a large enough environmental health department or departments of public health for the handful of cities that have that, and try to get them interested and into the loop.

In terms of, you know, cementing their interest from some of these counties, would it be worth it to invite them specifically to come to a future Guidance Panel meeting and perhaps -- I don't know if it would be appropriate, but if there was some part of their programming that related to biomonitoring, perhaps they could be asked to make a small presentation.

And another idea would be, since we almost always meet in Sacramento and occasionally in Oakland, obviously budget constraints, but could we go on the road to Los Angeles, at some point, and attract some new potential audiences down there.

The prenatal sample work is very exciting. I think, you know, there are more than half a million babies born in California every year. It's 560,000, something like that. So these kinds of results, once they would be available, if, you know, the QC issues are worked out, I

think this kind of data will be very compelling to communities.

Dr. Wilson has talked about the response he got in Martinez with the steel workers' hearing about contamination of cord blood. And, you know, when we first started doing biomonitoring a decade or so ago, when people first found out about it, they were, you know, taken aback. It's actually kind of shocking information. And those of us who've been around it for a decade have kind of become used to biomonitoring and what it tells us. But for new audiences, it can really be galvanizing.

So I think, you know, generating more data, if it's possible, about prenatal exposure will be very useful and helpful for the Program.

In terms of trying to attract medical students or nursing students that Dr. Lipsett has been working on at UCSF, are there other medical or nursing schools that have been approached? I realize there would be a number of hurdles before something like that could come to fruition, but, for example, USF is starting a new environmental health nursing program. Barb Sattler is the Director there. We know her. And if you haven't talked with her yet, that might be another program to just run it by and see if there's some interest.

I think, you know, at the end of the day, if we

could get medical students and nursing students to be biomonitored during their training, it would have effects that would be felt long after they graduated.

The election is over. It appears that the Democratic majorities in both houses have increased. And again, coming back to the prenatal study, if the samples can be available for $37 a sample, that does seem to be a relatively reasonable cost. And if we can interest some potential legislators who might have influence over the budget, I think there's going to be a lot of possibilities for talking about new revenue streams. So let's -- it's not your responsibility, of course, but for those of us in the public interest community, I think we're very interested to track this and see what we can do to help.

And then I guess, finally, on the website. Congratulations, Amy, we're -- you know, for those of us who are a bit older, we don't -- we're not wedded to our devices like some young people, but I think, you know, exploring new ways of getting information about the Program out are always going to be useful.

As I've said in the past sometimes at these meetings, I think that having actual data that is available to share with communities is the step that's really going to generate additional interest, get more people signed up for the listserv, get more people coming

to these meetings.

So to the degree -- and I didn't hear an update about this, but if there is going to be studies actually published in journals about the work of the Program so far, if those can be dovetailed or coordinated with the website release or at least have that data available when the website does go public, I think that would be useful and it would be helpful for us also to be able to point people to those studies.

So thanks for the chance to comment as always. I'm only going to be with you this morning. Unfortunately, I've got some other meetings this afternoon, but, as always, thank you for your work.

CHAIRPERSON LUDERER: Thank you very much.

Dr. Alexeeff, you had a comment as well.

OEHHA DIRECTOR ALEXEEFF: Yeah. With regard to the website, I just wanted to make a comment. So OEHHA is on Facebook and Twitter. And so we have been sending out Twitter feeds like regarding this program, so we'll be continuing that. And it has -- appears to bring in some additional people, so we'll continue that process as well.

CHAIRPERSON LUDERER: All right. So now I'd like to introduce again Dr. Myrto Petreas from the Department of Toxic Substances Control, who's going to be giving us an update on preliminary results from the California

Teachers Study.

Dr. Petreas.

(Thereupon an overhead presentation was presented as follows.)

DR. PETREAS: Good morning, everyone.

So Dr. Lipsett was saying our laboratory has completed its assignments for the 2 major studies, the FOX and the MIEEP. Now we're working on BEST, but mostly we're working on the Teachers study.

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DR. PETREAS: So today I'm going to spend some time and explain to you what we do on the Teachers Study, what it is. And before I start I want to acknowledge Dr. Peggy Reynolds, who is the principal investigator of the study, and who -- with the Cancer Prevention Institute of California and together with this presentation. So I acknowledge their contributions.

CHAIRPERSON LUDERER: Can you speak a little more directly into the microphone.

DR. PETREAS: Can you hear me now?

Sorry.

CHAIRPERSON LUDERER: Move closer.

DR. PETREAS: I am too close or should I come close?

CHAIRPERSON LUDERER: You need to move maybe a

little closer.

DR. PETREAS: All right. So as I said, I wanted to acknowledge my principal investigator, Dr. Peggy Reynolds from the Cancer Prevention Institute of California who helped me put these slides together.

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DR. PETREAS: So what I'm going to do today is talk to you about the California Teachers Study, which is the main major study, and then segue way into our substudy looking into persistent organic pollutants and breast cancer. This is a study we're working with Peggy Reynolds and her staff. So for that substudy, I want to describe what the study aims are and what protocols we used, what chemicals we're planning to analyze, and some challenges we found and how we overcame them. And finally, we'll give you some preliminary results.

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DR. PETREAS: But, first of all, the main California Teachers Study. This is a study that started in 1995. It's a cohort of female members of State Teachers' Retirement System, so it's teachers and also employees of schools. There are over 130,000 women that participate in this study. Every year, they get contacted.

Periodically, they have questionnaires on various

issues. And there's always a linking with the Cancer Registry, hospitalization, and other -- and mortality databases. So that's the major study.

All residences at the time of the inception of the study have been geocoded. So this started initially by Prop 99 funds, but subsequently has been funded by Federal and State research grants. So that's the major -- the main study.

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DR. PETREAS: And this is a map of California showing you in 1995 when they first started, these are the residences of the participants. So it really follows the population distribution of the State.

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DR. PETREAS: Now, from now on, I'll be talking about our substudy, which is looking at persistent organic pollutants in breast cancer using the original cohort.

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DR. PETREAS: So this is led by Dr. Reynolds from the Cancer Prevention Institute of California, and her staff are shown here. And collaborating are our laboratory, City of Hope and UC Irvine. This has been funded by the California Breast Cancer Research Program. And it's currently ongoing.

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DR. PETREAS: So what are our specific aims.

Number 1 was to screen for major predictors of PBDEs. And we have questions about behavioral factors, sociodemographic disparities and a lot of indoor and outdoor factors.

The second aim is to assess persistent organic pollutants as risk factors for breast cancer. And for that we use the case-cohort design from the main study.

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DR. PETREAS: More specifically, for the first aim, we targeted 360 participants who are not cases -- are not known to have cancer, breast cancer, and tried to oversample for women of color and also rural residence. So the target is to have 90 white, 90 black, 90 Hispanic, and 90 Asian Pacific-Islanders for that part of the study.

Data collection, meaning the blood samples, questionnaires, and GIS data of the residences are collected, started 2011 and we completed in 2013. So this is -- these are the samples that come to our laboratory.

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DR. PETREAS: For the second aim, we use a case-cohort design, and targeting a thousand cases and a thousand non-cases basically from the main study. And diagnoses were from 2007 to 2012. Data collection overlaps from the same of the previous aim, so it's again

2011, 2013. And again, we're getting the blood samples that we analyzed, questionnaires, GIS data.

And for that aim, we're using genotyping data that's already funded by the parent study.

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DR. PETREAS: In the laboratory, we measured the chemicals shown here, PBDEs, 19 congeners, 12 perfluorinated compounds, 15 PCBs, 7 chlorinated pesticides. And we send to a clinical laboratory specimens for measuring cholesterol triglycerides to calculate lipids and also thyroid hormones.

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DR. PETREAS: Now, one problem we had that the protocol for our Teachers Study was the phlebotomists were to go and visit participants at home or at work. So it was scattering throughout the State, making appointments. So it was very difficult to use the standard protocol of collecting -- drawing the blood and then leaving it to clot, centrifuging within a few years, freezing, shipping, and so forth.

So we designed a pilot study -- and I had briefly mentioned this before, but I'll say it again here -- to test alternative sample processing. And this would link with the questions we discussed with Dr. Lipsett before.

So the basic questions we wanted to address with

the pilot is can we have more flexibility in the field, can we have more time, and how long can samples be stored frozen afterwards?

So there are 2 different components in the question. To do that, a year ago -- last February, I believe, yes -- we did a little pilot, because I want to compare here the type of tube we use for the blood draw. The standard method is red top. This is a standard, no coating, no anticoagulant, a lot of -- the samples drawn, clotted, centrifuge, and then frozen.

The alternative is a serum separator tube, which only requires centrifuging within a few hours in the field, and then it can be shipped and processed in the lab.

The standard method again, it's only about within 2 hours, maybe 24 hours. But we wanted to stretch the time that it will take before we manage to freeze the sample to be 48 hours. So that was another question I wanted to address.

Aside from that, we thought of also adding a component to see how long do samples last in the freezer? So can we wait a month, can we wait 2 years? And this part is still ongoing.

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DR. PETREAS: So what we did, we had 11

volunteers who gave 6 tubes of blood, 3 red tops, and 3 serum separator tubes, and we processed them at different times, some of them are 2 hours, others are at 48 hours.

They were stored for 1 month, and then processed, analyzed, but they're still stored for -- our second question which is after 2 years -- so in February, we will complete 2 years of freezer storage and we'll repeat the same analysis on those stored samples.

So the first part, which were frozen only for 1 month were thawed and analyzed for persistent organics, pesticides PCBs, PBDEs, perfluorinated and new BFRs and also lipids.

So what we found was that there was no difference between using the 48-hour processing using serum separator tubes and the standard method. So that was great news, because this means that we can use the serum separator tubes, wait 48 hours, and analyze for persistent organics and lipids in our Teachers Study, but also as we can talk for maybe for future studies.

We will assess the effects of storing for 2 years after February 2013, so we'll repeat the same analysis of the stored samples. So we thought that was a very good set of data -- of information, because this way we have the ability to use these type of tubes.

So if I can say parenthetically here, so we have

the other request, can we use these other tubes that the genetic disease program uses and we got hold of the tubes and talked with the people who used them, we talked with the vendor, and we're very happen to find out just yesterday that both tubes are exactly the same, even though they look different. They have the same type of coating and the same type of gel.

So we're more confident, at least from the tube itself, there won't be any problem. But as we speak, we're testing with some bovine serum trying to see if there's any artifact there.

CHAIRPERSON LUDERER: Can I just -- I just wanted to interject a quick question. With the 48-hour serum separator tube, is that 48 hours at room temperature or are they stored cold?

DR. PETREAS: Room temperature, yes.

So what we plan to do with the perinatal study tubes is eventually do something similar, but before then, as Dr. Lipsett was saying, we want to visit the lab in Richmond. The DPH lab in Richmond also processes these types of tubes, so they -- we agree that we will visit and see how they are treated in that lab.

The fact that they're sitting open on the autosampler rack for so many years is a little, you know -- We feel uncomfortable about that, because for

those of you who have visited our lab, we have this super clean separate air system, sticky mats so no dust is taken into the lab.

Whereas, for their purpose, they don't need that. So there's a little concern about how every single lab that does that -- and it's only just one lab that we can negotiate, but all of them were they going to change the procedure, so -- but we'll know.

So we have some thinking in how to test different questions. So what Dr. Bradman said and others have -- we're taking notes on how to assess a future pilot.

Okay Back to the Teachers Study now.

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DR. PETREAS: So what makes this study very interesting is because it's large. It's a well defined cohort, very diverse geography Statewise. We have a lot of questionnaire information and GIS data. And also, we can independently assess outcomes through linking with the Cancer Registry. We use state-of-the-art techniques in the lab and we also have statisticians to do some pretty interesting data analysis.

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DR. PETREAS: So where are we? Results.

So as of last week, we had received over 1,500 samples. And this includes cases and non-cases. These

have been collected starting in May of 2011, and up to this past October. We received several shipments from different places. Everything with chain of custody and everything has gone well so far.

So as we receive samples, the first thing we do after we log them in is to do the aliquoting. Aliquoting is quite intensive and complex and very critical, because that's where you open -- you thaw the samples, and you open them and you dispense the right amount in different vials correctly labeled, and then you store them frozen until each type of analysis needs them to come out of the freezer.

So, so far, we have aliquoted 638 samples, have been shipped for lipids, and we have received the results for the lipids of those. We have results for 279 of perfluorinated compounds and 80 samples for PBDEs.

And when I say we have these, these are the ones that have gone through all the QC, and the reviews have been communicated back to our collaborators. But we continue analyzing as we speak, so at the same time, we -- in fact, we have done more than double the number already of what I'm showing you there. But they haven't gone through our QC, so I can't talk about them yet, because we haven't cleared them. But we continue working full speed on those.

So from now on I'll be talking only about the 279 samples for PFCs. And these are the results I'm going to show.

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DR. PETREAS: First of all, these 279 came from these different locations. So again, wherever most of the population density is, that's where these come. And as we add samples, we'll do more dots on the map.

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DR. PETREAS: The characteristics of age, as you can see here, this is a very old cohort. I mean the range is from 40 to 94 years old. And the mean age is 68. In terms of race and ethnicity, it's mostly white, but we have every other group there. And we will be updating this as we acquire more samples and we analyze them. So these are only the ones for which I'm going to present data now.

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DR. PETREAS: So these are our first results, and these are in nanograms per milliliter. The main components here are the PFOS, PFOA, and so forth. The first row shows the detection frequency. So you can see most everyone has -- these are the major components. So these are measured in almost everyone.

We're showing a range and median, a geometric

mean, and for comparison, we're showing the -- from the NHANES, the geometric mean for females over 20 years old. Now, remember that NHANES data, the latest one, are from 2009/2010. Our data were collected approximately 2 years later.

So when we make this comparison, keep in mind that all these PFCs -- must of these PFCs are on a decline. So NHANES has shown the data over the years are dropping. So we should see lower than NHANES. And usually we are, with some exceptions, and I'm going to talk about them.

So the exception actually is the hexa, PFHxS. This we are higher than NHANES. This also is dropping, but, for some reason, you know, we have high value here. The other odd piece of information is that nona, PFNa, is on the rise in NHANES, and from other data we have. So data should be higher and yet they're not.

So, of course, we only have 279 samples so far. We'll collect more. Now, these are older women. They're mostly white older women. Some of them have cancer. So we're not sure if -- we haven't looked at any case-control analysis yet. So just an update on how -- when we compare with NHANES, it's not really a direct comparison yet. But as we get more numbers and after we do some group analysis, we can have more information.

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DR. PETREAS: So the other piece of data for the lesser -- lower values for the other minor PFCs, I would say, some are -- detection frequency is as little as 20-something percent.

Of these, NHANES doesn't report any summary statistics or geometric means, because of the low detection frequency. We can only compare with one -- only for one, the method PFOSA. And again, we have some differences and we're not sure yet, but -- so this is the first batch of data we can share with you. And they will be uploaded on the website along with newer data as they become available and added to these tables.

But I would like to hear if you have any questions on how to do it better here.

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DR. PETREAS: So where we are now, so we have to complete the pilot study by evaluating the freezing for 2 years. That will start in February. And recruitment for this study continues, and it will end by the end of 2013. So we have a whole year to recruit more and collect more samples.

And, of course, we continue sample analysis here. And the data would be -- as aggregates would be posted to the website.

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DR. PETREAS: So how this fits with the Biomonitoring California Program, it helps because it's statewide recruitment, and it's a special demographic, which hasn't been captured so for. So it's mostly older women. We have young mothers and babies. We have firefighters, but this is the mostly older women.

It's a collaborative effort with the Cancer Prevention Institute of California. It's partially funded by the Breast Cancer Research Program.

So what the benefits we have is that with the pilot, we found that using this new serum separator tube allows more flexibility in the field, so it can be used in other studies from biomonitoring and others.

I already said that this data will complement data from the other studies, expanding our database. And at least, in my mind, this is a very good model for future collaborations to sustain the program, where somebody else also does a lot of the field work, has a hypothesis, and we partner with them to generate more data for them and for us.

So with this, do you have any questions?

CHAIRPERSON LUDERER: Thank you very much, Dr. Petreas. That was very exciting to hear those results and see all the progress that's been made.

Dr. McKone.

PANEL MEMBER McKONE: Very interesting study.

I have a somewhat specific questions on slides 18 and 19, particularly 18, where you have NHANES information relative to this population.

I mean, although it's interesting to compare it at the geometric mean, there are -- I'm wondering how much more of an analysis of difference you might have done? For example, I would really like to see the full probability plot of both populations, because sometimes you -- things are close in the middle and then the curves. The trend line is very important across the population, because you can have some -- you know, one population where the median is about the same, but you have a lot of outliers and then the curves go different.

I guess the other thing would be a more, again just -- this is kind of a screening comparison where you just look at the 2 medians, but there are ways to test the hypothesis that these distributions are indeed different or are indeed the same. And I think it would be really interesting to do that to get a little more sense about --

DR. PETREAS: Oh, I agree with you, but this is very preliminary, so -- and we didn't want even to give them a mean and standard deviation, because -- so percentiles is not at this stage. So once we have more

samples, we'll do that. And it is a dialogue we have with the Program and how should we post data on the website. So for this time, we think let's give just averages and --

PANEL MEMBER McKONE: Although with 279 -- this is the 279?

DR. PETREAS: Yes.

PANEL MEMBER McKONE: Yeah, you have enough to do some pretty good statistical -- I mean, bring a statistician in to start testing hypotheses.

DR. PETREAS: We have Dr. Nelson as a statistician. And again, these are cases and non-cases together. So we haven't done any epidemiological analysis or anything on that. So this is just aggregate results for this program.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: Again. This is Julia Quint.

Another impressive accomplishment by the Biomonitoring Program. Thank you for sharing the preliminary results. I was just wondering, what are your chances of recruiting the numbers that you are -- would like to recruit, the oversampling for the different ethnic groups that you mentioned in the first slide, because now it's predominantly white, is that correct?

So I was wondering if you had any sense. I know you're recruiting the ongoing.

DR. PETREAS: You're right. Remember, those 360, 90, 90, 90 from each group were supposed to be non-cases. So there are -- the sampling is a little complex. I can tell you from what I hear that recruiting, as usual, doesn't go that well, so we lowered their expectations. So rather than having 1,300 cases, 1,300 non-cases, now we're talking about 1,000 each. In proportion, I think this 90, 90 may become 75, 75. So we're -- yeah. Anyone who has done recruiting knows it's not easy.

PANEL MEMBER QUINT: Right.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Thank you. Mike Wilson.

And thank you, Dr. Petreas. And just echoing the Panel's appreciation for the difficulty of this work. And carrying it through from recruitment all the way out to analysis and providing results, it's actually pretty astounding.

And I think, you know, my question, and maybe it's not something that could be answered at this point, but it's echoing Dr. McKone's question about the -- you know, what the distribution looks like and if there -- and the variability, and if it's -- and maybe it's premature, but if there -- if you have highly exposed or, you know, high levels in subgroups and so forth. And I'd be very interested in hearing about that at some point, but I

guess what you're saying is you don't feel that you have the data yet to do that, is that correct?

DR. PETREAS: Correct. Hopefully, next time, we'll have more and we can have more information to share.

PANEL MEMBER WILSON: Yeah. Okay. All right. Thank you very much.

CHAIRPERSON LUDERER: Dr. Alexeeff.

OEHHA DIRECTOR ALEXEEFF: Yeah. Hi, Myrto. I was just wondering just following up on those 2 questions, do the NHANES data provide the distribution of the results? Is that something that's --

DR. PETREAS: Yes, if the detection frequency is high enough.

CHAIRPERSON LUDERER: I had another question too about the blood samples. So you mentioned that these participants were recruited initially in 1995, and the blood samples that you presented the results from were from 2011-12, is that right?

DR. PETREAS: Yes.

CHAIRPERSON LUDERER: Would it be possible, are there archived blood samples where you could look at changes over time in these participants? Is that a possibility in this group?

DR. PETREAS: I believe through different research grants, there have been many studies on this

cohort. I can't -- we don't have access -- I don't have access to that. It wasn't done in our lab, and I doubt it will have these type of chemicals, but if there's anything, I mean, the Teachers Study has a lot of -- a wealth of information. So I'm sure in the analysis, they may want to go back and compare something, but that's not part of what we do.

CHAIRPERSON LUDERER: Thank you. Dr. Bradman, did you have a comment?

PANEL MEMBER BRADMAN: Just a quick question. For the NHANES comparison, is there a larger enough N within NHANES for women over 40 years old, so the comparisons can be within approximately similar age groups?

DR. PETREAS: Actually, what the NHANES shows to everyone is females, but I believe somebody has found this over 20 years and --

PANEL MEMBER BRADMAN: I think you can actually download the NHANES data.

DR. PETREAS: I got the -- no, I only got from the -- I was looking at the September update of the 4th report, but Lauren Joe, I guess -- you want to come up?

MS. JOE: Dr. Bradman, you're correct. Yeah, we downloaded --

CHAIRPERSON LUDERER: Can you identify.

MS. JOE: Oh, my name is Lauren Joe. I'm an epidemiologist with the Biomonitoring Program.

MS. JOE: The NHANES data is downloadable. And for the females over the age of 20, we used that data and calculated for the geometric means for this group. I didn't look to see if the over the age of 40 would be -- would have enough N to produce these numbers, but that's certainly the best comparison group. And we would look into that for this study and for the other ones that we're doing to make sure that the age group and the gender are the best fit for the comparison.

PANEL MEMBER BRADMAN: Right. Okay. And this is a related question. If you remember, the paper from Ami Zota, where they were able to work with the NHANES database and breakout California specific data. It seems like this might be an opportunity to do that as well for an older age group that matches this as California specific particularly for things that we think may be higher in California like flame retardants.

MS. JOE: That would be great if we could get that data. I think it's -- you know, we have to request it and things.

PANEL MEMBER BRADMAN: It's challenging.

MS. JOE: You're familiar with that. It's challenging, but this is certainly a goal.

DR. PETREAS: I would say that would be after we have more data from our study.

CHAIRPERSON LUDERER: Okay. I think this would be a good time to see if we have any public comments.

MS. DUNN: No public comments.

CHAIRPERSON LUDERER: Okay. Do we have any further discussion or questions from Panel members?

Dr. McKone.

PANEL MEMBER McKONE: Just probably a comment. I would just -- one of the things about NHANES is that the way it's structured is it's not a random sample geographically, but it has to capture certain regions of the country and it has to capture certain population types.

The way they do it is they set up, I think it's like, 15 locations or something. That's all they -- they don't have a large number of locations.

And when they come to California, they way oversample the State, not because they're trying to oversample, but because they meet so many of their criteria in California, and they do not have to be balanced across the State.

Now, they won't -- I mean, we can't pull that out -- you can't pull that information out unless you go in and go to one of their facilities and do the blind,

sort of, analysis. So they give you all the California data. It's stripped off and you can organize it. So this is -- that's what, I think, Ami did.

So it's possible to do this and really narrow it down. And it's likely that the N will be relatively larger than you would expect from just -- you know, it's going to be more than 10 percent -- California is about 10 percent of the country, but there are more than 10 percent of the members of NHANES that are from California, because of the way they sample, and set up their procedures.

CHAIRPERSON LUDERER: Sara, did you have anything?

MS. HOOVER: (Shakes head.)

CHAIRPERSON LUDERER: All right. If we have no further discussion from the Panel, I'd like to thank Dr. Petreas again, and then move on to the next talk.

So the next talk will be presented by Dr. Jianwen She from the California Department of Public Health. And he's going to be giving us an update on the Environmental Health Laboratory work and some preliminary results from some environmental phenols and polycyclic aromatic hydrocarbons.

Dr. She.

(Thereupon an overhead presentation was presented as follows.)

DR. SHE: Good morning, and welcome members of the Panel and the audience. I'm Dr. Jianwen She, Chief of the Biochemistry Section of the Environmental Health Laboratory Branch. Today, I will update -- I will provide an update and the preliminary results for some environmental phenols and the hydroxy-PAHs.

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DR. SHE: I'm going to update you on recent staff changes, methods in production, proficiency test results, project sample analysis, and the results, finally, our future work.

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DR. SHE: As Dr. Lipsett already mentioned, in September we hired Ying Li as an Environmental Scientist II. She is currently working on our OP metabolite method. Ying have a lot of experience pharmaceutical industry and analytical chemistry.

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DR. SHE: Last SGP meetings, we shared with you the 7 methods in production with over 40 analytes being measured.

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DR. SHE: Sorry.

Since July, we have 2 more methods in production, which are metals in urine with arsenic speciation in

urine. At the present, EHL has capability to measure over 50 analytes in urine, and the blood.

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DR. SHE: As I mentioned at the July meeting, we participated in the CDC PT programs. We'd like to report the results.

Recently, we received the result for the 2 CDC PT programs. We are enrolled in the biomonitoring non-persistent organic PT and the PT in arsenic speciation. PT program will lay the foundation for the data comparability between different laboratories. For the organic programs, we submitted results for our phthalates, OP specific metabolite, environmental phenols, and the hydroxy-PAH totaling 29 analytes.

This CDC PT program is the first of its kind. According to CDC's grading criteria, we successfully passed 21 out of 29 analytes. CDC's criteria may be considered more rigorous than other PT programs we participate in. Nevertheless, we have determined why the 8 analytes did not pass according to CDC's criteria.

We also submitted results for our arsenic speciation in urine method. We submitted the results for 6 analytes, and we are 100 percent proficient.

We are expecting another round of CDC PT samples this month, and continue to use the CDC PT program and

others as a tool to assess and improve our laboratory method.

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DR. SHE: I'd like to talk a little bit about our project status. So for our biomonitoring project, for the MIEEP; sample analysis is complete for all organic analytes in urine. Since the July SGP meeting, hydroxy-PAH data was complete and submitted to EHIB. We are working on releasing the DAPs data as well. We have some technical challenge on the DAP method, by the way. The metals and arsenic speciation analyses are completed and are currently under review.

In the bottom part of this slide, you can see for the FOX project, sample analysis is also completed for all organic analytes in urine and are currently under review. The metals in arsenic speciation analysis is currently in progress. We anticipate and submit all FOX data results to EHIB by spring 2013.

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DR. SHE: For the other project, the BEST project, participant recruitment is complete. We received 110 blood samples and 109 urine samples. Blood metal samples analysis is complete and the results have been submitted to EHIB.

In the next couple of slides, I will present the

preliminary environmental phenol results for the MIEEP project, and also for the hydroxy-PAHs result for the WHE project.

As you may know, MIEEP is a collaboration with UCSF and UC Berkeley. Convenience samples were from San Francisco General Hospital. We analyzed the urine samples for the 89 mothers enrolled. You may be aware in previous presentations that it was 91 samples, because 2 participants provided duplicate samples.

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DR. SHE: This table shows the environmental phenols data including method detection limit, sample detection frequency, geometric mean, and the 95th percentile values.

Our method can detect of very low -- I said ppb levels -- a fraction of ppb levels for the analytes, which is comparable to what CDC method can do.

These 3 analytes were measurable in almost all the MIEEP participant's urine samples. You can see the detection frequency is about 90 percent or around 90 percent.

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DR. SHE: Compared to the pregnant women in the 2005 to 2006 NHANES survey, we found 129 pregnant women's data from the NHANES survey for the year 2005 to 2006.

MIEEP women seems to have lower geometric mean values for BPA, BP-3, and triclosan. Further data analysis is underway to verify this observation.

This slide shows basically 95th percentile, which may mean our data, in certain cases, have a wider variation range, but it is very limited data. I cannot talk too much.

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DR. SHE: And the next study is a collaboration UC Irvine and the EHL are working together to analyze Women's Health and the Environment urine samples for hydroxy-PAH. Dr. Ulrike Luderer is the PI for this study.

For this collaboration, the WHE study question is focused on looking at the urinary PAH variability in relation to ovarian function. Fifty-one Orange County women were involved and the specimen was collected from September 2010 to March 2012. The women had to meet certain eligibility requirements to participate; for example, not using hormonal contraception, not surgically sterile or diagnosed infertility and not pregnant.

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DR. SHE: At the initial visit a blood and urine sample were taken from each of the participants. Daily, for 6 menstrual cycles, urine was monitored for hormones using a microelectronic dipstick. Participants also kept

a daily diary documenting illness, medication, alcohol intake, and et cetera.

The monthly urine collection was on the 10th day of the cycle and was the first morning urine samples. Participants stored these samples in their freezer at home for up to 2 months, and then the sample was transferred to UCI lab, where it was stored at minus 80 degrees.

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DR. SHE: EHL so far received 150 urine samples from UCI for hydroxy-PAH analysis. All samples are from the monthly collection, the 10th day of the menstrual cycle. This table represents the data from the first 51 samples received and analyzed. We have included method detection limits, detection frequency, and the range for each analyte we measured.

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DR. SHE: For the future, we will complete the FOX analysis and the data review. We will analyze pilot BEST sample and the WHE samples. We are also preparing for the next biomonitoring project, which is called Expanded BEST, by pre-screening urine and the blood collection containers for various analytes to make sure our device is contaminant free.

In September, our analyst received the in-house train for automated sample preparation. They are working

on developing a method for this.

Lastly, we are cross-training our analysts on various methods to cover -- to maintain our capability and the capacity in case staff may turnover.

Thank you.

CHAIRPERSON LUDERER: Thank you, Dr. She. It's wonderful to see the increasing capability and capacity of the laboratory and to have the -- be able to share data with us today. I'm sure all the other Panel members agree.

Do Panel members have any questions or comments at this point?

Dr. McKone.

PANEL MEMBER McKONE: Yeah. Again, it's really related to -- I know you're still doing preliminary analyses, but I guess my question is when you calculate percentiles, do you do that from the ranks or do you actually -- because the problem is you're going to have non-detects, and you can do some really strange things if you start treating them as half a detection or some other things.

So often the best way to treat it is not worry about the value but the rank, right? So the median -- so that's why I asked, because I like to see the median, because that's the middle point of the sample, and it gets

right around this problem. Hopefully the median point is above the limit of detection. It's not. On a lot of NHANES, the median is below, so it's still all -- anyway, so could you --

DR. SHE: You are right. For this -- for the environmental phenols, our detection frequency is about 88 percent. So when we calculate the geometric means, if that's -- in people if the detection frequency below 60 percent is harder to provider data. But you are right, median can tell how many are below detection, you still have median values, so I agree with that. We should provide it.

And in our draft slide, I have the median values. And later on, I have some comment to count on the data sheet. I deleted it, but in general the median value is very closed to the geometric mean.

PANEL MEMBER McKONE: Okay. So, again, I'd just sort of recommend what I do is that use probability plots, because they are rank-based, so you can actually see -- right. So even if you have, like, 20 percent of your samples are at -- below the limit of detection, the 21st sample, or the 21st percentile, is a real number and it's still the 21st percentile. So you just start -- right, there's these ways to do it by rank, so you don't get this artifact of trying to give value to something below the

detection.

Again, this is getting a bit technical, but I think, you know, it's very important to do this. Otherwise, you can add some really odd biases to the mean if they're calculated by assigning any value to something below detection.

DR. SHE: Yeah. That's a very good point. We will -- when we do the complete data -- further data analysis, we definitely take your consideration -- take your concern into the consideration.

CHAIRPERSON LUDERER: Any other questions or comments from Panel members, at this time?

Then, if not, this might be a good time for our public comments if we have any.

MS. DUNN: We do not have any public comments.

CHAIRPERSON LUDERER: All right. We have time for additional discussion or questions.

Dr. Quint.

PANEL MEMBER QUINT: Julia Quint.

I just had a question. You have a number -- I'm sure you've explained this before, but I've forgotten. You have a number of review steps when you were showing the status of the various determinations, peer review, supervisor review, you know, various reviews. So this is just internal QA/QC procedures within the laboratory.

Could you say a little bit more about what's going on with the various -- at the bottom of your slide here.

DR. SHE: Yeah. Actually, that's -- all of this review kind of slowed down our process. You can see for the FOX and for the MIEEP, analysis is finished, but some of them are under the peer review, some of them are on a QA review, and a supervisory review.

So the process for peer review is basically the peer chemist we will check -- go to the instrument and make sure the analyst conduct the analysis and use the right parameter, make sure, and then when we look at the peak, we -- how big is the peak, and where the location of the peak, did the chemist identify the peak correctly, make sure confirmation peaks information still available. So we have quantitation peaks. We have confirmation peaks. And they also have a certain relationship. And all this kind of review will be done by the peer review.

And then in the QC reviews, they checked more and said okay, did the laboratory have contaminations of how the blank is running, how your duplicate samples are running, how your blind and your control sample, quality control samples are running?

So with this kind of a review and then transfer the provider. The provider more on the project levels. So I think the -- I will say a peer review on each sample

levels and the peer review made on one levels, a batch levels, and the quality provides on the project level to look for, is this a specific batch of run have a significant difference than previous batch, what's the possible reason?

So this process is tedious, and then slowing. We try to at least some mechanic part we can automate it. We are working it. So I don't know if I answer your question.

PANEL MEMBER QUINT: No, very well. You answered it very well.

So now you're -- in addition to that, you're sending samples to CDC and participating in another level of review with the samples you sent to CDC, is that correct?

DR. SHE: Yes. Actually, at the beginning, we send some samples to CDC, but CDC is very busy to work on, and so we didn't get the result back. That's a long time ago. But right now, CDC send us samples. They send us PT samples, which we called external quality control samples, so -- which is provided to us. Right now, they send us, for example, hydroxy-PAH. They send us 5 different level of samples. And then they require you to run the sample in the same exact way as you run your unknown samples, and then you report back to them.

Under the CDC, one of the criteria, if you -- for this 5 samples, if you pass the 4 of them within the -- they use this score. If this score is smaller than 3, then 4 of them with this score small than 3, you passed. If you fail the 2, you fail.

And for this -- because of this is the first kind of external PT with so many analytes the CDC tried to do, and, at this moment, I think very few labs' data can be used as a reference. CDC's own data is used as a reference to judge other lab at this moment, as far as I understand.

PANEL MEMBER QUINT: Thank you very much for indulging me. That's really -- I understand it now. It's very rigorous. Very good. Thank you.

DR. SHE: Thank you.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Sure. Thank you, Dr. She. And it's just a quick question on the UC Irvine study, is that being funded by the CDC?

DR. SHE: Dr. Ulrike, you want to talk a little bit more about the bigger fund. I know you funded us with something, but I don't know where you get your funds.

CHAIRPERSON LUDERER: It was an NIH funded grant, funded by the National Institute of Environmental Health Sciences.

PANEL MEMBER WILSON: Oh, NIEHS.
CHAIRPERSON LUDERER: Yeah.
PANEL MEMBER WILSON: Okay, great. Thank you.
CHAIRPERSON LUDERER: All right. Well, it looks like we're ahead of schedule here for the morning.
Thank you very much, Dr. She.
So we can take lunch now or -- yes. Okay. And we had an hour, I think, allotted for lunch. Do you want to continue allotting an hour or come back --
MS. HOOVER: Hi. This is Sara Hoover. I would suggest we come back at 1.
CHAIRPERSON LUDERER: At 1. All right. Everyone, we'll see you at 1, and reconvene then.
Thank you.
(Off record: 11:51 AM)
(Thereupon a lunch break was taken.)

AFTERNOON SESSION

(On record: 1:09 PM)

OEHHA DIRECTOR ALEXEEFF: Okay. If I could have your attention, we'd like to get ready to begin again. We'll wait one more minute for one Panel member to return, but she just stepped out for a second.

CHAIRPERSON LUDERER: All right. I'd like to welcome everyone back. I hope you all had a good lunch. And we have several interesting topics to discuss this afternoon. The first discussion is going to be of potential designated chemicals p,p'-bisphenol As and diglycidyl ethers of p,p'-bisphenols. And Dr. Laurel Plummer from the Office of Environmental Health Hazard Assessment is going to be presenting that.

Dr. Plummer.

DR. PLUMMER: Hello, everyone. I hope you had a nice lunch.

Okay. So I'm going to start today introducing our potential designated chemical document.

(Thereupon an overhead presentation was presented as follows.)

DR. PLUMMER: And so the purpose of this agenda item is to provide to you, the Panel, information regarding the potential designation of the group that we've classified as p,p'-bisphenols and diglycidyl ethers

of p,p'-bisphenols.

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DR. PLUMMER: And this is to facilitate your deliberation on whether or not to designate this group of chemicals.

All right. So in this side, I'd just like to review how chemicals can be considered for biomonitoring. They can be designated based on their inclusion in CDC's National Report on Human Exposure to Environmental Chemicals Program.

And then secondly, the Panel can also recommend that chemicals be added to the designated list for the Program.

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DR. PLUMMER: Okay. So this slide provides some background just on how we've arrived at the development of this document, which I'm going to summarize with my presentation today, and just give a general review of it, which you've received in your packets in advance.

And so some activities that recently the Program has completed in past meetings include in March we presented a preliminary screening table on bisphenol A or BPA substitutes and structurally related compounds. And then at that meeting, the Panel provided feedback on suggestions for what next steps we could take regarding

chemicals to focus on or chemicals with specific use profiles.

And then in July, the Program provided an interim update on additional screening of these substitutes and structurally related compounds, which included come newly published papers and kind of a more focused list of chemicals for consideration.

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DR. PLUMMER: Okay. So based on Panel advice and our additional research, the Program prepared a potential designated chemical document for the group p,p'-bisphenols and diglycidyl ethers of p,p'-bisphenols. And so, as I said in this talk, I'm going to provide a general overview of the document.

And so here, this slide just shows some example structures that represent chemicals in our group. In the top right-hand corner of the slide, you'll see a representative structure of a p,p'-bisphenol, and of which there are others on the slide.

In the bottom right-hand corner of the slide is a diglycidyl either. And the example of chemical we have is BADGE. p,p'-bisphenols have 2 phenol groups with hydroxy groups at the para positions. They're joined by a carbon or a sulfur bridge.

And then the diglycidyl ethers, as you can see in

the structure of BADGE, have epoxypropyl ether groups that replaced the hydroxy groups there.

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DR. PLUMMER: And so a little bit of background and justification for why we think considering these chemicals as a group is reasonable, is that it will facilitate broad laboratory screening of these chemicals, which are structurally similar, as I showed in the last slide and also in -- there's some more example structures in the document that you received. And it will also allow the Program to look for emerging chemicals that are part of this general group, which we've talked about in the past, the laboratory screening kind of as an alternative approach to just strictly literature screening.

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DR. PLUMMER: And then so I just want to remind the Panel and the audience that the criteria for -- what the criteria for designation for our chemical or chemical class are -- that are set forth in the enabling legislation, which is Senate Bill 1379.

And just as a reminder, these criteria are independent of each other and so they don't have to all be met for a chemical to be designated. And so I'll just go through them briefly.

The first one is exposure or potential exposure

to the public or to specific subgroups; known or suspected health effects based on peer-reviewed scientific studies; the need to assess the efficacy of public health actions to reduce exposure to the chemical; the availability of a biomonitoring analytical method with accuracy -- with adequate accuracy, precision, sensitivity, specificity, and speed; the availability of adequate biospecimen samples and consideration of the incremental analytical cost to perform biomonitoring analysis.

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DR. PLUMMER: And so 7 chemicals are highlighted in the document that the Program has prepared for you. Many of these chemicals have production volumes that are reported at over 1 million pounds. And this is based on the 2006 inventory update reporting. So we don't know the more recent values for many of these yet.

Many of them have also been detected in consumer products and in dust, and some also have been detected in biomonitoring studies.

And then in regards to health effects, or known or suspected health effects, several of them have evidence of in vivo endocrine activity, and then even more have in vitro indications of endocrine activity.

And then lastly, TGSA is a chemical that was identified through the U.S. EPA's Design for the

Environment assessment for substitutes for thermal paper. And they identified TGSA as having the potential for formation of the epoxide reaction product, which is highly reactive and poses potential toxicity concerns. So that we've grouped under "other concerns".

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DR. PLUMMER: So just to expand a little more on the different criteria. Major uses for many of these chemicals include as protective coatings that are used inside food and beverage containers, just for example, and then also BPS and TGSA have known or suspected use in cash register receipts. Actually, both of these are known to be used, I'll say that.

And then some of the other chemicals in this group are also used to make plastics or dental sealants.

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DR. PLUMMER: But I just want to note also that many of these studies that determine potential use and exposure were conducted in Europe and Asia. And so really little is known about use patterns in California and the United States.

So this slide just goes a little more into details specifically what type of consumer products the chemicals highlighted in the document were detected in. And as you can see, many were detected in, you know, the

cans, which includes, you know, specifically measuring from the lacquer or the can lid, and then many types of canned food, you know, oily and aqueous food substances. Beverages as well.

And then BPS there's quite a bit of evidence from 1 study New York about evidence of use in paper products. And then also the New York study -- or a separate New York study evaluated presence of the first 4 chemicals in indoor office, home, and office and home dust.

And then, again, many of these studies were conducted in Canada, Europe, or Asia. And so there's only, you know, one study that we found that evaluated it in the United States from the late 1990s.

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DR. PLUMMER: Okay. And then many -- there's a few biomonitoring studies that have been conducted. The New York group detected BPS in 81 percent of urine samples. That included samples from New York and 7 other countries. BPB was detected in urine samples and serum samples in 2 studies from Europe. And then BADGE was detected in saliva of dental patients after application of a dental sealant.

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DR. PLUMMER: So this slide summarizes known or suspected health effects that we've identified so far,

based on scientific -- or published scientific studies. And some of the chemicals in this group have evidence of both in vivo and in vitro endocrine activity. BPS, BPF, and BPAF had positive responses in the in vivo rodent uterotrophic assay, which indicates a potential for estrogenicity.

In vivo studies have reported that many bisphenols and also some diglycidyl ethers bind to hormone receptors, such as the estrogen receptor. They're active -- some are active in hormone receptor-mediated reported gene assays, and some have been found to increase cell proliferation in cell-line MCF7 breast cancer cells.

And then a few of these chemicals also have been shown to be related to adipogenesis in vitro. And this avenue came from a suggestion from the Panel to look into that potential health effect or potential for that health effect. And then also some of the chemicals had positive responses in vitro genotoxicity assays.

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DR. PLUMMER: Okay. And so just to address another question that came up in our last meeting about the relevance of using in vitro and in vivo studies to look at the health effects, there's a group Yamasaki and colleagues have looked at the relationship between the in vivo uterotrophic assay in rodents and relationships

between estrogen receptor binding and estrogenic activity in reporter gene assays, and found, in many cases, that the activity correlated well between the in vivo and the in vitro studies.

And this was for a group of chemicals that were known estrogen receptor agonists, and then some additional chemicals as well. But they chose ones that had various receptor binding affinities to kind of cover the range of those. And I have those papers if you're interested in seeing them more.

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DR. PLUMMER: And so analytical methods. The program would need to adapt or develop analytical methods, based on, you know, existing methods that we have for other environmental phenols, but also using published methods from the literature. And the labs have identified that reference standards are available.

These chemicals most likely will be measured in urine, and due to their structural similarities could likely be bundled and run as a panel as is done with many other chemical groups.

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DR. PLUMMER: Okay. So one of the other criteria is looking at the need to assess efficacy of public health action to reduce exposure to specific chemicals. And we

do know that increasing use of some bisphenols is expected for certain applications, for example, TGSA in thermal paper. And the Design for the Environment Project from the U.S. EPA goes into a lot more detail on that.

And then for many others -- for many other chemicals included in this group, the extent of use and exposure really is unknown and more information is needed.

And biomonitoring this group of chemicals would help assess the extent and level of exposure in Californians.

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DR. PLUMMER: And so lastly, we'll just summarize the options that we're suggesting for the Panel. You can consider recommending for designation p,p'-bisphenols and diglycidyl ethers of p,p'-bisphenols as a group or you could select to recommend designating one or more of the chemicals that are included in this document that you've received. You could recommend against designating or can postpone your recommendation.

And so with that, I'd like to take any clarifying questions that you might have.

CHAIRPERSON LUDERER: Are there any questions from the Panel?

Thank you for that excellent overview, Dr. Plummer.

Dr. Quint and then Dr. Wilson.

PANEL MEMBER QUINT: Thank you for that -- again for that excellent presentation. This is Julia Quint. You mentioned that New York urine -- let's see, I don't know which group of chemicals had been measured in the urine of some cohort in New York, and I wanted to know more about --

DR. PLUMMER: It was BPS.

PANEL MEMBER QUINT: I'm sorry?

DR. PLUMMER: BPS is the one.

PANEL MEMBER QUINT: Okay. BPS. Do you know more about who the urine came from? I mean, what sort of sample that was of New Yorkers.

DR. PLUMMER: I do, yeah. It was from -- mostly from people living in Albany.

PANEL MEMBER QUINT: So it was just -- yeah.

DR. PLUMMER: Yeah. And so the urine was collected both from males and females that ranged from ages 2 to 84. So that's a pretty large range of people. And I have the paper. I don't exactly -- I think -- I can't tell you the exact number of individuals that were tested, but I can -- if you wanted to know that, I could tell you.

PANEL MEMBER QUINT: No. That's fine. I just was wondering if -- yeah. So they had a method -- they

have a developed method for measuring BPS?

DR. PLUMMER: They do, yeah, and they've published that. They published 3 papers on BPS in the past -- in this year.

PANEL MEMBER QUINT: So when you said that there aren't -- most of the studies are from Asia and some from Canada and not many in the U.S., those are for all of the compounds or for in dust or just -- I mean --

DR. PLUMMER: So the dust paper -- oh, sorry. Go ahead.

So the dust paper looked both -- they're kind of companion papers, so they looked in similar countries as they measured -- for where they measured urine. So since it's from the same group, they, you know, I guess work with their collaborators in the same fashion.

But for a lot of the detections in consumer products, they were done, you know, in other countries. So we're pretty limited in our knowledge of which kinds of chemicals are being used in the U.S.

PANEL MEMBER QUINT: Right. And just one final question. In this Design for the Environment -- oh, sorry. In the Design for the Environment study, which I didn't have a chance to -- I don't know if it's available, but I didn't have --

DR. PLUMMER: Yeah, it's available on-line.

PANEL MEMBER QUINT: Yeah, I didn't have a chance to read it. I was wondering if, you know, aside from TGSA, if there were other substitutes that were not structural analogues of this group of chemicals that were being developed or in use or did they find anything else that -- emerging that didn't belong to this group of chemicals?

DR. PLUMMER: Yes, they definitely did. And we presented those chemicals as part of our preliminary screen. And with Panel recommendation and further research, we narrowed it down to the chemicals that were structurally similar, which is really helpful since we're a laboratory-based program, to really help move forward our understanding of potential exposure. So that's kind of the path we came down.

And so there are quite a bit -- the group has worked with industry, and so they really have some firsthand knowledge, you know, straight from the producers that, yeah, this is being used or things like that. So it's a pretty exhaustive list they have, but they're doing -- and Sara has done quite a bit of research on kind of further substitutions, which we haven't looked completely into, but it looks like they're just, you know, taking another approach to possibly reduce activity, but again, those aren't included in this document.

PANEL MEMBER QUINT: Right. No, I was just more interested. So there are safer substitutes for these chemicals that don't raise concerns about toxicity. I guess that's what I was mostly concerned about.

DR. PLUMMER: I'm not sure if they've really identified ones that they say are completely safe in that assessment.

PANEL MEMBER QUINT: Okay. All right.

MS. HOOVER: Sara Hoover, OEHHA.

Just adding to what Laurel was saying. So basically, yes, we are very interested in derivatives. For this initial step, we're only including bisphenols and diglycidyl ethers. We have not done the research to make the conclusion of, yes, these are safer. We're just speculating that likely some of the substitutions that are being made are possibly, you know, with a view to reducing biological activity, but we're just -- at this point, we're speculating.

PANEL MEMBER QUINT: No, right. I understand.

MS. HOOVER: And we -- later in the day when you're talking about agenda items for 2013, this is another avenue that we could pursue. So, right now, we were just biting off, you know, a discrete piece, and then we could do additional research and bring back more information on the other types of derivatives.

PANEL MEMBER QUINT: Right. I was just wondering if the EPA report had talked about -- had done any --

MS. HOOVER: Yes. So the EPA actually did an extensive -- so I'm just saying we haven't digested that information.

PANEL MEMBER QUINT: I understand.

MS. HOOVER: It doesn't -- it's not that it doesn't exist. It's just that we can't comment in detail, at this point, because we haven't digested it. We digested this set.

PANEL MEMBER QUINT: No, I understand.

MS. HOOVER: But, yeah, they actually went through and they did ratings. You know, they looked at toxicity. They looked at environmental degradation. They looked at all -- you know, it's quite an extensive document. So that, if we did pursue, you know, some of these derivatives, there's a wealth of information that we could call on to answer those questions.

PANEL MEMBER QUINT: Thank you.

DR. PLUMMER: And we worked really close too with Cal Baier-Anderson from the DFE report. And so she's been a really valuable resource for us moving forward in this.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Yes. Mike Wilson here. And thank you, Dr. Plummer, for that presentation and also

for the preparation materials. You know, very helpful and very well written and so forth. I appreciate that.

And so if I -- I have a question about your sense of the use of these particular substances in California specifically. And my understanding, if I remember, is that the National Toxicology Program identified bisphenol A in 2008 as having effects among, I think, children and infants, brain effects, behavior effects, prostate gland, I think, effects for -- at current human exposure levels for fetuses, infants, and children in 2008. And then last year, Governor Brown signed AB 1319 that prohibits the use of bisphenol A in children's, I think, sippy cups and --

DR. PLUMMER: Baby bottles.

PANEL MEMBER WILSON: Yeah, and bottles at greater than 0.1 parts per billion, I think, for use by children under 3 years of age. So fairly, you know, specific targeted piece of legislation there.

So is it your sense that, you know, now we're a year after that piece of legislation, that you're expecting that California, in particular, will be seeing a greater use of these particular -- these substances as substitutes for bisphenol A, not only in those products, you know, the sippy cups and so forth, but in other products as well?

DR. PLUMMER: Yeah, definitely. And I think a

couple of the chemicals that we presented earlier in the preliminary screens, some of the proprietary chemicals, in addition to the ones that we were talking about today, that could structurally be used in the different, you know, applications for plastics and can linings. And, I mean, I think, not to go too far, but I think with thermal paper as well, I mean, the awareness from BPA is -- in that instance for the sippy cups and things, is influencing manufacturers, you know, across the board in different industries.

So while we don't know specific uses of these substitutes in California really or the U.S., based on current production volumes, just based on all this activity within the past year and prior to that, I would expect these chemicals to be increasing in use definitely.

Did that answer your question?

PANEL MEMBER WILSON: Sure. Yes, it did. And I guess it's -- you know, in my own experience, I've seen labeling -- a growing number of labels, it seems to me, of bisphenol A free products.

DR. PLUMMER: Definitely.

PANEL MEMBER WILSON: Okay.

DR. PLUMMER: Well, and I think -- so the 2 chemicals we talked about in the preliminary screen, there's evidence that they're being used in plastic, like

you know, bottles like the hard plastic bottles. And they have done some studies. There are posters at SOT looking at the different -- or like toxicity of these alternatives.

And those don't appear to be particularly toxic in the studies that they've done, but I can't really comment too much further on that. But, yeah, there are lots of alternatives that are coming out, definitely.

MS. HOOVER: Again, Sara Hoover, OEHHA. Just to add to that.

So the alternatives that Laurel was just referencing are not part of this group, so those are different alternatives.

In terms of this group, Laurel did find a paper that tested BPA-free thermal paper, I think, or paper in general. It was paper. Yeah, BPA-free paper, and found BPS, I think. So we know BPS for sure. BPS is being found -- if you look at the New York study, it's being found in a lot of paper. I mean kind of an amazing amount of paper products.

We -- did you want to add?

DR. PLUMMER: Just one other. So with all the measurements in dust as well, we know like BPF is out there, but we don't know where it's coming from necessarily at this point.

MS. HOOVER: Yeah, that was a good point. So we don't really have clear evidence of production volume for BPF. If you looked in the document, actually Laurel discovered some information on manufacturer websites, where BPF is being used to make certain epoxy resins. And then New York did find, you know, detections of BPF in dust, which was maybe higher than you'd expect based on the kind of production volume we're finding.

So, essentially, our answer is we don't really know. You know, we're speculating. And kind of the point of -- the point, as Laurel was talking about, of looking -- of just let's call it a group, is to allow the lab kind of more freedom to take bulk urine samples, samples from volunteers, and if these are designated, they could actually do this in program studies, and just see what's there, you know, as much as possible.

And, of course, our hope is to have the ability to do non-targeted screening or -- I guess you'd still call it targeted in this group, but broader, you know, targeting of looking for what's there, rather than trying to chase particular chemicals, because we really didn't feel -- after doing this, we don't feel confident that we can actually tell you what's out there, what's being used, what's being substituted. We just don't have that kind of confidence.

I would say, in terms of use, we have a little bit more confidence in information about some of the derivatives, and some of the alternatives that Laurel was pointing to not in this group, but we prioritized this group also for health-based reasons and so forth.

PANEL MEMBER WILSON: Thank you.

CHAIRPERSON LUDERER: Actually, I kind of have a follow-up to Dr. Wilson's question, which is you showed in those really nice tables and also in more detail in the document that quite a few of these chemicals have endocrine activity, in particular estrogen receptor-binding activity and stimulating MCF7 cell growth and reporter assays. And I was wondering if you could make any kind of general comparisons of the potency relative to BPA, since that's one we're maybe all more familiar with.

DR. PLUMMER: That is an avenue I tried to go in. And I think what we were trying to do is report what data is out there. And unfortunately, it's inconsistent when it comes to relative -- you know, one in vitro study will say put the chemicals in one order, and then another study will put them in a sightly different order.

And so there was a little too -- there wasn't enough consistency for us to pull some order like that out unfortunately.

CHAIRPERSON LUDERER: And then one more question which is having to do with the -- so at the back of your -- at the end of your document, you have this extensive table of other chemicals that fall into these same -- that fit this structural pattern, and I was wondering whether the ones that you chose to highlight, did you chose those based on availability of information, production volume, kind of everything together?

DR. PLUMMER: Yeah, you're exactly right. And I meant to say that during the talk, but these are the chemicals that we had, you know, more than a handful of studies on. Some of the ones in the back there's actually no studies on. And the list of chemicals was pulled from the NTP report. They just -- I think we mentioned this at another meeting where they're working on evaluating BPAF with, you know, the whole range of chronic and reproductive studies and things like that.

So they provided a really exhaustive list in the back. And so a lot of those structures came from that. I don't know, did you want to say something else?

MS. HOOVER: And, yeah, just to -- for the back. In the end, what we did was we actually went through and annotated which papers those appeared in. I also went through and searched for production volume, and I think just 1 or 2, you know, popped up. So because it was '06

data, we didn't really feel comfortable relying on that. So I would say not really based on production volume, but more based on being cited a number of times. And also kind of just to illustrate the range of types of compounds that we're considering to be in this group, that was the purpose of that last table.

CHAIRPERSON LUDERER: Dr. Bradman.

PANEL MEMBER BRADMAN: Asa Bradman.

I just want to highlight your comments on the analytical methods. And you mentioned that these compounds would likely be able to be run as a panel, so to speak, I assume in the phenols analysis with bisphenol A. So it sounds like the laboratory development processes would be challenging, but clearly possible, especially if standards and other references are available.

I'm just curious, are there any QA/QC programs with respect to these compounds, for example, with CDC? And, in general, maybe you could provide a sense of when the laboratory capabilities would be in place?

DR. PLUMMER: So in regards to the PT question, I don't really know the answer to that yet. I would assume they're could be some kind of collaboration with the New York Laboratory or consulting with them.

And then your second question -- I'm sorry, can you remind me again what it was.

PANEL MEMBER BRADMAN: The second question was about the time frame for getting those capabilities.

DR. PLUMMER: I might have Dr. She answer that.

DR. SHE: I think since the last meeting when we started talk about the topics, we purchased some standard. I don't know exactly which one we purchased. Some of them -- and then we have the instrument ready for this kind of analysis. So it could be bundled with the current environmental phenol method.

Also, regarding your first question about the PT program, I think in addition to New York group, that Dr. Liao and Kannan did some study published. And at UCSF, I've heard they tried to do some kind of PT program, but I'm not sure which phenol they exactly worked on, but we will find out more.

So in regard to time frame, I think that's -- if we have proper standards and should quite easy end up for some of them.

CHAIRPERSON LUDERER: Dr. Wilson.

DR. LIPSETT: Michael Lipsett.

I just wanted to add a comment about part of the discussion earlier looking at the relative potencies of these bisphenol A analogues, and that is that it's probably not bisphenol A that is problematic as an estrogen receptor, in terms of its transcriptional

activity, but one of its metabolites that's active at like 2 to 3 orders of magnitude lower concentrations.

And so when we talk about the relative potencies of these different analogues, we don't -- I mean, it would make more sense globally to look at the spectrum of their different metabolites and how those operate, but that's not really what we're doing here. We want to just try and get a sense of the breadth of exposure to these different compounds.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Thank you.

Dr. Plummer, another question for you. I was noticing that in the tables that you provided in the materials that some of these substitutes are -- you know, looks like substitutes for bisphenol A, some of them are fairly environmentally persistent. But for the most part, they're not really bioaccumulative.

And I guess that's also true for bisphenol A. And yet, of course, we see it in the NHANES study -- NHANES findings. And I'm just wondering if you could say something about if these are all basically going to behave the same with regard to bioaccumulative potential. And I guess my understanding is that, you know, we've continued to see bisphenol A in the NHANES findings because people are continually exposed, even though it has a fairly short

half-life in the body.

So, I guess, I'm curious about that point, if that's actually correct, and how that would play out with these substitutes?

DR. PLUMMER: So, I mean, the numbers and things in the tables that you have are based on PBT Profiler, which is a majority of the values, except where we've noted that it's experimental. So it's really not known how these chemicals behave, you know, actually in the environment. That's really the best I can do.

MS. HOOVER: Yeah, I mean, I think that you observed that there wasn't a lot of evidence of bioaccumulative issues. You know, BPAF appears to be more persistent. And then there was actually this one study cited by NTP as having found BPF in adipose tissue.

DR. PLUMMER: You mean BPAF.

MS. HOOVER: Yeah, I said BPAF. Maybe I slurred it -- BPAF in adipose tissue. NTP cited that, but when we actually looked at the paper, it wasn't clear if they actually detected it in adipose tissue or if they were just predicting where it would elute, if it were in adipose tissue. So we contacted the authors and we haven't been able to reach them yet.

That would, you know, be a different story obviously if they were finding it in adipose tissue. But

I think that your description of pseudo-persistence by virtue of extensive use and continual exposure is probably most likely for most of these.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: This is Julia Quint. Yes, and in that same vein, I mean, for some of these uses, like for the thermal paper, I would think you would have occupational exposures being of real concern, because where most of us handle some of these things, you know, we probably all have similar exposures to the derivatives that are in canned -- lining cans and things like that. But for some of these, people are handling them continually throughout their, you know, work days and stuff.

So I think, you know, that's another reason that it's important to look at these.

DR. PLUMMER: Yeah, definitely. And another thing too is that the New York paper where they were measuring it in paper products, they looked at a number -- I mean, not just thermal receipts, like cash register receipts, they were looking at, you know, airline luggage tags, different cardboard, you know, packaging materials and things.

And so that's -- you know, there's many, many different sources like that. And whether they're adding

the BPS to those materials or whether it's a byproduct of them being recycled and somehow, you know, contaminate that way, we didn't look too much into that, but that's, you know, kind of an interesting thing to consider.

PANEL MEMBER QUINT: Right.

CHAIRPERSON LUDERER: Dr. Bradman.

PANEL MEMBER BRADMAN: Just a quick response to Dr. Wilson's question. You know, for many -- some of these compounds that have relatively high Kow's, if they metabolize quickly, they're excreted quickly and have short half-lives in the body. And a relatively small proportion can actually accumulate in adipose tissue, just if you look at the equilibrium. So, for example, like chlorpyrifos has a relatively high Kow. In indoor environments it can be fairly persistent.

We probably expect bisphenol A to be persistent, you know, in its plastic container, but I would expect that if people were exposed to it, it moves through the body quickly. We know it has a short half-life, so it's not likely to be accumulative, and measurements usually would reflect ongoing exposure.

And I think that's kind of -- it's clear when you look at some of the studies that came out from CDC on day-to-day and within-day variability. Given the level of fluctuation, it's probably reflecting ongoing current

exposures rather than any real potential to accumulate in the body.

CHAIRPERSON LUDERER: Dr. McKone.

PANEL MEMBER McKONE: Just expanding on that, I know in CHAMACOS when we started the chlorpyrifos again, it doesn't last long in the body. The household environment retains it for a very long time in that case because chlorpyrifos is degraded photolytically, but that pathway doesn't exist. There's not enough light intensity indoors. I don't know about bisphenol A what its breakdown is, but there are a lot of semi-volatile chemicals now we're seeing that have -- some of the phthalates have extremely long half-lifes in the indoor environment.

And so it essentially becomes -- you almost have to look at it as an extension of the individual and this is the reservoir. And you can quit the use, but you may have months before it fully disappears as an exposure pathway. So it really does add -- in a way, we almost wish we could extend this to biomonitoring homes, as well as the people in those homes, to really kind of see this coupled system working.

DR. PLUMMER: Well, and I think that's particularly -- I think, to me, that's why the measurements in indoor dust are particularly interesting,

for that reason. I mean, you kind of expanded on it there, where things may persist indoors, so it, you know, helps us understand where -- you know, that there may be exposure, but just it's hard to know at this point where it comes from.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: On that note, since I mentioned occupational exposure, you have toddlers with dust and hand to mouth, so I think it just, you know, raises -- I just really want to commend the Program for this looking -- I mean, taking the forward look of looking at these substitutes that are emerging, because I think that really is so important, because, you know, we know about BPA, so the focus is there, but then these other analogues are coming onto the market as substitutes. And we've seen the regrettable substitution thing throughout the whole -- you know for a lot of these chemicals. So I think it's just great that you're doing this.

DR. PLUMMER: Yeah, I agree.

CHAIRPERSON LUDERER: Okay. I think we should take some public comments, if we have any at this point.

All right. We have one public comment. This is from Nancy Buermeyer from the Breast Cancer Fund.

Sorry if I mispronounced your name.

MS. BUERMEYER: Trust me, you wouldn't be the

first to mispronounce my name. It's Nancy Buermeyer from the Breast Cancer Fund.

The Breast Cancer Fund has spent a great deal of time and energy looking at BPA and trying to educate the public about the concerns and get it out of consumer products. And to speak a little bit to Dr. Wilson's question earlier, the law in California is certainly important, but the FDA also recently banned the use of BPA in baby bottles.

Interestingly enough, they did it in response to a petition by the American Chemistry Council, which argued that the market had already abandoned the use of BPA in baby bottles nationwide, and so they made it formal.

And what I think it speaks to is the fact that BPA is on the down -- is on a down spiral. Companies understand how much consumer concern there is about this chemical. We have launched a project recently called Cans Not Cancer that's focused on BPA in food can linings.

And of growing concern to us, as companies like Campbell have just recently announced that they will remove BPA from their canned food linings is what are they going to replace it with. And they have been far less than transparent, and I'm being kind there, about what chemicals that are going to be used in place of this endocrine disruptor.

So I think what has driven a lot of the research and the progress that we've made on BPA is the NHANES data, looking at the fact that, you know, over 90 percent of the public is exposed to this stuff. And so ergo, we should find out what it does, and that has spurred a -- just a explosion of scientific research on this chemical. And it really has been pushed by the fact that we all have it in us.

And so I think it is critically important that we move forward wherever we can to see what are the substitutes they are using and what are they -- and are they showing up in us, because that's going to spur more research.

My impression is that the research that we have about the toxicity of a lot of the substitutes, to the extent that we know what those substitutes are is paltry. Like, we just don't know very much about BPS. We don't know very much about these other chemicals. And it's going to take education about what they are, finding them in people to spur that scientific research, so that we know what those chemical impacts are, those health impacts are, because we don't have a system in place right now that requires thorough testing before these chemicals are put into use.

So that's a very long-winded way of saying that I

really hope that the Panel moves forward with these chemicals. I think any information we can get about human exposure to the chemicals that are being used to replace BPA is going to be really important.

And I would submit that the amount of BPA used is certainly in some of the consumer product categories that we've worked on has been reduced dramatically since the 2006 data. So we need to be figuring out what else are they using and working to find out if they really are safer alternatives and moving forward with that.

So I hope that the great work that the Program has done results in some data about what's getting into us.

So thank you very much.

CHAIRPERSON LUDERER: Thank you very much.

Do we have any additional comments or discussion from the Panel or are the -- Dr. McKone.

PANEL MEMBER McKONE: It's probably a clarification, but -- so bisphenol A is already in the NHANES set, right? So anything that's in NHANES is already, from our perspective, listed. So what we're really talking about now is listed everything in this category of chemicals, other than bisphenol A, we're just adding to the list, I guess, is that right?

CHAIRPERSON LUDERER: Yes.

DR. PLUMMER: Yes, that's true. And also BPA is a priority chemical for the Program, so it's already moved ahead to -- from designation to priority.

PANEL MEMBER McKONE: Well, I just want to make that clarification, because we're actually adding more chemicals to, in a way, a family that's already there, but only represented by one chemical.

DR. PLUMMER: Essentially, yes.

CHAIRPERSON LUDERER: Dr. Wilson?

PANEL MEMBER BRADMAN: I think also -- am I interrupting?

CHAIRPERSON LUDERER: No. Dr. Bradman, go ahead.

PANEL MEMBER BRADMAN: I just wanted to clarify too, it sounds like there's 2 options -- 3 options we have today. One is to recommend against designating these compounds. The other is to designate it, put it on the list. And the third would be to make it a priority. So I just want to clarify that --

DR. PLUMMER: No, just --

CHAIRPERSON LUDERER: Not to make it a priority, but not to recommend against them as a class -- sorry. So recommend against, recommend them as a class of chemicals, or we could choose certain ones that we think should be designated, not the entire list.

PANEL MEMBER BRADMAN: Right, but still even

within those categories though, they can be designated as being on the list, but we can also elevate them to make them priority compounds.

CHAIRPERSON LUDERER: That's not under discussion today. I think we have to do the designation first and then priority is another discussion in the future.

DR. PLUMMER: So with priority, we would prepare a potential priority table. Yeah, so that's a different step. So we would bring that to you, you know, to provide information about listing as a priority. This is just for --

PANEL MEMBER BRADMAN: Okay. So the decision today is just around designating it.

DR. PLUMMER: Yeah.

PANEL MEMBER BRADMAN: Okay. Thank you.

CHAIRPERSON LUDERER: Dr. McKone and then Dr. Wilson.

MS. HOOVER: Dr. Luderer, can I just add, and our lawyer just indicated, that you can request that we do that right away. So if that was something you wanted to add to your recommendation, you could request the Program bring it back to us, you know, as soon as you can work it into the agenda or however you want to make that recommendation.

PANEL MEMBER McKONE: But bisphenol A already is

in that category, right?

Right, so we already have one --

MS. HOOVER: Bisphenol A is a priority chemical. We actually noted in the document it's part of this group. And, you're right, just like PBDEs, you know, PBDEs were on our list, and then we made the larger group of brominated and chlorinated flame retardants. So this is kind of similar, you're right. So it's the same family, but it's not designated, and we would have to have another step to make them priority.

PANEL MEMBER McKONE: So my question is pretty practical, basically in the laboratory, since we already -- you already have to do bisphenol A, right, so you've got to do the chemical analysis for it. These are all in the same family of chemicals and they're there, right? So it literally is just fine-tuning -- you know, if we designate it, the only amount of added work is just looking for more peaks, isn't it? I mean, you're not going out and doing an extraction method or --

MS. HOOVER: I mean, I think looking for more peaks is a lot -- you know, it's still a lot more work. I mean, it sounds easy, but --

(Laughter.)

MS. HOOVER: -- you know, it's still a lot of work. But, you're right, that it's not -- you know, we're

not breaking, you know, totally new ground here. There's methods. There's standards available. It's definitely doable I think as Dr. She was indicating. Did you want to add anything, Jianwen?

DR. SHE: I agree with Sara is a little bit more work because -- and of few more peaks. It's possibly you do like some qualitative work, the quality control, how to make sure your data is accurate in quantitative ways is -- take a little bit longer.

But overall, if the structure is very similar, we can predict the fragmentation in the source I do not think is too much work, you are right.

PANEL MEMBER McKONE: But it's -- what, it's about 6 or 7 more chemicals or are there even more? I'm not sure how many are in this other general category. Anyway.

CHAIRPERSON LUDERER: I think to answer that last question, there's the table at the end of the document would -- those chemicals would also be included.

MS. HOOVER: Yeah. We don't have a count. I mean, it could be a vast number. And I can tell you that I did additional research, as did Laurel, and there's many -- I mean, we have a whole bunch more that we didn't even include in the document. So these -- the 6 or the whatever that are highlighted -- 7. Thank you, Laurel.

The 7 that are highlighted, they're just the 7 that we chose to highlight. So the group is not the 7. The group is the entire group.

CHAIRPERSON LUDERER: Dr. Wilson, did you want to make a motion?

PANEL MEMBER WILSON: Sure. Mike Wilson.

I mean, I think there's 2 points here. One is that, without question, this group of substances satisfies the criteria for designation under the Program, if not all of the criteria.

And second, that given where we are with the market and the extent to which any number -- any single of these substances might emerge as the most prominent substitute for bisphenol A - in other words, we don't really know at this point - I think it makes sense to designate the group. And so I would like to make a motion that the Panel recommend for designation under the California Biomonitoring Program p,p'-bisphenols and diglycidyl ethers of p,p'-bisphenols as a group; and that the Program follow up with further information to the Panel that could support potentially prioritizing this group of substances.

CHAIRPERSON LUDERER: Thank you, Dr. Wilson. I'd like to just repeat that, make sure we all -- that I got it right.

So we have Dr. Wilson moves that the Panel recommends that the p,p'-bisphenols and the diglycidyl ethers of p,p'-bisphenols be recommended as designated chemicals by the California Environmental Contaminant Biomonitoring Program; and further, that the Program come back at one of the subsequent meetings with some information about possibly elevating some of these chemicals to priority status.

CHAIRPERSON LUDERER: Dr. Quint, did you have a comment before that.

PANEL MEMBER QUINT: No.

PANEL MEMBER McKONE: Can we second with a comment?

CHAIRPERSON LUDERER: Please do.

(Laughter.)

PANEL MEMBER McKONE: I second the motion, but I think it's not just the chemicals. It's an important opportunity - we've said this before - when things are in transition, right, chemical substitutions, getting them on the list and getting action going soon gives us a very important opportunity to see a transition.

And I think not just for health, but for a lot of environmental exposure, you know, science, just for understanding it better is very important to see those transitions. It looks like this is another opportunity to

not just collect information on what's in people, but actually watching it change in time.

And we don't want to miss that opportunity, which is why I would second the motion and probably be a little more inclined to move faster to get these in the system.

CHAIRPERSON LUDERER: All right. Then I'll just ask the entire panel, starting with Dr. Quint, to vote on the motion.

PANEL MEMBER QUINT: I vote yes.

PANEL MEMBER WILSON: Mike Wilson, aye.

CHAIRPERSON LUDERER: Ulrike Luderer, yes.

PANEL MEMBER McKONE: Tom McKone, yes.

PANEL MEMBER BRADMAN: Asa Bradman, yes.

CHAIRPERSON LUDERER: Okay. And so the Panel has recommended -- the Panel unanimously recommended designation of these chemicals as a class.

All right. Thank you.

All right. So our next agenda item for today is - and we are well ahead of schedule - chemical selection planning. This is discussion of synthetic musks for potential future consideration. And this will be presented by Dr. Gail Krowech from the Office of Environmental Health Hazard Assessment.

Dr. Krowech, thank you.

(Thereupon an overhead presentation was

presented as follows.)

DR. KROWECH: Good afternoon.

Before I get into the discussion of synthetic musks, I wanted to just give a little background on how we have come to look at them. The Program has been -- was asked to look at synthetic musks as possible candidates for biomonitoring from several sources, from State staff in the query of State scientists a few years ago, on recommendations for biomonitoring by the public, and by the Panel.

So the purpose of the agenda item today is a preliminary review of some information on potential exposure.

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DR. KROWECH: Synthetic musks are widely used in personal care products and in some cleaning products as well, such as perfume, body lotion, deodorant. In the cleaning products, there's high use in furniture polish, laundry detergent, and fabric softeners.

There are 4 classes of musks: Nitro musks, polycyclic musks, macrocyclic musks, and alicyclic musks.

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DR. KROWECH: So this is a -- the next 2 slides will be slides of example structures for these 4 classes.

The first one are the nitro musks. And the

example is musk xylene. The polycyclic musks, this is Galaxolide and I'm going to be often using trade names when I talk about the musks, because it's easier to keep track of them that way.

--o0o--

DR. KROWECH: The next class is macrocyclic. And this is an example of ethylene brassylate. And alicyclic musks, the example Romandolide.

--o0o--

DR. KROWECH: In terms of the nitro musks, commercially, the most important ones have been musk xylene and musk ketone. They have been declining in use worldwide since the late 1980s. We know that they're not included on the list from the International Fragrance Association list of fragrance ingredients in 2010.

You can see musk ketone is not reported in 2006. The import production volume is less than the U.S. EPA reporting threshold. And we don't really know what's happening right now. The latest we have is 2006.

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DR. KROWECH: This page shows the persistence and bioaccumulation information. Musk xylene has been concluded to be very persistent and very bioaccumulative by the EU under REACH. And it's been designated as a Substance of Very High Concern.

So this table shows the predictions of PBT Profiler, the U.S. EPA screening tool for persistence and bioaccumulation, for each of the musks. And also I've included the Log Kow's that are referenced in PBT Profiler. Those are all -- they were all noted to be experimental values.

Both of these 2 -- these musks have been found in blood, breast milk, adipose tissue, and environmental samples as well.

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DR. KROWECH: So on to the polycyclic musks, which were the original replacements for nitro musks. And I think all of the recommendations to the Panel -- to the Program to look at synthetic musks were basically to look at polycyclic musks. The commercially most important ones have been Galaxolide and Tonalide. And we have documentation that there's been declining use in Europe since the 1990s. We don't know what's happening in the United States. We don't have the most recent information.

It looks -- that seems consistent with the information on Tonalide that was below the reporting threshold for -- in 2002 and in 2006.

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DR. KROWECH: And just -- this slide just is to give you an example of how much musks are in products.

And in this study, they looked at 60 consumer products and looked at the levels of musks. So this is the highest level of Galaxolide that they found in these various products, which you can see is pretty high.

And also, I wanted to note that some products had more than one musk and definitely more than one fragrance material. So the perfume sample had over 1,000 parts per million Galaxolide and 451 parts per million Tonalide.

--o0o--

DR. KROWECH: Let's see -- I missed one. Okay. And here's the persistence in bioaccumulation, predictions from PBT Profiler predicting persistence for both of these musks, and bioaccumulation for Galaxolide, and you can see the Log Kow's are over 5.

They have been detected in house dust, in wastewater. Fish collected near effluent sites had fairly high levels, particularly of Galaxolide, and those also in the United States.

They were -- the polycyclic musks have been found in bivalves in San Francisco Bay, in marine mammals, and in humans, in adipose tissue, breast milk and blood.

--o0o--

DR. KROWECH: This is a structurally-related fragrance, Iso E Super. And it's structurally similar to Tonalide. You can see the import production reporting is

increasing from 1986 to 2006. And unlike some of the other synthetic musks, there isn't information about a decrease. I didn't find any information about decreasing use in Europe. I did find something in Sweden that showed there was increasing use from 2003 to 2010.

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DR. KROWECH: And here is the prediction from PBT Profiler in terms of persistence and bioaccumulation as well as the Log Kow.

Iso E Super has been detected in house dust in Canada, in wastewater in the U.S. and Europe.

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DR. KROWECH: This is the next class of musks, the macrocytic musks. And they're likely an emerging class of musks. And this table shows the available volume of use in pounds for four of the musks of this category. So I have the U.S. EPA inventory update reporting to 2006, and then the International Fragrance Association report from 2008 showing for North America 200,000 -- about 200,000 to 2 million pounds for each of these.

The worldwide use of ethylene brassylate was reported by the same organization to be greater than 1,000 tons or greater than 2 million pounds.

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DR. KROWECH: This slide shows 23 macrocyclic

musks, each of which was the subject of a separate toxicity review. And all of these were published in 2011. And this is just to give you an idea of the activity on macrocyclic musks.

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DR. KROWECH: And again, this is the prediction from PBT Profiler for the 4 macrocyclic musks that were in the production -- import production volume table. They were predicted to not be persistent. One of them was predicted to be bioaccumulative, and you can see the Log Kow's are all over 4.

One of them, ethylene brassylate, was looked for in a study on house dust and detected.

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DR. KROWECH: The final class may also be an emerging class of musks. And I was able to find import production volume for one of these, Helvetolide. It was reported as less than 500,000 pounds. We also know that it was first produced commercially in 1990, and it hadn't been reported in 2002 or before then.

All of these were predicted to be persistent by PBT Profiler. Helvetolide also was predicted to be bioaccumulative. The first 2, Helvetolide and Romandolide are in commercial use, and I don't think the third one on that list is.

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DR. KROWECH: This is a table about how dust from a 2012 study -- this is part of the Canadian house dust study where samples were taken from 2007 to 2010. So it gives an idea of something that's more recent -- fairly recent. And you can look at the different categories of musks.

The polycyclic musks were detected 100 -- had 100 percent detection frequency. The Galaxolide lactone is an oxidation product of Galaxolide. And the levels also of the polycyclic musks are -- you can see, are pretty high, the median levels.

The nitro musks were -- also had high detection frequencies, particularly musk xylene, but the median levels were much lower.

Iso E Super, the structurally-related fragrance, had a detection frequency of 82 percent. And ethylene brassylate was the one macrocyclic musk that they looked for and the detection frequency was 43 percent.

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DR. KROWECH: This is a table of findings from biomonitoring studies in blood and adipose tissue. The first 2 were from Austria. And just to give you a sense of percent detection for Galaxolide, Tonalide, and the study from Austria looked at musks -- at nitro musks as

well.

So the detection frequency was very high for Galaxolide, much lower for Tonalide. And for the nitro musks, musk xylene, also a high detection frequency. I didn't include it here, but the median levels for the first study were 400 nanograms per liter for Galaxolide and 11 nanograms per liter musk xylene. They didn't report Tonalide.

The adipose tissue study was from New York City. And they found high levels both of Galaxolide and Tonalide.

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DR. KROWECH: The final biomonitoring study, again from New York, and these were from breast milk samples in 2004. The top rows show breast milk samples from women who had not previously nursed children, and the bottom rows are the samples from women who had nursed one or more children.

So, you know, you can see the levels of Galaxolide are very high and decreased after in the second category. That's true for -- the decrease is true for all of the groups.

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DR. KROWECH: And then to end with a preliminary summary. So what do we know about these categories?

Well, the nitro musks, the use and exposure clearly seems to be declining, but they're still detected, and there's evidence of persistence and bioaccumulation.

The polycyclic musks, based on available information, members of this class still appear to be in use. There's declining use in Europe, and there's also evidence of persistence and bioaccumulation.

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DR. KROWECH: The structurally-related fragrance, Iso E Super, there appears to be an increasing trend in U.S. volume between 1986 and 2006. There's an increasing trend in reported volume in Sweden from 2003 to 2010. And it's predicted to be persistent and bioaccumulative.

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DR. KROWECH: In terms of the macrocyclicmusks, they're likely increasing in use, based on the 2008 data, and declining use of polycyclic musks. They're predicted to be nonpersistent. The Log Kow's are greater than 4.

In terms of the alicyclic musks, they're possibly another emerging class. Volume of use data was located for only 1 alicyclic musk. That was in 2006. They're predicted to be persistent and some bioaccumulative.

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DR. KROWECH: So questions for the Panel. What would the Panel suggest as our next steps on this project?

Would the Panel suggest that we do additional screening of synthetic musks?

Would the Panel suggest we look at other fragrances as well?

Do you suggest we proceed with potential designated documents on particular synthetic musks, on classes of musks, or other fragrances?

Or do you have other suggestions?

And I'll stop here.

CHAIRPERSON LUDERER: Thank you very much. That was a very interesting presentation and overview.

Do Panel members have any clarifying questions at this point before we ask for public comments as well?

Dr. McKone.

PANEL MEMBER McKONE: On the last thing, when the question is other fragrances, are those in a similar chemical class or would those be quite different? You know, it's kind of a broad designation, but are they likely to be --

DR. KROWECH: It was hard to think about how to include this structurally similar chemical that's not a musk, but has a structure similar to the polycyclics. So it could be that, or it could be other -- look at other fragrances as well.

I mean, it's kind of an open question, really.

CHAIRPERSON LUDERER: I have a question as to whether you have any sense about the apparently declining use patterns that you're seeing. What is driving those? Is it the concerns about persistence? Is there concern or evidence of toxicity?

DR. KROWECH: I think with the nitro musks, there's both. It's the persistence, the bioaccumulation, and there's concerns about toxicity. With the polycyclic, I think there are concerns about toxicity, and there's bioaccumulation and persistence.

So I think those might be the drivers. I mean, that's what -- that's what the papers say, so it's hard to say.

CHAIRPERSON LUDERER: Dr. Quint. Thank you.

PANEL MEMBER QUINT: Julia Quint.

Thank you. This was another excellent presentation. I would be inclined, in terms of the question about more fragrances or, you know, continue with these. I guess I would like to, you know, feel that we've looked as much as we need to for the musks, and -- but you are the best -- you're in the best position, you know, as -- because you've done the research as to what more is out there?

I mean, if you were to continue with these, what would be left to do? I mean, what would you -- if we

stuck with them -- if we just, you know, did not pursue other fragrances and wanted to pursue this further, what are we talking about in terms of additional work?

DR. KROWECH: If we stuck with these and just continued to pursue this after --

PANEL MEMBER QUINT: Continue to pursue this class of fragrances, what would be -- what would that look like in terms of further work, I guess I'm asking?

DR. KROWECH: We would -- are you referring to -- so would we -- we would prepare a document.

PANEL MEMBER QUINT: Yes. Okay. Right.

DR. KROWECH: That would be. We would prepare a document --

PANEL MEMBER QUINT: I mean, it's so thorough, it looks like part of the document, but this isn't the document. I understand that.

Right. I guess I would favor that, because you've made a good argument for -- I mean, you have persistence and you have toxicity and you have -- I mean, even the declining use, it's a persistent chemical, so we need to have a snapshot of what's going on now. You have emerging chemicals that, you know, we don't know if they're -- you know, that fit the profile of causing the same sorts of -- having the same sorts of concerns. So I think, to me, I would like to follow that pattern. I

mean, you know, have you prepare a document and see and do that rather than extend it to other things, because I think this makes a very compelling argument for biomonitoring.

CHAIRPERSON LUDERER: Although I guess the -- it is still the question that you have the musks and then you have the structurally related compound, and, you know, whether there are other structurally related compounds that may be coming in as substitutes. I mean, it sounds like that one is increasing in use, and there may be others.

DR. KROWECH: I'm not sure that one is exactly a substitute. It may be -- have been around for a long time. It just didn't -- it isn't picked up. So I don't think many people are really looking for it.

CHAIRPERSON LUDERER: I actually also have sort of a naive question, which is what actually makes something a musk, because these structures are so different?

DR. KROWECH: Okay. I had -- it's a great question, because I had the same problem, and it's the fragrance. So it's the odor. It took me awhile to figure that out.

(Laughter.)

CHAIRPERSON LUDERER: Let me just ask now whether

we have any public comments?

Oh, we have another clarifying question.

Dr. Wilson and then we'll take public comments.

PANEL MEMBER WILSON: Mike Wilson.

Just a clarifying question on your -- on the preliminary summary with the macrocyclic musks. So with the Log Kow of greater than 4, and then there were others listed with a BCF rate ranging from 280 to 5,300, is the conclusion here that these range from moderately bioaccumulative to very bioaccumulative?

DR. KROWECH: Well -- okay, so the 5,300 obviously is -- meets the category of very bioaccumulative.

PANEL MEMBER WILSON: Right.

DR. KROWECH: The others -- the reason I put the Log Kow, because I think that the predictions may be don't take everything into effect -- into account, and so this is experimental data that we have. And that's all I -- for this part of looking at it, that's all I really did. So I don't know, maybe they are bioaccumulative. Even if the prediction is low, we don't know the -- you know, this is not experimental. The only thing that's experimental here is the Log Kow. And greater than 4 may well be.

PANEL MEMBER WILSON: Right. I think that's evidence for bioaccumulation under OEHHA's Hazard Traits,

right, Kow greater than 4?

DR. KROWECH: I don't know. I know that the musks -- the nitro musks had Log Kow's around 4.

DR. MARTY: Relying on my memory is not good these days.

Melanie Marty - sorry - OEHHA.

So in the hazard trait reg, we do have a Kow and there was a lot of argument whether it was over 4 or 5. And I honestly can't remember what we ended up? I am remembering 5. I could be wrong, but if anybody has the Internet they can look it up right now.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: Julia Quint. I have a really quick question. I notice that they were -- these musks, one of -- or several were in body lotions. And I'm wondering if any baby body lotions that -- have any been found in body lotions that are used on babies or targeted to babies, do you know?

DR. KROWECH: I didn't know the answer to that. I didn't come across it, but again, I didn't do a thorough literature search. It's a good question.

PANEL MEMBER QUINT: Thanks.

CHAIRPERSON LUDERER: Dr. Bradman.

PANEL MEMBER BRADMAN: I have a follow-up question to that. Also things like diapers, those kinds

of products, baby wipes. And then also you mentioned here they're used in some cleaners. I think the only real cleaner mentioned was laundry detergent, but I'm wondering is it also used in a scent in like household cleaning products or any of these compounds are used as scents in household cleaning products or air fresheners, that sort of thing?

DR. KROWECH: You know, I want to say yes to air fresheners, but I'd have to go back and check for sure.

PANEL MEMBER BRADMAN: And a follow-up question again also, is there information on the pharmacokinetics of these compounds?

DR. KROWECH: There may well be. I tried to look for it, in terms of the macrocyclic musks. I didn't see anything. But again, I haven't done a thorough literature search. It was just trying to look at the broad range.

CHAIRPERSON LUDERER: Okay. Thank you again. And we do have some public comments, I understand

MS. DUNN: One from the internet.

CHAIRPERSON LUDERER: Okay. Great.

All right. So this comment came in on the Internet from Megan Ekstrom.

She says, "Good afternoon. Thank you for the opportunity to submit public comments and questions regarding Biomonitoring California's

Scientific Guidance Panel meeting.

"The questions I have are specifically related to synthetic musks. The first question is can you please share which specific musks are of interest to OEHHA?

"Two, what is the basis of OEHHA's concerns - e.g. Scientific literature search for trace substances in human tissues including milk, human health, or environmental concerns?

"Three, how will you conduct biomonitoring and analysis?

"And 4, what will be done with the results? Will results be made public?

"Thank you."

Would you like to respond? I think you answered a lot of those questions in your presentation.

DR. KROWECH: Okay. Well, the first question was the only one I managed to write down, which was which musks are we interested in? And we're interested in all of the ones that I mentioned in this presentation.

What was the second question?

CHAIRPERSON LUDERER: So what is the basis, scientific literature search, human health concerns?

DR. KROWECH: Okay. The basis, just from this approach, was -- or is the widespread use, the fact that

many of them are found in people. They're bioaccumulative. And so that's the main concern. Okay.

CHAIRPERSON LUDERER: And I think the third question is how will you conduct biomonitoring and analysis? And that's obviously --

DR. KROWECH: I think that's another step.

CHAIRPERSON LUDERER: Thank you.

Dr. Wilson.

PANEL MEMBER WILSON: Mike Wilson.

You know, I think it -- sort of just echoing the sentiments of the Panel, I think this is a good target actually to be going after. One of the -- a project that we did for Senator Simitian's office was looking at chemical ingredients in consumer products, and the extent to which they are revealed or not. And one of the sort of continuing problems that you ran up against was that class of substances -- of musks, you know, for which there was no further information. You know, musks were just given as that generic term.

And so, in our mind, that didn't -- you know, didn't qualify for adequate transparency, because as you've demonstrated here, there are all kinds of, you know, problematic chemicals that followed in this class. And we found musks in a lot of different kinds of consumer products across, you know, different categories and so

forth, some of which we were surprised to find them in.

So I think this is, you know, really interesting and important work, and I think it's a good target for the Program to be going after.

So thank you for your work on this.

DR. MARTY: Can I answer Dr. Wilson's question?

CHAIRPERSON LUDERER: Absolutely.

DR. MARTY: Okay. This is Melanie Marty.

And so fortunately somebody had a device I could use. And, indeed, the hazard trait is associated with bioaccumulation is a log octanol-water partition coefficient greater than or equal to 4. So, yes.

And just another comment that something could have a high Log Kow, but not necessarily be persistent because of degradative processes that occur. So it's pretty dependent on the chemical structure.

PANEL MEMBER WILSON: I mean, that's -- so Mike Wilson. I guess it would be more a measure of bioaccumulation and you'd evaluate that with the other -- with BCF and so forth.

DR. MARTY: Right.

PANEL MEMBER WILSON: Thank you.

CHAIRPERSON LUDERER: Do we have any other comments or questions from Panel members?

I think what I'm hearing from the Panel is that

there's a great interest in pursuing this further. And I've heard from several Panel members that we think that pursuing a designated chemical document for this class of compounds would be of great interest.

Is that it?

I think the next item on the schedule was a break, so we'll give our transcriptionist a break.

MS. HOOVER: Yeah. We're running a little early, but I think this is a good time for a 15-minute break, and then we'll continue after that.

So back at 2:45.

(Off record: 2:33 PM)

(Thereupon a recess was taken.)

(On record: 2:51 PM)

CHAIRPERSON LUDERER: Okay. Could everyone please take their seats, we'd like to get started again.

Okay. If everyone could please sit down, all the Panel members are here. Welcome you all back from break, and we'll move on to our final 2 -- 3 items of the afternoon. So the next agenda item is input on Scientific Guidance Panel agenda items for 2013. And Sara Hoover is going to be introducing that topic.

(Thereupon an overhead presentation was presented as follows.)

MS. HOOVER: Yeah. Hi. I'm Sara Hoover, Chief

of the Safer Alternatives Assessment and Biomonitoring Section in OEHHA.

And typically, you know, we informally consult with the Panel throughout meetings on possible agenda items, but we decided to, when we have the opportunity, take some time and ask for input from both the Panel and the public on the agenda items upcoming for next year.

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MS. HOOVER: So I'm going to just review some possible agenda items for SGP meetings just to sort of get the discussion going. And we really welcome, you know, any ideas beyond what are on these slides.

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MS. HOOVER: So we plan to continue the typical Program updates and laboratory updates. We're suggesting some possibility to look at Program planning issues, like Program sustainability. In terms of laboratory planning, at certain times, the Panel has actually kind of prioritized the priority list, so looked at the priority list and made suggestions about chemicals that you want the lab to start to pursue in terms of methods. So that's another option.

Of course, we'll continue to have ongoing presentations on Biomonitoring California results, as soon as they become available.

We're also going to bring to you, when this information is available, some post-results reporting. So there's going to be some follow-up in the firefighter population with the survey, and in the maternal and infant population with interviews.

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MS. HOOVER: So moving on to chemical selection. We'll continue some chemical selection activity. You've seen examples of that, of both of these items today, both screening for potential future consideration, and we could do -- we still have on our list to do selected pesticides from the California Department of Pesticide Regulation's top 100 list.

We also could suggest some other potential designated chemicals. So I mentioned earlier today that we could look at other bisphenol A isomers instead of just the p,p', and other derivatives that we're aware of being in use.

The Panel has actually already asked us to come back now with a potential designated chemical document on musks and possibly other fragrances.

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MS. HOOVER: And we plan -- so we had -- in past years, we've had many discussions with the Panel about potential priority chemicals. And typically we prepare a

table regarding the criteria for priority chemicals and the laboratory capacity.

So a couple of suggestions here. One is Dr. She mentioned that EHL can now measure additional metals, so we wanted to bring forward those additional metals to you and ask your opinion about are they a priority to include in studies. Another possibility might be to consider non-halogenated aromatic phosphates. And then we already heard from the Panel earlier that you do want us to bring forward the p,p'-bisphenols and diglycidyl ethers as possible priority chemicals.

And then we also hope to give you some more information about the website launch, the public input we receive, and the next steps.

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MS. HOOVER: So with that -- oh, so actually one more item. Sorry. So the April meeting of the SGP was actually planned to coincide with BFR 2013. And we've been in touch with a couple of possible guest speakers. And topics that they could speak to are things like emerging issues in biomonitoring and exposures to novel flame retardants.

So these are just some possibilities we've come up with. And we're just really interested in hearing from the Panel, not just about these ideas, but your other

ideas and other follow up you want us to pursue.

CHAIRPERSON LUDERER: Okay. Thank you, Sara. Any initial questions or comments from the Panel members?

I have one question about the metals -- the additional metals, that was arsenic and the speciation, right, arsenic speciation and what other metals?

MS. HOOVER: Arsenic is already a priority chemical. So I'm actually talking, there's a number of designated metals that are not priority chemicals, a long list of designated metals. And actually the law asks the Program to ultimately be measuring all designated chemicals, but we want to bring to you -- and I think I've maybe alluded to, or possibly Dr. She has alluded to in the past, that when have -- you know, metals can be measured as a panel fairly easily. We are measuring a subset for certain projects that have identified as priority, and we're just very interested in the Panel's opinion about should we expand that metals panel. So that's what that's regarding.

CHAIRPERSON LUDERER: So that would be a presentation at another meeting where you would talk about what those metals were and we would --

MS. HOOVER: Exactly. Yeah. We would prepare the typical kind of table giving you a little bit more information about each metal and explaining what the

laboratory capacity is currently.

CHAIRPERSON LUDERER: Dr. Wilson, did you have a question?

PANEL MEMBER WILSON: Not yet.

CHAIRPERSON LUDERER: No, okay.

Any other Panel members have questions comments?

Dr. Wilson.

PANEL MEMBER WILSON: Mike Wilson.

Sara, is there -- do you anticipate in this next year opportunities for doing an additional biomonitoring study on another group of -- you know, the population or group of people?

MS. HOOVER: So I would ask Dr. Lipsett to address that.

DR. LIPSETT: Our resources are already stretched really thin with 3 field studies, 2 of which the data have already been collected, but the chemicals are still being analyzed. And we have a third one with Kaiser, where we're going out into the field. This is the Expanded BEST study. That one was -- I guess the Program had planned to have another extension of that subsequently in the next year as well, but I think it's -- we may end up actually -- we haven't talked about it internally yet. I would like to combine those 2, just because it's so much effort to go out into the field.

I think, at this point, it's probably premature to think about planning for another field study. Although, there may be possibilities for doing some other in-house studies that I'll -- if -- I'll talk to you about at the next meeting, okay?

CHAIRPERSON LUDERER: And, Dr. Lipsett, actually maybe before you sit down, you also had mentioned this morning the possibility of using samples from the Newborn Screening Program. Is there a potential time frame for that? I mean, they're not available till 2013 you said?

DR. LIPSETT: We're waiting till the regs are finalized for the availability of those, but we're not even sure yet that we will be able to use them. It really depends on the results of the QC testing that ECL is doing. And that may turn out to be non-viable as an option.

And then I mentioned also as well, I'm starting to explore the feasibility of working with medical and nursing students. But having initiated contact with the administration at UCSF, I can assure you it's going to be a prolonged process before that happens, if it does.

CHAIRPERSON LUDERER: I'd be happy to talk to people at UC Irvine Medical School if the Program is interested.

DR. LIPSETT: Well, I may very well take you up

on that. Thank you.

CHAIRPERSON LUDERER: Dr. Wilson.

Oh, sorry.

Do the Panel members have any comments on the ideas that were presented for possible agenda items? Maybe you could run through the slides again just so everybody could refresh their memory about what those were, in terms of which, in particular, Panel members are enthusiastic about.

Dr. Wilson.

PANEL MEMBER WILSON: So between now and the next meeting in April, are the results from both the FOX and the MIEEP interviews going to be going out, do you anticipate that?

MS. HOOVER: I'm going to have to direct that question to Dr. Lipsett or someone else in DPH. The timing of -- you're saying the timing of the post-results reporting there?

PANEL MEMBER WILSON: Right, actually --

MS. HOOVER: Oh, when the results are being released.

PANEL MEMBER WILSON: Right. When the results will be released, both to the --

MS. HOOVER: Are you saying to the participants or beyond the participants?

MS. HOOVER: Both, to the participants but then also to the public. Yeah, we can speak to that. We do have timelines. I don't have them in my head, but --

DR. McNEEL: I'm Sandy McNeel with the California Department of Public Health.

We are in the process of going through IRB review for the second round of results return materials for the FOX project. We anticipate getting approval for those results by the end of December.

At this point, I'm a little unclear on when we will have the full extent of our second round of test results, including some of the urine chemicals. And Dr. She has, I think as I recall, mentioned that some of those may not be available until spring. So we may not be able to make our participants aware of their results until March or April, but that's kind of our next goal is once we have approval for the results return documents, and once we have our results in hand, then we'll be ready to ship those out to the participants.

But if there are some delays in getting results, for whatever reason, then it may not be until March or April before those go out to the participants. And then it's always a little after that that we are able to put something together for a public release of those results.

PANEL MEMBER WILSON: So it sounds like the

public release would happen after the next April meeting of the this Panel.

DR. McNEEL: I think that's probably likely

PANEL MEMBER WILSON: Okay.

DR. McNEEL: Yes, as -- Sandy McNeel again.

As far as the results for the MIEEP participants, we just sent their first set of chemicals out. We're trying to get the second set of chemicals out in January or February. So we may have some publicly available results from that particular project by the next meeting. But again, it will just depend on how the logistics go in the meantime.

Thank you.

CHAIRPERSON LUDERER: Dr. Alexeeff.

OEHHA DIRECTOR ALEXEEFF: Well, I'm not sure this is a good suggestion or not, but I'm wondering if there's -- when we're expecting releases of reports on NHANES, and if it makes sense to bring any new reports to the Panel's attention? So I don't know if we have any idea as to what the planning is or maybe that's just something that just happens.

DR. FENSTER: Hi. I'm Dr. Laura Fenster, and I'm an epidemiologist with the Program. I don't know how informative this is, but many of us are on the listserv for NHANES, so we get notification of releases. And then

we use that data for comparison.

So, for example, the PFC data was just released, so that's the data that we're using, you know, to look at the levels of PFC that were just determined in the data.

We could somehow notify the Panel of those releases, but it's really just getting on a listserv and then they let you know when their data sets are being released.

CHAIRPERSON LUDERER: Thank you.

Dr. Bradman.

PANEL MEMBER BRADMAN: I just have a couple comments. One, I know personally I'm really looking forward to information on the analyzing the participant understanding of return results. And I know that's already on the agenda. But just to kind of highlight something, I think we're looking forward to it. It's the topic of a lot of discussion over the past years.

Also, how to combine and aggregate results from the different community-based studies, and maybe some discussion about how and if and, you know, that can be compared to national data and statewide data. You know, we have this ongoing issue of wanting to do a statewide representative survey, but we're not able to do that, so maybe some discussion about, you know, how we can interpret the data we do have.

And I know some of the information, for example, that went into the reports, you know, it's very basic because of this concern about releasing information on a pre-publication basis, but it would be great if we could have some sort of aggregate or overall view of what's been found. And because publications can take so long, we might think about how we can present the data in a more concrete form that, you know, would be acceptable to some of the PIs on some of the subprojects. A potential topic for discussion next year.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: This is Julia Quint. I would also be interested in -- and you do this on an ongoing basis at meetings. When you do pilot studies, you talk about, or you present, how these can inform a more representative statewide biomonitoring, you know, effort, should we have the resources to ever do that.

And I would just like to see, in maybe one presentation, you know, how the results of how the pilot studies have informed the larger study. You know, it ranges from sample collection. I mean, each one of the pilots you've been very careful to point out how that will inform -- you know, what, of that pilot study, will inform a larger study.

And it would be nice to see that in all -- you

know, as these studies are completed, to have all of those lessons learned, for lack of a better term, presented as a whole, because I think you've made such maximum use of resources by doing these smaller studies, even though the Program was designed to do, you know, a statewide sample.

So, however that could be done, you know, to take a look back at what you've actually learned along the way from these would be very informative, because, you know, we could tomorrow have the money to do a statewide sample. I don't think that's likely.

(Laughter.)

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: So following up on that. Yeah. Mike Wilson. I had earlier mentioned, you know, the story of speaking with a room full of steel workers, and that their real interest in the end was around biomonitoring studies, and the findings in umbilical cord blood.

And I'd asked Amy Dunn, you know, to sort of -- can we put this on the website, resources for workers, you know, on the biomonitoring website? And it sort of grows out my perennial interest in trying to bridge some of these, you know, disciplines.

And so I guess I want to just say again that I actually recognize that that's a larger project than

simply putting a button up on a website, that it actually requires some resources from OEHHA to, you know, figure out how to communicate this information to -- that would be -- in a way that would be meaningful to workers.

And I think, you know, you've done some of this work. In fact, I think you know, the report that you and Dr. Quint did looking at the Prop 65 chemicals that were relevant to occupational exposures, it's the same kind of thing. I think that made an enormous contribution, the report that you did around Prop 65 chemicals.

I think it would -- you know, it would make a similar contribution to do the same sort of thing around biomonitoring and begin that with this sort of resource link on the website that would, you know, perhaps identify substances that are likely to be used in workplaces, used in products, and overlay those against NHANES data, and have something up there about the problem of occupational exposures, the intensity and duration and so forth of exposures as a place to begin.

And so I guess my point here is I realize in making that request to Amy that it's actually a larger suggestion or recommendation to OEHHA to take that on as a, you know, possible project.

MS. HOOVER: Yeah. I mean, that was a really interesting project that Julia and I worked on together.

And I have been getting various indications that it would be useful to update that work, and revisit it. So that would be an interesting way to do it with the intersection with biomonitoring.

PANEL MEMBER WILSON: As I said earlier, I'd be happy to help with that in whatever way would be useful.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: Yeah. Julia Quint.

I think some of the issues, you know, related to work -- biomonitoring in an occupational setting are very different. And we had a whole session where we talked about some of those. But just in communicating results and the prior biomonitoring that's been done in workers, the Biological Exposure Indices. They're just a number of different things, so it would require, you know, probably some significant effort to do that. And I think there's probably a lot of support, certainly a lot of need for it.

But I think in term of, you know, one of the things you brought up about guest speakers, I think one of the ways that we could start to make this very important integration of biomonitoring, what's going on here, with some of the other programs like -- that are dealing with toxic chemicals as a focus of the programs, is by having, you know, some sharing, having them -- you know, people in DTSC, like Debbie Rafael, come and talk about the Safer

Alternatives Program.

Where I see a lot of overlap in terms of, you know, what we're doing, in terms of emerging toxicants, how you have to be very careful about the safer, you know, substitutes, whether or not they're really safer. So some cross-pollination with other Departments, through maybe having them present here, so we can see where the similarities are and where there's a potential for nexus between some of the directions, I think, would be very important. The Cosmetics Program, Michael DiBartolomeis's program, I think is a really important for us to hear what that regulation has -- you know, what's happened as a result -- as a result of the Safe Cosmetics Act, and whether or not they're emerging things that are coming onto the market as, you know, the Prop 65 chemicals in some cosmetics are being monitored more carefully.

I would also like to see, you know, Thu Quach of the Nail Salon Collaborative who's doing research in that group, really important intersection between employers and employees in a special -- you know, in the Vietnamese community, and how, you know -- also with a chemical focus, but doing some extra research, which I think would be important for us to hear about and learn about.

So through the guest speakers I think we could, you know, sort of build some bridges with other efforts,

and see where there's a possibility that we might join forces. The same with the CARB -- safer -- their consumer products regulation. I think there's a lot of opportunity there as they ban the chlorinated hydrocarbon solvents in a number of consumers products. Other chemicals will pop up.

And they do surveys where they have an opportunity to see -- have more detailed data on some of these products. So I think would be an important -- for us to keep track of those and to see where there's chances for collaboration or extension of their efforts.

CHAIRPERSON LUDERER: Dr. McKone.

PANEL MEMBER McKONE: Well, I just want to second that point, and kind of expand it a bit. I do think one of our important opportunities here is to watch -- not be looking backwards, but look forward and really try to keep track of what's coming into the marketplace, and getting lined up to see it happening, as opposed to just always being reacting and finding out, "Oh, NHANES found this, so we should do it".

So, you know, again, it's a lot of work, because it really means looking at how products are changing, and it's difficult to get that information, but I think it is a very important use of this kind of -- pot just seeing what's there, but watching how it evolves. Because

biomonitoring, one of the best things you can do with it is see trends. I mean, not often, you can't always do absolutes. You can't always do a good health study. But if it's done well, it actually can really see trends from year to year, or from group to group and as they change.

I don't want to expand too much, but I think learning more about how to do that is something we really -- we can use some of our meeting time to hear some ideas in those areas about how to anticipate.

MS. HOOVER: So I just moved the slide, with that, to this issue of screening. So if -- I don't know if any of you have thoughts today, but other kinds of emerging chemicals are things for us to start looking at.

You don't have to give us the input today. You know, feel free to email us or -- if you have thoughts now, though, we'd love to hear them.

CHAIRPERSON LUDERER: Well, a related kind of topic, which we have talked about before, and we heard a presentation at a Scientific Guidance Panel meeting awhile ago, was about this idea of screening biospecimens for unknown compounds. You know, I know there's really a lot of enthusiasm, you know among the Panel, and I think that's something that we shouldn't abandon that possibility.

MS. HOOVER: Yeah. No, I -- yeah, that's

definitely still a forward focus.

So, Dr. Lipsett.

DR. LIPSETT: Yeah, in the funding that we have been getting under the Cooperative Agreement -- Michael Lipsett, Department of Public Health.

The funding we've been from getting from the CDC under their cooperative agreement, calls for the purchase of a TOF for a ECL for next year. And so this will be one of the focuses of the Program going forward.

You know, it's not a straightforward process, but we will at least have the instrumentation available to at least initiate this process.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Mike Wilson.

I'm sort of riffing on Dr. Quint's point about the other, you know, BDO's, and also Occupational Health Branch outside of this agency and the work that they're doing, I think, would -- you know is relevant and would be of interest to the Panel.

And I don't know if that -- if the appropriate venue would be an actual, you know, session like this or if we would attend something that OEHHA would host.

But in addition to the -- it was ARB. I think you mentioned ARB, DTSC, and Occupational Health Branch, specifically the cosmetics group. You know, CalEPA's

Environmental Justice working group that is really struggling with the -- how to assess cumulative exposures and so forth.

In a similar way, you know, that's -- I think that's of interest to the Panel. It would be of interest to the Panel. And they might have some very interesting ideas about things that the Biomonitoring Program, you know, could or should be focusing on.

MS. HOOVER: Okay.

CHAIRPERSON LUDERER: Actually, I just did have one question about one of the other items, I think, on the other slide about the Program sustainability and whether one of the things we should be thinking about -- I mean, you know, the CDC grant has a finite funding period, and whether that's something that we should, you know, be discussing at a Panel meeting in the near future.

MS. HOOVER: Yeah. I mean, that was the highlight here on Program sustainability, exactly that. So, yeah, I think the answer to that is yes.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: So one other thing on that. On your second slide about the pesticides, I mean, one of the things that I think we were contending with earlier was the changing nature of that set of 100 -- you know, sort of top 100 pesticides. And are you sort of

continuing to track that information from the pesticide use reports through DPR?

MS. HOOVER: Yeah.

PANEL MEMBER WILSON: Yeah, I mean, I think that would be -- I would be interested in hearing, you know, what your sort of understanding of that set of substances is, and, you know, how it's changed even since, you know, the Program -- the Biomonitoring program began, and if there are, you know, a handful of those top 100 that we should be looking at, you know, that have, you know, surfaced or, for whatever reason, are, you know, emerging.

MS. HOOVER: Yeah. We're definitely keeping an eye on that. And that's -- we continue to highlight this as an important item.

Okay.

CHAIRPERSON LUDERER: Great. Are there further comments from Panel members?

Do you feel like you've gotten sufficient feedback on the topic from us?

MS. HOOVER: Yeah, I mean, this is great. So again, the conversation is not closed and maybe you could also check if there's public comment on this item.

CHAIRPERSON LUDERER: Yeah. Do we have any public comment on this item?

MS. DUNN: I don't believe there's any.

CHAIRPERSON LUDERER: We do have time allotted now for open public comment period. Did we have any requests for that as well.

MS. DUNN: No.

CHAIRPERSON LUDERER: All right.

MS. HOOVER: Well, there you have it. So again, we'd just encourage if -- I know that sometimes, you know, in a meeting you can't necessarily think of things, so if the Panel or the public have ideas and -- we continue to receive ideas that we follow up on, so we just really encourage additional feedback on the agenda items and just the Program in general?

CHAIRPERSON LUDERER: Thank you.

So then if we have no additional public comments, the -- we are ready to adjourn and wrap up the meeting. And I just wanted to remind everyone again that there will be a transcript of this meeting available on-line, hopefully in about a month. And our next meeting will be on April 11th, which is a Thursday. And this will be in Oakland. So that will be in the Elihu Harris State Building in the auditorium there.

So I look forward to seeing everyone there and thank you all for coming today, for a very interesting and productive meeting.

And with that, the meeting is adjourned.

Thank you.

(Thereupon the California Environmental Contaminant Biomonitoring Program, Scientific Guidance Panel meeting adjourned at 3:23 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 Scientific Guidance Panel meeting was reported in shorthand by me, James F. Peters, a Certified Shorthand Reporter of the State of California, and thereafter transcribed under my direction, by computer-assisted transcription.

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

IN WITNESS WHEREOF, I have hereunto set my hand this 12th day of November, 2012.

JAMES F. PETERS, CSR, RPR
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